IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

ASSOCIATION OF AIR MEDICAL SERVICES,
909 N. Washington Street, Suite 410
Alexandria, VA 22314,

Plaintiff,

v.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES,
200 Independence Avenue SW
Washington, DC 20201,

XAVIER BECERRA, in his official capacity as Secretary of Health and Human Services,
200 Independence Avenue SW
Washington, DC 20201,

U.S. OFFICE OF PERSONNEL MANAGEMENT,
1900 E Street NW
Washington, DC 20415,

KIRAN AHUJA, in her official capacity as Director of the U.S. Office of Personnel Management,
1900 E Street NW
Washington, DC 20415,

LAURIE BODENHEIMER, in her official capacity as Associate Director, Healthcare and Insurance, in the U.S. Office of Personnel Management,
1900 E Street NW
Washington, DC 20415,

U.S. DEPARTMENT OF LABOR,
200 Constitution Avenue NW
Washington, DC 20210,

MARTIN J. WALSH, in his official capacity as Secretary of Labor,
200 Constitution Avenue NW
Washington, DC 20210,

Civ. No. 1:21-cv-3031

U.S. EMPLOYEE BENEFITS SECURITY ADMINISTRATION,
200 Constitution Avenue NW
Washington, DC 20210,

ALI KHAWAR, in his official capacity as the Acting Assistant Secretary for the Employee Benefits Security Administration,
200 Constitution Avenue NW
Washington, DC 20210

U.S. DEPARTMENT OF THE TREASURY,
1500 Pennsylvania Avenue NW
Washington, DC 20220,

JANET YELLEN, in her official capacity as Secretary of the Treasury,
1500 Pennsylvania Avenue NW
Washington, DC 20220,

LILY L. BATCHELDER, in her official capacity as Assistant Secretary of the Treasury (Tax Policy),
1500 Pennsylvania Avenue NW
Washington, DC 20220,

INTERNAL REVENUE SERVICE,
1111 Constitution Avenue NW,
Washington, DC 20224,

CHARLES RETTIG, in his official capacity as Commissioner of the Internal Revenue Service,
1111 Constitution Avenue NW,
Washington, DC 20224,

and

DOUGLAS W. O'DONNELL, in his official capacity as Deputy Commissioner for Services and Enforcement in the Internal Revenue Service,
1111 Constitution Avenue NW
Washington, DC, 20224,

Defendants.

COMPLAINT

Plaintiff the Association of Air Medical Services (AAMS) brings this complaint against the U.S. Department of Health and Human Services; Xavier Becerra, in his official capacity as Secretary of Health and Human Services; the U.S. Office of Personnel Management; Kiran Ahuja, in her official capacity as Director of the U.S. Office of Personnel Management; Laurie Bodenheimer, in her official capacity as Associate Director, Healthcare and Insurance, in the U.S. Office of Personnel Management; the U.S. Department of Labor; Martin J. Walsh, in his official capacity as Secretary of Labor; the U.S. Employee Benefits Security Administration; Ali Khawar, in his official capacity as the Acting Assistant Secretary for the Employee Benefits Security Administration; the U.S. Department of the Treasury; Janet Yellen, in her official capacity as Secretary of the Treasury; Lily L. Batchelder, in her official capacity as Assistant Secretary of the Treasury (Tax Policy); the Internal Revenue Service; Charles Rettig, in his official capacity as Commissioner of the Internal Revenue Service; and Douglas W. O'Donnell, in his official capacity as Deputy Commissioner for Services and Enforcement in the Internal Revenue Service (collectively, Defendants), and alleges as follows:

INTRODUCTION

1. This is an action under the Administrative Procedure Act to set aside interim final rules (the Rules or IFRs) issued by the Department of Health and Human Services, the Department of Labor, the Department of the Treasury, and the Office of Personnel Management (collectively, the Departments) to implement the No Surprises Act, Pub. L. No. 116-260, 134 Stat. 1182, div. BB, tit. I (2020). The Rules are inconsistent with the statute's text and purpose and impose through administrative fiat policies that Congress expressly considered and rejected.

2. Indeed, the Chairman and the Ranking Member of the House Ways and Means Committee recently described the Rules as reflecting "an approach that Congress did not enact in the final law" and "in a very concerning manner." *See, e.g.*, Exhibit 1 (Oct. 4, 2021 letter). More

than 150 additional members of Congress from both parties have similarly stated that the Departments' approach is "contrary to the statute" and could "narrow provider networks and jeopardize access to patient care" and "exacerbate existing health disparities and patient access issues in rural and urban underserved communities." Exhibit 2 (Nov. 5, 2021 letter).

3. The administrative overreach in the IFRs promises to impact one segment of the healthcare sector differently from all others: the air ambulance industry. The air ambulance industry fills a critical need in the American healthcare system because the faster a person who suffers a traumatic injury or other medical emergency reaches a hospital, the better the overall outcome.[1] Yet more than 85 million Americans—greater than one quarter of the Nation's population—live further than a one-hour drive from the nearest Level 1 or Level 2 trauma center.[2] For those Americans, lifesaving emergency medical care is not a guarantee. Nor is the situation improving. Nineteen rural hospitals closed in the United States in 2020, and more than 180 rural hospitals have closed since 2005—about a 10% decrease.[3] The sad reality is that access to hospitals is decreasing for most Americans living, visiting, or traveling through rural areas at great distances from trauma

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[1] Hannah Pham et al., *Faster On-Scene Times Associated with Decreased Mortality in Helicopter Emergency Medical Services (HEMS) Transported Trauma Patients*, 2 Trauma Surgery & Acute Care Open 1, 4 (2017) ("It is imperative that trauma victims receive care as soon as possible, whether it be prehospital or definitive care. From our observations, we have identified that faster time of arrival on-scene and departure from scene are directly related to decreased mortality."); Patrick Schoettker et al., *Reduction of Time to Definitive Care in Trauma Patients: Effectiveness of a New Checklist System*, 34 Injury 187, 187 (2003) ("[P]rolonged time to definitive care has been identified as an issue preventing optimal care of injured patients. Early transfer of severely injured patients to a major trauma centre has been shown to be associated with better survival.").

[2] Am. Med. Ass'n, *Air Ambulance Regulations and Payments* (2018), perma.cc/2WR8-D747.

[3] *Rural Hospital Closures*, Cecil G. Sheps Ctr. for Health Servs. Rsch., (visited Nov. 15, 2021), perma.cc/LE9K-U3QX.

centers. If air ambulances stopped operating, many patients could not receive emergency or definitive care within the time required to ensure an optimal outcome.[4]

4. Air ambulances are on standby 24 hours a day, seven days a week, and they respond when they are called. They play no role in deciding which patients to transport. First responders (such as police and firefighters) and physicians (typically at community hospitals) decide when patients should be airlifted to a facility, and it is they who call air ambulances when necessary. Air ambulances respond to these time-sensitive emergency calls and carry out the transport so long as conditions are safe for air travel. And they do so without regard to a patient's ability to pay, insurance coverage, or insurance-network status.

5. While air ambulances are essential and life-saving tools, their use also comes at a cost. To provide these services, air ambulance providers must make substantial investments in aircraft, air bases, medical personnel, medical products and equipment, and regulatory compliance measures. These fixed costs are unavoidable and incurred regardless of whether an air ambulance completes zero transports in a day or several of them. Because air ambulances are typically responding on-demand to unplanned medical emergencies, they cannot schedule or predict the timing of specific transports. For similar reasons, it can be challenging for an air ambulance provider to reliably project its future volume of transports over time.

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[4] David Michaels, et al., *Helicopter Versus Ground Ambulance: Review of National Database for Outcomes in Survival in Transferred Trauma Patients in the USA*, 4 Trauma Surgery and Acute Care Open 1, 3 (2019) ("After adjusted analysis, we found that helicopter use is associated with decreased mortality in trauma patients. The higher level of care provided by helicopter medical personnel and the faster on-scene arrival of air transport is still associated with better outcomes compared with ground transportation."); Pham, *supra*, at 3 ("The faster the [helicopter EMS] is able to reach the scene, the faster critically injured patients will receive medical care. It is evident that trauma is time sensitive, especially in its earliest moments, and [helicopter EMS] provides a faster method of reaching and caring for severely injured patients.").

6. These unique characteristics of air ambulance operations deter group health plans and issuers from entering into network contracts with independent air ambulance providers, notwithstanding the providers' best efforts to negotiate such contracts. Under ordinary circumstances, group health plans and issuers steer increased patient volume to "in-network" providers in exchange for the network providers accepting discounted rates. But this network contracting model is a poor fit for the air ambulance industry; air ambulance providers deliver emergency transports on call, and they cannot pick and choose their patients. Group health plans and issuers, in turn, have no ability to steer increased patient volumes in return for discounts. Despite air ambulance providers' good-faith attempts to negotiate network contracts with group health plans and issuers, payers often refuse to offer rates sufficient to offset the significant fixed costs of air ambulance operations. As a result, air ambulance companies are often forced to stay "out of network." And out-of-network air ambulance providers must then negotiate billing arrangements with issuers on a case-by-case basis.

7. This case concerns the No Surprises Act, through which Congress sought to restructure this inefficient process that effectively placed patients in the middle of payment disputes between health plans or issuers and air ambulance providers. Prior to the Act, when a plan or issuer failed to negotiate or adequately reimburse a provider, the patient would receive a bill for the unpaid balance of the invoice not covered by her insurance—a so-called balance bill.

8. Through the Act, Congress required plans and issuers to come to the negotiating table with air ambulance providers to reach a fair and reasonable rate for these critical services. Barring that, Congress provided that the dispute would be resolved through an efficient independent dispute resolution (IDR) process in which an independent entity would consider the information enumerated in the statute and then select the appropriate rate from one of the offers submitted by the parties. Through this design, Congress strongly incentivized providers and payers to resolve disputes amongst themselves or to submit the most reasonable offer.

9. Congress's design, however, was swiftly undone by the Departments through the IFRs. In July 2021, the Departments issued Interim Final Rule Part I without notice and comment. *Requirements Related to Surprise Billing; Part I*, 86 Fed. Reg. 36,872 (July 13, 2021) (attached as Exhibit 3). In October 2021, they followed up with Interim Final Rule Part II, again without notice and comment. *Requirements Related to Surprise Billing; Part II*, 86 Fed. Reg. 55,980 (Oct. 7, 2021) (attached as Exhibit 4). Critical elements of the IFRs diverge wildly from the structure Congress created with the Act and must be vacated in part.

10. *First*, IFR Part II deems the "qualifying payment amount" (QPA) (which is determined by plans and issuers) presumptively dispositive of the payment dispute and *requires* the IDR entity to select the offer that is closest to that amount. 86 Fed. Reg. at 56,104. It does so notwithstanding the statute's enumerated list of circumstances that the IDR entity "shall consider," only one of which is the QPA. Public Health Service Act (PHSA) § 2799A-2(b)(5)(C). To overcome the IFR's presumption, a provider must offer information that "clearly demonstrates" that the QPA is "materially different" from the "appropriate out-of-network rate." 86 Fed. Reg. at 55,984. In this way, the Departments have adopted an IDR process that is not actually "independent" and flouts the process that Congress enacted; indeed, it is not a meaningful dispute resolution process at all.

11. The Departments are transparent on that point too, explaining that they wanted to "allow for predictability" and "certainty" by "encourag[ing] plans, issuers, providers, and facilities to make offers that are closer to the QPA" and to "avoid the Federal IDR process altogether." 86 Fed. Reg. at 56,061. But an IDR process rigged simply to reaffirm the QPA is neither an independent process nor faithful to Congress's directive to consider multiple enumerated factors in making a decision.

12. *Second*, Part I compounds this error by intentionally depressing the QPA for air ambulance services in a manner contrary to the statutory language and wholly divorced from

market realities. Under the statute, the QPA is supposed to reflect the median of the "contracted rates recognized by the plan" offering the "same or similar" service provided by a provider in the "same or similar specialty" and "geographic region." PHSA § 2799A-1(a)(3)(E)(i)(I). IFR Part I defies this language in three interrelated ways: (1) it excludes most categories of agreed-upon payments between air ambulance providers and health plans; (2) it fails to distinguish between hospital-based air ambulance services and independent air ambulance services; and (3) it relies on overbroad geographic regions.

13. First, while IFR Part I defines a "contracted rate" as the amount "a group health plan has contractually agreed to pay," it specifies arbitrarily that a contract between an air ambulance provider and a plan "for a specific participant . . . does not constitute a contract." 86 Fed. Reg. at 36,953. This exception conflicts with the statute, which reaches *all* "contracted rates," and it arbitrarily excludes from calculation of the QPA the single-case rates for air ambulance services that are actually negotiated "under such plans or coverage." PHSA § 2799A-1(a)(3)(E)(i)(I).

14. Excluding single-case agreements and other types of historical payments results in intentional QPA deflation. Single-case rates are, by definition, contracted rates. The single case rate represents what the group health plan or issuer actually will pay and the provider will accept. The circumstances under which they are negotiated make them a market rate, particularly given the limited history of network contracting in the air ambulance industry.

15. Second, IFR Part I fails to distinguish between hospital-based air ambulance providers and independent air ambulance providers for purposes of calculating the QPA. Eliminating single-case agreements and treating these different providers the same will further deflate the QPA. That is because hospital-based air ambulance providers' rates comprise a larger number of the contracted rates in the QPA analysis. In-network agreements with payers are, in general, reached more often for hospital-based air ambulance providers because the hospitals enter into global agreements for all of their service lines (including air ambulance) which can cross-subsidize the

cost of the air ambulance services. Hospitals can also negotiate volume discounts across the full suite of hospital services that independent air ambulance providers simply do not offer. Indeed, sometimes the negotiated in-network rates are altogether illusory, negotiated by hospitals that do not even conduct air ambulance transports. In-network rates negotiated for hospital-based air ambulance services, such as they are, therefore do not cover "similar" specialty services (*id.*) or reflect market conditions for independent air ambulance providers. The Departments accounted for this distinction for other types of providers, for example, by treating hospital-based and freestanding emergency departments separately. 86 Fed. Reg. at 36,892. But when it came to the air ambulance industry, the Departments arbitrarily chose to depress air ambulances' QPAs by treating all providers the same.

16. Third, the Departments exacerbated these distortions by arbitrarily defining "geographic region" to mean Census-defined metropolitan statistical areas (which are derived without any consideration of the factors that actually affect air ambulance services or pricing), extending the relevant geographic regions for determining region-specific QPAs by hundreds of miles, far beyond what common sense and experience support.

17. The Departments' arbitrary approach to defining the QPA reflects an arbitrary, counter-textual decision to depress the QPA for air ambulance services, in contravention of the regime that Congress adopted. Indeed, the Departments readily concede in IFR Part I that they have purposefully adopted standards designed to deflate the QPA below actual "contracted rates recognized by the plan or issuer" for air ambulance services reimbursed "under such plans or coverage" (PHSA § 2799A-1(a)(3)(E)(i)(I)). *See* 86 Fed. Reg. at 36,891. That approach is inconsistent with both the statutory text and purpose, and if not vacated, will diminish the availability of air ambulance services, with devastating consequences for individuals in need of those services.

18. In sum, the Departments tasked with implementing the Act have turned the statutory text on its head. They adopted a policy that was rejected by Congress in the Act itself to

administratively deflate the amount an out-of-network provider can hope to get from a group health plan or issuer by excluding ubiquitous types of "contracted rates" from consideration in the QPA. And they have dictated the outcome of the IDR process by making the QPA presumptively dispositive, forcing the provider to take that purposefully deflated rate. In so doing, the Departments have gutted the IDR process that Congress created and jeopardized the ongoing viability of air ambulance providers generally. Without adequate payments to cover their fixed costs, air ambulance providers will be driven out of the market. These harms are imminently approaching, with the IFRs' requirements set to apply to plan years beginning January 1, 2022.

19. Congress did not intend to cripple the air ambulance industry like this. The Act was supposed to remove patients from the payment disputes between group health plans or issuers and providers and to give both sides the necessary tools to reach prompt and reasonable resolutions of those disputes. The IFRs twist Congress's balanced design into an indefensibly one-sided scheme that disfavors air ambulance providers. They are arbitrary and contrary to law and should be swiftly set aside in part.

PARTIES

20. Plaintiff the Association of Air Medical Services is the international trade association that represents over 93% of air ambulance providers in the United States. Together, AAMS's 300 members operate more than 1,000 helicopter air ambulances and 200 fixed wing air ambulance services across the United States. AAMS represents every emergency air ambulance care model, including hospital-based aircraft, independent aircraft at bases in rural areas far from hospitals, and many hybrid variations. AAMS represents and advocates on behalf of its members in a variety of forums. As part of that mission, AAMS brings litigation, including the instant action, on behalf of its members to challenge government action that will harm them.

21. Defendant U.S. Department of Health and Human Services is the federal department charged with substantial responsibility for public health.

22. Defendant Xavier Becerra is the Secretary of Health and Human Services. The Secretary of Health and Human Services is the official charged by law with administering the Public Health Service Act. He is sued in his official capacity only.

23. Defendant U.S. Office of Personnel Management is the federal agency charged with administering the Federal Employees Health Benefit Program.

24. Defendant Kiran Ahuja is the Director of the U.S. Office of Personnel Management. She is sued in her official capacity only.

25. Defendant Laurie Bodenheimer is the Associate Director, Healthcare and Insurance, in the Office of Personnel Management. She is sued in her official capacity only.

26. Defendant U.S. Department of Labor is the federal department with substantial responsibility for labor issues.

27. Defendant Martin J. Walsh is the Secretary of Labor. The Secretary of Labor is an official charged by law with administering the Employee Retirement Income Security Act of 1974 (ERISA). He is sued in his official capacity only.

28. Defendant U.S. Employee Benefits Security Administration (EBSA) is an agency within the U.S. Department of Labor. The EBSA has delegated authority for administering ERISA.

29. Defendant Ali Khawar is the Acting Assistant Secretary for the Employee Benefits Security Administration. He is sued in his official capacity only.

30. Defendant U.S. Department of the Treasury is the federal department with substantial responsibility for managing federal finances and for enforcing finance and tax laws.

31. Defendant Janet Yellen is the Secretary of the Treasury. The Secretary of the Treasury is the official charged by law with administering the Internal Revenue Code. She is sued in her official capacity only.

32. Defendant Lily L. Batchelder is Assistant Secretary of the Treasury (Tax Policy). She is sued in her official capacity only.

33. Defendant Internal Revenue Service (IRS) is a federal agency within the Department of the Treasury. The IRS has delegated authority for administering the Internal Revenue Code.

34. Defendant Charles Rettig is the Commissioner of the Internal Revenue Service. He is sued in his official capacity only.

35. Defendant Douglas W. O'Donnell is the Deputy Commissioner for Services and Enforcement in the Internal Revenue Service. He is sued in his official capacity only.

JURISDICTION AND VENUE

36. AAMS brings this suit under the Administrative Procedure Act, 5 U.S.C. §§ 551 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. § 2201.

37. The court's jurisdiction is invoked under 28 U.S.C. § 1331.

38. Venue is proper in this district under 28 U.S.C. § 1391(e) because at least one defendant resides in this district and a substantial part of the events or omissions giving rise to the claim occurred in this district.

FACTUAL ALLEGATIONS

A. The air ambulance industry

39. The air ambulance industry is an integral part of the emergency medical system. Air medical services are often the only lifeline that critically ill and injured patients have to definitive care, especially in rural areas.

40. Traumas, stroke, heart attacks, burns, and high-risk neonatal or pediatric cases account for 90 percent of all helicopter air ambulance transports. Without helicopter air ambulances, more than 85 million Americans would not be able to reach a Level 1 or 2 trauma center within an hour when these emergent circumstances arise.

41. Air ambulance providers play no role in determining whether or when to transport a patient. Instead, first responders, like local police and fire departments, or treating physicians, decide when a patient needs to be transported.

42. Air ambulance providers do not question a first responder's or physician's request for services; indeed, in many states, emergency medical services providers have a duty to respond imposed as a condition of licensure. Thus, air ambulance providers determine only whether aviation conditions are safe to fly the patient.

43. At the outset, air ambulance providers are never aware of a patient's ability to pay or their health insurance status. Instead, the goal is to efficiently provide the highest quality of transport safety and patient care and to respond to transport requests within minutes.

44. Air ambulance providers operate under an incredibly complex regulatory regime, with regulatory obligations flowing from numerous federal and state authorities. Air ambulances typically must maintain an air carrier certificate from the Federal Aviation Administration (FAA) to conduct on-demand operations under 14 C.F.R. Part 135 (called a Part 135 certificate), maintain a state-issued ambulance license, and meet the conditions of participation for Medicare, Medicaid, and other federal and state healthcare programs. The Part 135 certificate authorizes the air ambulance to engage in air transportation, while the state ambulance license is necessary for providing medical ambulance operations and billing for the services rendered.

45. The overlap between federal and state regulatory authority is important because more than 33% of helicopter air ambulance flights will cross a state border and nearly all cross a county or municipal boundary. Nearly all fixed-wing air ambulances cross state borders. Seamless interstate delivery of services is possible in part because the Airline Deregulation Act preempts many state laws relating to air carriers. *See* 49 U.S.C. § 41713(b).

46. The delivery of on-demand, heavily regulated, life-saving air ambulance services in emergencies requires substantial investments in specialized aircraft, air bases, technology, personnel, and regulatory compliance systems. For example, to maintain a 24-hour on-demand service, an air ambulance provider would need to have on staff at least 4 pilots, 4 nurses, 4 paramedics, and a mechanic. These costs remain the same regardless of how many transports a provider makes. Variable costs—like fuel and consumed medical supplies—are an important but relatively small proportion of a provider's costs.

47. Though an air ambulance provider's costs are mostly fixed, the volume of emergent and unplanned transports, particularly in rural areas, can vary greatly across both geography and time for reasons outside the air ambulance provider's control. A rural community without a hospital may only need a helicopter air ambulance on an infrequent basis, but, when the need arises, it is most often critical. And it is increasingly critical given that 138 rural hospitals have closed since 2010. *Rural Hospital Closures*, Cecil G. Sheps Ctr. for Health Servs. Rsch. (visited Nov. 15, 2021), perma.cc/LE9K-U3QX.

48. Because of the emergent and unplanned need for services, transport volume can be unpredictable. Regardless, issuers or group health plans cannot steer patients toward particular air ambulance providers in exchange for discounted rates like they can by putting a particular physician or hospital in their network to encourage patients to choose those providers. These structural features of air ambulance operations provide a natural disincentive for issuers and group health plans to contract with air ambulance providers.

49. The structure of air ambulance providers also affect their ability to procure network contracts. Air ambulance services are not typically offered as a public service, like police and fire department services are. Some air ambulances are operated by a hospital or a community organization or split between two or more such entities. But most air ambulances are operated by

standalone operators that hold both federal and state authorizations and are not affiliated with a single hospital or community organization.

50. These differences in structure have naturally driven how air ambulance providers negotiate rates for services. For example, entities that bill through a hospital system commonly enter into a network agreement with an issuer based on a much broader universe of hospital-based services that the hospital system offers and can take into account the universe of hospital services when negotiating payment. A negotiating hospital is not likely to focus on a discrete and comparatively small service line like air ambulance when negotiating a global agreement; indeed, they sometimes agree to an air ambulance rate even when they do not offer the service. As a result, air ambulance transport rates in hospital contracts are often far lower than the true cost of providing care in the area. Hospital-contract rates are thus a factually insupportable comparator for rates that independent air ambulance service providers could agree to.

51. Group health plans have, at various times, offered to bring air ambulance providers in-network by offering to pay at rates equal to Medicare rates. But Medicare rates are often significantly below the cost of providing air ambulance services. Xcenda, *Air Medical Services Cost Study Report* 15 (Mar. 24, 2017), perma.cc/H4M3-W93D; *see also* Gov't Accountability Off., *Air Ambulance: Data Collection and Transparency Needed to Enhance DOT Oversight* 13-14, 16-18 (July 2017), perma.cc/3XGW-JNGA. An air ambulance provider that was paid only on Medicare rates could not generate sufficient revenue to cover its costs. Indeed, in areas with a high percentage of Medicare and Medicaid patients, air ambulance bases have been forced to close.

B. The No Surprises Act

52. The disincentives for group health plans and issuers to bring air ambulance providers in network have historically placed patients and air ambulance providers in an untenable situation. Patients needed the emergency air ambulance transport, and air ambulance providers had a duty to provide it as safely and efficiently as possible without regard to the patient's ability to

pay. Those same features of the air ambulance industry made it exceedingly difficult for air ambulance providers (especially independent ones) to procure network contracts that would enable them to cover their high fixed costs and meet all federal and state regulatory requirements.

53. By keeping air ambulance service providers out of network, group health plans and issuers left patients with the responsibility to pay out-of-pocket substantial portions of the bill for critical air ambulance services. If the patient could not afford the bill, the burden of covering the cost would fall on the air ambulance provider, jeopardizing its ability to recoup sufficient revenue to cover its costs and maintain its ongoing operations.

54. Patients also found themselves in the middle of payment disputes. It was common for a group health plan or issuer to send a below-cost payment for the air ambulance services to the patient and then instruct the provider to bill the patient. That practice put the patient in the position of conducting a three-way arbitration of the payment amount.

55. Congress sought to address the problem of placing patients in the middle of what is, at bottom, a payment dispute between the patient's group health plan or issuer and the provider.

56. On December 27, 2020, the President signed the Consolidated Appropriations Act, 2021, Pub. L. No. 116-260 into law. The No Surprises Act (or the Act) was enacted as Title I to Division BB of the Consolidated Appropriations Act, 2021.

57. The Act generally obligates group health plans and issuers to apply the same cost-sharing levels to out-of-network and in-network emergency services, prevents emergency service providers from holding a patient liable for the balance of a bill, and provides an independent dispute resolution process for group health plans and issuers and out-of-network providers to reach a fair payment amount.

58. Given the unique nature of air ambulance services, Congress addressed such services on their own, separate from all other services. Section 105 of the Act includes provisions specific to air ambulance services. It includes the same provisions three times over—by amending

the Public Health Service Act, the Employee Retirement Income Security Act (ERISA) of 1974, and the Internal Revenue Code—so that it reaches commercially insured patients whether enrolled in private sector group health plans or health insurance coverage. It also amended the Federal Employees Health Benefit (FEHB) Program Act to require carriers offering FEHB plans and providers serving FEHB-insured patients to comply with the substantive obligations of the Act with respect to FEHB plans.[5]

59. The Act is designed to establish parity between in-network and out-of-network providers from the patient's perspective. It thus provides that when a participant enrolled in a relevant group health plan or insurance product "receives air ambulance services from a nonparticipating provider" and "if such services would be covered if provided by a participating provider," then:

> (1) the cost-sharing requirement shall be the same for the nonparticipating provider as for a participating provider, and any coinsurance or deductible shall be based on rates applicable to a participating provider;
>
> (2) any cost-sharing amounts will be counted towards the in-network deductible and in-network out-of-pocket maximum in the same way as if it were furnished by a participating provider; and
>
> (3) the plan or issuer shall (A) send an initial payment or notice of denial of payment to the provider within 30 calendar days after the provider transmits its bill and (B) pay a total plan payment to the provider equal to the determined out-of-network rate less the amount of any patient cost-sharing or any initial payment to the provider.

See PHSA § 2799A-2(a).

[5] For ease, we cite to the provisions amending the Public Health Service Act only, by citing to the PHSA itself. The provisions enacted into ERISA and the Internal Revenue Code are the same in all material respects.

60. The Act then establishes a two-stage process for resolving disputes about the applicable out-of-network rate for an air ambulance provider. The parties first engage in open negotiations and, if negotiations fail, they enter the IDR process to have a neutral party independently determine the amount owed.

61. First, there are private negotiations between the provider and the group health plan or issuer. Within 30 days after the provider receives an initial payment or notice of denial of payment, the provider or group health plan or issuer may "initiate open negotiations . . . for purposes of determining, during the open negotiation period, an amount agreed on by such provider, and such plan or coverage for payment (including any cost-sharing) for such service." The open-negotiation period lasts for 30 days following the date of initiation of open negotiations. PHSA § 2799A-2(b)(1)(A).

62. Second, if no payment determination is reached by the close of the open-negotiation period, the parties can proceed through the IDR process wherein a neutral party will decide the amount owed. Either the provider or the group health plan or issuer may "initiate the independent dispute resolution process" within the four days following the close of the open-negotiations period by submitting a notification to the other party and to the relevant Secretary. PHSA § 2799A-2(b)(1)(B).

63. The parties must then agree to use a particular certified IDR entity within three business days or the Secretary will select one. PHSA §§ 2799A-2(b)(4)(B), 2799A-1(c)(4)(F).

64. The statute then provides for a "final offer" or "baseball-style" determination of the payment amount. That is, within 10 days after selection of the IDR entity, each party must "submit to the certified IDR entity" "an offer for a payment amount for such services furnished by such provider" along with any information requested by the IDR entity and any information relating to the offer the party wants to submit. PHSA § 2799A-2(b)(5)(B).

65. The IDR entity must then, within 30 days following its appointment, "select one of the offers submitted" by the parties to be the payment amount for the services. PHSA § 2799A-2(b)(5)(A).

66. The statute describes in detail what the IDR entity must consider in determining the payment amount. *See* PHSA § 2799A-2(b)(5)(C). It does not state or imply that any particular factor is the primary or presumptive factor. Instead, it provides that the IDR entity "*shall consider*" "the qualifying payment amounts" for the applicable year for "comparable" services "in the same geographic region" *and* "information on any [additional] circumstance" listed in the statute or requested by the IDR entity. *See id.* § 2799A-2(b)(5)(C)(i)(I), (II) (emphasis added).

67. The statute enumerates the relevant additional circumstances, in addition to the QPA and information the IDR entity requests, that it "shall consider." Those include:

> (I) The quality and outcomes measurements of the provider that furnished such services.
>
> (II) The acuity of the individual receiving such services or the complexity of furnishing such services to such individual.
>
> (III) The training, experience, and quality of the medical personnel that furnished such services.
>
> (IV) Ambulance vehicle type, including the clinical capability level of such vehicle.
>
> (V) Population density of the pick up location (such as urban, suburban, rural, or frontier).
>
> (VI) Demonstrations of good faith efforts (or lack of good faith efforts) made by the nonparticipating provider or nonparticipating facility or the plan or issuer to enter into network agreements and, if applicable, contracted rates between the provider and the plan or issuer, as applicable, during the previous 4 plan years.

PHSA § 2799A-2(b)(5)(C)(ii).

68. The "qualifying payment amount" is also defined in the statute. PHSA § 2799A-2(c)(2) (incorporating PHSA § 2799A-1(a)(3)). It is generally the "median of the contracted rates

recognized by the plan or issuer" "for the same or a similar item or service" as of January 31, 2019, that are offered in the same insurance market (i.e., the individual market, large group market, small group market, or self-insured group health plan market) and in the same geographic region, increased by the consumer price index. *Id.* § 2799A-1(a)(3)(E)(i).

69. The statute further directs the Secretaries to determine "the geographic regions applied for purposes of this subparagraph, taking into account access to items and services in rural and underserved areas, including health professional shortage areas" and that they may "take into account . . . quality or facility type (including higher acuity settings and the case-mix of various facility types) that are otherwise taken into account for purposes of determining payment amounts with respect to participating facilities." PHSA § 2799A-1(a)(2)(B).

70. When the group health plan or issuer lacks sufficient information to determine a median contracted rate, the statute authorizes the plan or issuer to determine the QPA through resort to information from a third-party database (*e.g.*, FAIR Health). PHSA § 2799A-1(a)(3)(E)(iii).

71. The statute prohibits the IDR entity from considering certain specific factors—the usual and customary charges of the provider, the amount that the provider would have billed the patient absent the ban on balance billing, or the reimbursement rate that would be paid under governmental health programs. PHSA § 2799A-2(b)(5)(C)(iii).

72. Aside from the prohibition on considering certain factors, the No Surprises Act does not deem any other circumstances presumptively reasonable or owed more weight. Instead, the IDR entity is required to consider them all. This was purposeful. Congress specifically considered and rejected a proposal that would have mandated that payment be "the recognized amount," i.e., an amount set by state law or the median contracted rate. *See* Ban Surprise Bill Act, H.R. 5800, 116th Cong. § 2(a) (2020) (proposing new PHSA § 2719A(f)).

73. Instead, under the No Surprises Act, after considering the QPA, the additional circumstances, and any requested information, the IDR entity then selects one of the party's offers to be the rate for the service.

74. The statute requires the group health plan or issuer to pay the amount owed to the provider (less any cost-sharing or initial payment amounts) not later than 30 days after the IDR entity makes its independent determination. PHSA § 2799A-2(b)(6).

75. To ensure that disputes over payment remain between the provider and the group health plan, the statute also bars air ambulance providers from billing a plan participant for more than the cost-sharing amount if she has air ambulance benefits. In other words, the statute prohibits "balance billing." The statute provides that, when a participant has air ambulance benefits under her plan, an air ambulance provider "shall not bill" the participant "for a payment amount for such service furnished by such provider that is more than the cost-sharing amount for such service." PHSA § 2799B-5.

76. To ensure the timely implementation of the Act, Congress directed the Secretaries of Health and Human Services, of the Treasury, and of Labor to engage in rulemaking by specified statutory deadlines.

(a.) By July 1, 2021, the Secretaries were to "establish through rulemaking" the "methodology" to "use to determine the qualifying payment amount"; the "information" the plan or issuer must "share with the nonparticipating provider … when making such a determination"; the "geographic regions . . . taking into account access to items and services in rural and underserved areas"; and "a process to receive complaints of violations." PHSA § 2799A-1(a)(2)(B). In setting "the geographic regions" the rulemaking is required to "tak[e] into account access to items and services in rural and underserved areas, including health professional shortage areas" (*id.* § 2799A-1(a)(2)(B)(iii)) and may "take into account quality or facility type

(including higher acuity settings and the case-mix of various facility types) that are otherwise taken into account for purposes of determining payment amounts with respect to participating facilities" (*id.* § 2799A-1(a)(2)(B)).

(b.) Within one year of enactment, i.e., December 27, 2021, the Secretaries were to "establish by regulation one independent dispute resolution process" under which "a certified IDR entity . . . determines . . . the amount of the payment under the plan or coverage" for qualified air ambulance services. *Id.* § 2799A-2(b)(2)(A).

C. The Interim Final Rules

77. To implement the Act, the Departments issued two interim final rules without a notice-and-comment period. But the voluminous IFRs are "interim" in name only. They could have been developed and issued only through a coordinated inter-agency process driven to conclusion by the Executive Office of the President and are thus plainly the consummation of the Departments' collective decision-making process. They create rights and impose obligations on air ambulance providers, group health plans, and issuers. While the Departments invited comment on certain aspects of the IFRs, they are not under any binding legal obligation to review and consider comments, much less issue final, superseding rules. Indeed, the Departments designed the IFRs to operate ad infinitum by enacting a QPA-calculation methodology that adjusts with the consumer price index (86 Fed. Reg. at 36,894) and a fee structure for IDR entities that the Departments will "review and update . . . annually" (86 Fed. Reg. at 56,005).

1. IFR Part I: Qualifying payment amount methodology

78. On July 13, 2021, the Departments issued the interim final rule entitled *Requirements Related to Surprise Billing; Part I*, 86 Fed. Reg. 36,872 (July 13, 2021). IFR Part I took effect on September 13, 2021, and is applicable to plan and policy years beginning on or after January 1, 2022. 86 Fed. Reg. at 36,872.

79. Among other things, IFR Part I generally addresses the calculation of the QPA pursuant to Congress's directive to issue regulations on methodology by July 1, 2021. *See* PHSA § 2799A-1(a)(2)(B).

80. In particular, IFR Part I purports to establish the methodology for calculating the QPA for air ambulance services.

81. In the preamble, the Departments posit that the "statutory intent" of the Act was to "ensur[e] that the QPA reflects market rates under typical contract negotiations." 86 Fed. Reg. at 36,889. But in practical effect, the IFR administratively deflates the QPA well below what market conditions actually produce.

82. IFR Part I defines the "same or similar item or service" as a service "billed under the same service code." 86 Fed. Reg. 36,954. For air ambulance services, there are generally two air mileage service codes—A0435 (fixed-wing) and A0436 (rotary-wing). *Id.* at 36,895, 36,955.

83. Though it defines a "provider in the same or similar specialty" generally as "the practice specialty of a provider, as identified by the plan consistent with the plan's usual business practice," it sets a completely different definition for air ambulance services: "with respect to air ambulance services, *all* providers of air ambulance services are considered to be a single provider specialty." 86 Fed. Reg. 36,954 (emphasis added).

84. It defines a "geographic region" "[f]or air ambulance services" as "one region consisting of all metropolitan statistical areas . . . in the State, and one region consisting of all other portions of the State, determined based on the point of pick-up." 86 Fed. Reg. at 36,954. When a plan does not have "sufficient information" to calculate the median contracted rate, then the geographic region becomes "one region consisting of all metropolitan statistical areas . . . in each Census division and one region consisting of all other portions of the Census division." *Id.*[6]

[6] There are only nine Census divisions: Pacific, Mountain, West North Central, East North Central, Middle Atlantic, New England, South Atlantic, East South Central, and West South Central.

85. The plan must then calculate the "median contracted rate" by "arranging in order from least to greatest the contracted rates of all group health plans of the plan sponsor (or the administering entity . . .) 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." 86 Fed. Reg. at 36,954. For purposes of contracted rates, the health plan only looks at rates it has "contractually agreed to pay a . . . provider of air ambulance services for covered items or services," expressly excluding any "single case agreement, letter of agreement, or other similar arrangement . . . for a specific participant or beneficiary in unique circumstances" as "not constitu[ting] a contract." *Id.* at 36,953. The preamble to the rule does not justify this exclusion.

86. The plan then calculates the QPA by increasing the median contracted rate consistent with the consumer price index and then multiplying it by the number of "loaded miles," *i.e.*, the number of miles the individual is transported. 86 Fed. Reg. at 36,955.

87. If the plan lacks sufficient information to calculate a median contracted rate, then the plan may determine the QPA via third-party database. 86 Fed. Reg. at 36,895-36,897.

2. IFR Part II: IDR process

88. On October 7, 2021, the Departments issued the interim final rule entitled *Requirements Related to Surprise Billing; Part II*, 86 Fed. Reg. 55,980 (Oct. 7, 2021). IFR Part II took effect on October 7, 2021, and is, in general, applicable to plan, policy, or contract years beginning January 1, 2022, though a handful of requirements took effect immediately. 86 Fed. Reg. at 55,980.

See Census Regions and Divisions of the United States, Census.gov (last visited Oct. 29, 2021), https://www2.census.gov/geo/pdfs/maps-data/maps/reference/us_regdiv.pdf.

89. Among other things, IFR Part II generally addresses the IDR dispute resolution process pursuant to Congress's directive to issue a single set of regulations on the process within one year. *See* PHSA § 2799A-2(b)(2)(A).

90. IFR Part II flips the statutory IDR process on its head by giving the QPA nearly conclusive weight in an IDR entity's decision. Specifically, IFR Part II dictates that "[t]he certified IDR entity *must* select the offer closest to the qualifying payment amount" unless one of two circumstances occurs: "[1] the certified IDR entity determines that credible information submitted by either party under paragraph (c)(4)(i) *clearly demonstrates* that the qualifying payment amount is materially different from the appropriate out-of-network rate, or [2] if the offers are equally distant from the qualifying payment amount but in opposing directions." 86 Fed. Reg. at 56,104 (emphasis added). "In these cases, the certified IDR entity must select the offer as the out-of-network rate that the certified IDR entity determines best represents the value of the qualified IDR item or services, which could be either offer." *Id.*

91. To rebut the IFR-created presumption that the offer closest to the QPA should be the rate, IFR Part II requires the submission of additional information, including "information on the size of the provider's practice," "information on the practice specialty," "information on the coverage area of the plan, the relevant geographic region for purposes of the qualifying payment amount, whether the coverage is fully-insured or partially or fully self-insured," and "[t]he qualifying payment amount." 86 Fed. Reg. at 56,103.

92. IFR Part II then relegates the remaining factors Congress required the IDR entity to consider to afterthoughts, merely permitting submission of information concerning the "additional circumstances" that the statute expressly requires the IDR entity to consider in every case. IFR Part II

- lists the statutory factors—"the level of training, experience, and quality and outcomes measurements of the provider"; "[t]he acuity of the participant . . . or the

complexity of furnishing the qualified IDR item"; "[d]emonstration of good faith efforts (or lack thereof) made by the provider . . . or the plan to enter into network agreements with each other" (*see* PHSA § 2799A-2(b)(5)(C)(ii));

- adds two circumstances—"[t]he market share held by the provider . . . or that of the plan in the geographic region" and the "[t]he teaching status, case mix, and scope of services of the facility"; and
- allows for "[a]dditional information submitted by a party, provided the information is credible and relates to the offer submitted by either party and does not include information on factors" on which consideration is barred.

Id. at 56,104.

93. But IFR Part II limits consideration of these additional circumstances and information only for purposes of rebutting the IFR-created presumption of choosing the QPA and only if it satisfies a heightened credibility standard. *Id.*

THE INTERIM FINAL RULES ARE UNLAWFUL

94. The Interim Final Rules are contrary to law and arbitrary and capricious. The purpose of the Act was to protect patients from surprise medical bills from out-of-network providers by limiting their cost-sharing to in-network levels and removing patients from payment disputes between plans and providers.

95. Congress intended to facilitate negotiations between the provider and the group health plan or issuer to resolve payment disputes and, when that does not work, to allow an independent entity to decide the payment amount by selecting between each party's final offer. This structure forces providers and group health plans or issuers to reach reasonable and efficient outcomes through rational business and legal judgments that account for available information about market rates, out-of-network payments, operating costs, and the IDR entity.

96. The Act does not authorize the Departments to artificially deflate payment amounts

from group health plans or issuers to air ambulance service providers in a manner entirely out of step with the history and economics of the air ambulance industry. That, however, is what the Departments have done through the IFRs. And they have done so in ways that directly contravene the statute.

97. IFR Part II dictates the outcome of the IDR process by making a purposefully deflated QPA—calculated exclusively by the group health plan or issuer—the presumptively correct payment amount. IFR Part I ensures that the QPA for air ambulance is at an artificially low rate by excluding from consideration the case-specific or other agreed-upon rates actually negotiated for covered air ambulance services and refusing to distinguish between hospital-based and non-hospital-based providers. The rule also extends the relevant geographic region without justification to certain Census-defined levels. These choices and the presumption defy the statute and squarely conflict with the Act's goal of facilitating reasonable and efficient outcomes while protecting patients from being put in the middle.

A. IFR Part II is unlawful.

98. Through IFR Part II, the Departments effectively nullify the statutory IDR process that Congress envisioned, replacing it instead with nearly insurmountable deference to the QPA.

99. The Act provides for a "final offer" or "baseball style" determination of the payment amount by a certified independent dispute resolution entity after considering various factors listed in the statute. Final-offer dispute resolution "is designed to not only persuade parties to settle their disputes to avoid unpredictable and uncompromising hearings, but also to submit reasonable proposals before the hearing." Matt Mullarkey, Note, *For the Love of the Game: A Historical Analysis and Defense of Final Offer Arbitration in Major League Baseball*, 9 Va. Sports & Ent. L.J. 234, 245 (2010). The "all-or-nothing approach is designed to promote reasonable offers because every dollar that a [claimant] adds to his proposal moves up the midpoint and decreases his chance of winning." *Id.* In final-offer resolution, there is typically no written opinion or reasoning

behind the decision, further encouraging the push for reasonableness between the parties. *Id.* at 238.

100. Congress's design was thus to encourage payers and air ambulance providers to resolve their monetary disputes through negotiations between each other to avoid having to risk it all in an IDR determination with little guidance as to what a particular IDR entity would view as the reasonable payment amount. And, even if the parties could not reach an agreement through negotiations, final-offer dispute resolution creates strong incentives for both sides to put forth their most reasonable offer and then for the certified IDR entity to choose the one that it deems most reasonable. The need to make a reasonable offer is reinforced by the statute's obligation on the losing party to bear the costs of the IDR process.

101. IFR Part II unapologetically vitiates this design and, in so doing, conflicts with the statutory language.

102. The statute provides that the IDR entity shall, "taking into account the considerations specified in subparagraph (C), select one of the offers submitted under subparagraph (B) to be the amount of payment for such services determined under this subsection for purposes of subsection (a)(3)." PHSA § 2799A-2(b)(5)(A). The "considerations specified in subparagraph (C)" that the IDR entity "*shall consider*" are numerous—the QPA, the provider's quality and outcomes measurements, the medical personnel's level of training, experience, and quality, the acuity of the individual and complexity of service, ambulance vehicle type, population density of the pick up location, and each party's demonstration of good faith efforts to reach a contracted rate. *Id.* § 2799A-2(b)(5)(C). The statute treats each of these factors equally, with no weight placed on any particular one. But, under IFR Part II, these statutorily mandated factors are rendered nearly meaningless.

103. IFR Part II irrevocably slants the "independent" dispute resolution by dictating outcomes. It demands that the certified IDR entity "*must* select the offer closest to the qualifying

payment amount," subject only to two narrow exceptions: if "[1] the certified IDR entity determines that credible information submitted by either party under paragraph (c)(4)(i) clearly demonstrates that the [QPA] is materially different from the appropriate out-of-network rate, or if [2] the offers are equally distant from the [QPA] but in opposing directions." 86 Fed. Reg. at 56,104 (emphasis added). Then the IDR entity "must select the offer as the out-of-network rate that the certified IDR entity determines best represents the value of the qualified IDR item or services." *Id.*

104. According to the preamble, "emphasizing the QPA will allow for predictability" because "even before beginning negotiations, all parties involved will know that the QPA is the primary factor that the certified IDR entity will always consider (while other factors may be considered, depending on the circumstances)." 86 Fed. Reg. at 56,061. In the Departments' view, "[t]his certainty will encourage plans, issuers, providers, and facilities to make offers that are closer to the QPA, and to the extent another factor could support deviation from the QPA, to focus on evidence concerning that factor" and "may also encourage parties to avoid the Federal IDR process altogether and reach an agreement during the open negotiation period." *Id.*

105. IFR Part II thus writes the independent dispute resolution process out of the statute. No longer does the IDR entity determine *independently* a reasonable payment amount based on various inputs that the statute requires it to consider. Instead, the IDR entity is forced to choose the QPA in nearly all cases, despite that the QPA is effectively set by the payer itself.

106. If Congress intended the QPA to be practically dispositive, it would have said so. Indeed, it could have chosen to simply mandate the QPA as the payment amount. *See* Ban Surprise Bill Act, H.R. 5800, 116th Cong. § 2(a) (2020) (proposing new PHSA § 2719A(f)). It did not. It chose final-offer dispute resolution and called for open-ended consideration of a number of specified factors. The Departments, however, have disregarded that directive, casting aside all considerations other than the QPA in the vast majority of cases. Independent dispute resolution was not intended to be perfectly predictable, nor to force the parties to accept the QPA, especially a QPA

so unreliably derived. By strictly curtailing the IDR entity's ability to independently select the amount of payment, IFR Part II contravenes Congress's design.

107. It is no answer to say that a provider has a narrow escape hatch from the QPA by providing evidence to "clearly demonstrate[] that the qualifying payment amount is materially different from the appropriate out-of-network rate." 86 Fed. Reg. at 56,104. It is instead circular. The statute defines the "out-of-network rate" as the amount that the parties negotiate or the IDR entity selects for the service at issue. PHSA § 2799A-1(a)(3)(K). A party cannot logically provide evidence to "clearly demonstrate" that the "qualifying payment amount is materially different" from the amount the parties have not yet had a chance to negotiate or the IDR entity has not yet determined. In practical effect, the Departments have ensured that the QPA will end matters, an outcome that Congress could have adopted but instead rejected.

B. IFR Part I is unlawful.

108. IFR Part I dictates a QPA that is, by the Departments' own admission, administratively deflated for independent air ambulance service providers but will ensure that patients are not "required to pay higher cost-sharing amounts." *See* 86 Fed. Reg. at 36,891.

109. The statutory starting point for calculating the QPA requires taking "the median of the contracted rates recognized by the plan or issuer" as of January 31, 2019 "for the same or a similar item or service that is provided by a provider in the same or similar specialty and provided in the geographic region in which the item or service is furnished, consistent with the methodology established by the Secretary." PHSA § 2799A-1(a)(3)(E)(i)(I).

110. By its plain terms, the contracted rates contemplated by § 2799A-1(a)(3)(E)(i)(I) include case-specific contracts for covered services. IFR Part I, however, excludes a wide range of relevant contracts from the calculation of the median contracted rate and instead focuses only on a small portion of inapposite payment arrangements. The QPA, for example, excludes historic out-of-network payments made under the patient's health plan, letters of agreement, arrangements

used to supplement a payer's network, incentive-based and retrospective arrangements, and single case agreements. Yet these are all "contracted rates recognized by the plan or issuer" for covered services from which Congress directed the calculation of median reimbursement. *Id.*

111. The Departments acknowledged in IFR Part I that only 25% of air ambulance transports in 2012 and 31% in 2017 were made under a traditional in-network contract. 86 Fed. Reg. at 36,923. Yet under the IFRs, this unrepresentative sample of transports drives the QPA for *all* transports. The Departments' unexplained decision to disregard the majority of actual contract rates is arbitrary and contrary to law. Given these unlawful exclusions, the Departments have ensured that the methodology will not produce QPAs that actually reflect how payers and providers have historically resolved payments via negotiation.

112. The statute further directs that the rulemaking must determine "the geographic regions applied for purposes of this subparagraph, taking into account access to items and services in rural and underserved areas, including health professional shortage areas." PHSA § 2799A-1(a)(2)(B)(iii). And the rulemaking "may . . . take into account quality or facility type (including higher acuity settings and the case-mix of various facility types) that are otherwise taken into account for purposes of determining payment amounts with respect to participating facilities." *Id.* § 2799A-1(a)(2)(B).

113. For purposes of air ambulance services, however, the agency gives no meaning to the requirement that the service be the "same" and the "provider [be] in the same or similar specialty" nor does it adequately consider "facility type." PHSA §§ 2799A-1(a)(3)(E)(i)(I), 2799A-1(a)(2)(B). IFR Part I simply deems hospital-based and independent non-hospital-based air ambulance providers to be a "single provider specialty." 86 Fed. Reg. at 36,891. Yet the history and structure of the industry does not support treating these two vastly different service providers as the same. The Departments know this. The preamble to IFR Part I specifically explains that the

Departments "understand that hospital-based air ambulance providers sometimes have lower contracted rates than independent, non-hospital-based air ambulance providers." *Id.* But they refused to treat these distinct types of providers differently due solely to cost-sharing considerations: "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." *Id.*

114. That is unsupportable. *First*, the judgments made for hospital-based air ambulance providers negotiating global agreements for numerous hospital service lines do not reflect the economic considerations that would determine a reasonable rate for an independent air ambulance provider negotiating for only air ambulance services. Air ambulance service providers that bill only for air ambulance services must ensure that rates with group health plans or issuers are sufficient to maintain services in a community. Otherwise, they cannot cover their costs. Treating these two admittedly distinct types of providers as commanding the same negotiated rates is arbitrary and capricious.

115. *Second*, the arbitrariness of the Departments' conclusion is confirmed by its treatment of hospital-based emergency departments differently from standalone emergency departments. 86 Fed. Reg. at 36,892. The Departments explained: "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." *Id.* The Departments' inexplicable

decision to treat air ambulance service providers differently from hospital-based and freestanding emergency departments is arbitrary and capricious.

116. *Third*, the statute does not tie a patient's cost-sharing amount to the QPA. *See* PHSA § 2799A-2(a)(1). Instead, it directs that cost-sharing for air ambulance services be "based on rates that would apply for such services if they were furnished by such a participating provider[.]" *Id.* Congress knew how to tie cost-sharing to the QPA because it did so for emergency services, requiring cost-sharing to be calculated based on the "recognized amount," which specifically includes the QPA as one base for its calculation. *See id.* § 2799A-1(a)(1)(C)(iii), (a)(3)(H). That Congress did not do so for air ambulance services shows that it rejected intertwining patient cost-sharing and the QPA and that such concerns about patient cost-sharing cannot support the Departments' efforts to depress air ambulance reimbursements.

117. *Finally*, IFR Part I arbitrarily ignores Congress's directive to consider service providers by "geographic region." Where there are an insufficient number of contracts to determine the QPA based on state lines, IFR Part I requires the QPA to be determined using all metropolitan statistical areas in a Census division or all other areas in that Census division. But Census divisions are large. *See Census Regions and Divisions of the United States*, Census.gov (last visited Oct. 29, 2021), perma.cc/4QWX-7738. This requirement would mean that a contracted rate from Alaska or Hawaii could dictate the QPA for a medical air transport in California; or a contracted rate in Florida could dictate the QPA in Washington, D.C. By requiring calculation tailored to a "geographic region," Congress cannot have meant to have geographically and economically unique markets dictate payments in completely different markets that are thousands of miles, and even oceans, apart. The over-broadening of the geographic region cannot be justified by concern about not having a sufficient number of "contracted rates." Instead, that is a problem of the Departments' own making by purposefully excluding substantial volumes of contracts and agreements from the QPA calculation. IFR Part I is thus contrary to law.

118. Put together, the Interim Final Rules take a statute intended to protect patients by removing them from payment negotiations between providers and payers and transform it into a rate-setting rule that will ensure that air ambulance providers receive artificially low rates (indeed, lower than the health plans paid previously) and drive them out of business, jeopardizing the access to emergency healthcare services by the very patients Congress sought to protect. The IFRs are arbitrary and capricious and contrary to law.

C. The IFRs harm air ambulance providers, including AAMS's members

119. As participants in the air ambulance industry, AAMS's members will be directly injured by the IFRs. Many of AAMS's members have been unable to procure in-network agreements with health plans or issuers in areas where they operate, and they are therefore subject to the No Surprises Act. The IFRs supplant the Act by purposefully depressing the QPA and then pushing AAMS's members into a one-sided dispute resolution process designed to impose the QPA. The natural and intended outcome of the implementation of the IFRs will be a reduction in payment to AAMS's members that could force its members out of the market altogether and, as a result, reduce access to critical emergency services for patients. These injuries are actual and imminent because the IFRs become effective for plan years starting January 1, 2022.

120. One publicly available data point that demonstrates the injury the IFRs will inflict on air ambulance providers is a report issued by FAIR Health—a non-profit claims database that CMS has certified as a Qualified Entity (QE) for the CMS QE Program. *See* FAIR Health, *Air Ambulance Services in the United States: A Study of Private and Medicare Claims* (Sept. 28, 2021), perma.cc/2EA6-PK8E. FAIR Health has determined that "[t]he average estimated allowed amount" for the base rate for an air ambulance transport is $18,668. *Id.* at 2 & n.1. The Act authorizes group health plans and issuers to use third-party databases such as FAIR Health to determine the QPA when the plan or issuer lacks sufficient information to calculate a median in-network rate. As such, FAIR Health is marketing its "average estimated allowed amount" and underlying

data to plans and issuers for that purpose, and their use of the FAIR Health information is imminent given the historically limited network contracting between plans and issuers and air ambulance providers.

121. PHI Health, LLC (PHI) is an AAMS members that will be directly injured by the IFRs. *See* Exhibit 5 (Foster Declaration). PHI delivers rotor-wing air ambulance services from 77 air bases located in 15 states and fixed wing air ambulance services from 3 air bases in California and Missouri. *Id.* ¶ 2. PHI expects that the IFRs will drive payments by group health plans or issuers to a level at or below the QPA because the IFRs eliminate any rational business reason for plans or issuers to enter into a network contract with an air emergency ambulance provider at a rate exceeding the plan's or issuer's QPA. *Id.* ¶ 11. PHI estimates that, if all plans and issuers began paying $18,668 or less for the base rate for out-of-network air ambulance transport beginning on January 1, 2022, then most of PHI's air bases would experience reductions in revenue. *Id.* ¶ 16. Indeed, PHI expects that the "reductions in revenue would be so great that as many as 33 of [PHI's] air bases would cease to cover their costs, and it would become necessary for [PHI] to close or consolidate some or all of those air bases as soon as possible in calendar year 2022," causing an irreparable injury. *Id.* ¶¶ 16-19.

122. Global Medical Response, Inc. (GMR) is an AAMS member that will be directly injured by the IFRs. *See* Exhibit 6 (Preissler Declaration). GMR delivers rotor-wing and fixed-wing air emergency ambulance services from 340 air bases located in 28 states. *Id.* ¶ 2. GMR likewise has concluded that the IFRs will drive payments by group health plans or issuers to a level at or below the QPA. *Id.* ¶ 11. GMR estimates that, if all plans and issuers began paying $18,668 or less for the base rate for out-of-network air ambulance transport beginning on January 1, 2022, then most of GMR's air bases would experience reductions in revenue. *Id.* ¶ 16. GMR anticipates that up to 10% of GMR's total annual emergency transports for all air bases in calendar year 2022 will be paid by reference to the FAIR Health database or other QPA equivalent. *Id.* ¶ 17. If group

health plans and issuers use the FAIR Health average estimated allowed amount of $18,668 as the base rate when paying for 10% of GMR's total annual transports for all air bases, then "most of GMR's bases would experience reductions in revenue for calendar year 2022." *Id.* ¶ 18.

123. Air Methods Corporation (AMC) is an AAMS member that will be directly injured by the IFRs. *See* Exhibit 7 (Portugal Declaration). AMC delivers rotor-wing air ambulance services from 257 air bases located in 42 states and fixed-wing air ambulance services from 27 air bases located in 15 states. *Id.* ¶ 2. AMC has concluded that, if all plans and issuers began paying $18,668 or less for the base rate for out-of-network air ambulance transport beginning on January 1, 2022, then eighty percent of AMC's air bases would experience reductions in revenue. *Id.* ¶ 16. AMC estimates that up to 7% of AMC's total annual transports in calendar year 2022 will be paid by reference to the FAIR Health database or other QPA equivalent. *Id.* ¶ 17. If group health plans and issuers use the FAIR Health average estimated allowed amount of $18,668 as the base rate when paying for 7% of AMC's total annual transports for each air base, then "eighty percent of AMC's bases would experience reductions in revenue for calendar year 2022." *Id.* ¶ 18.

CLAIMS FOR RELIEF

Count I
Administrative Procedure Act
IFR Part II - arbitrary, capricious, and contrary to law weighting of QPA

124. AAMS incorporates and re-alleges the foregoing paragraphs as though fully set forth herein.

125. IFR Part II is final agency action subject to review under the APA. 5 U.S.C. § 704. IFR Part II marks the consummation of the Departments' collective decision-making, establishes the rights and obligations of air ambulance providers, group health plans, and issuers, and is one from which legal consequences will flow.

126. The APA empowers courts to "hold unlawful and set aside agency action, findings, and conclusions found to be . . . arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A).

127. It likewise authorizes courts to set aside agency action "in excess of statutory jurisdiction, authority, or limitations." 5 U.S.C. § 706(2)(C).

128. IFR Part II violates these APA requirements. It squarely conflicts with the provisions of the statute establishing the IDR process, which require equal consideration of all the enumerated factors, and it is therefore in excess of statutory limits.

129. IFR Part II is also arbitrary and capricious because it gives presumptively dispositive weight to a QPA that itself is calculated in an arbitrary and capricious manner, as described herein.

130. Accordingly, those elements of the Interim Final Rule Part II that require IDR entities to give presumptively dispositive weight to the QPA must be set aside. 5 U.S.C. § 706(2).

Count II
Administrative Procedure Act
IFR Part I - arbitrary, capricious, and contrary to law derivation of QPA

131. AAMS incorporates and re-alleges the foregoing paragraphs as though fully set forth herein.

132. IFR Part I is final agency action subject to review under the APA. 5 U.S.C. § 704. IFR Part I marks the consummation of the Departments' collective decision-making, establishes the rights and obligations of air ambulance providers, group health plans, and issuers, and is one from which legal consequences will flow.

133. The APA empowers courts to "hold unlawful and set aside agency action, findings, and conclusions found to be . . . arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A).

134. It likewise authorizes courts to set aside agency action "in excess of statutory jurisdiction, authority, or limitations." 5 U.S.C. § 706(2)(C).

135. The Interim Final Rule Part I violates these APA requirements. IFR Part I conflicts with the relevant provisions of the statute, and it is therefore in excess of statutory limits, by excluding swaths of case-specific contracts and agreements from the definition of "contracted rates."

136. The preamble to IFR Part I also recognizes, but then disregards, the critical differences between hospital-based and independent air ambulance service providers, justifying its decision to treat them the same based purely on a desire to reduce patient cost-sharing. That reasoning fails to "articulate . . . a 'rational connection between the facts found and the choice made,'" "offer[s] an explanation for its decision that runs counter to the evidence before the agency," "fail[s] to consider an important aspect of the problem," and "relie[s] on factors which Congress has not intended it to consider." *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).

137. Further, by lumping independent and hospital-based air ambulance providers together, while not doing so in similar cases (like hospital-based and freestanding emergency facilities), it "applies different standards to similarly situated entities and fails to support this disparate treatment with a reasoned explanation and substantial evidence in the record." *Anna Jaques Hosp. v. Sebelius*, 583 F.3d 1, 7 (D.C. Cir. 2009).

138. IFR Part I also broadly construed the geographic region to reach the Census-division level, potentially allowing contracted rates in Hawaii to dictate rates in rural Washington. By doing so, the agency "failed to consider an important aspect of the problem." *State Farm*, 463 U.S. at 43. And it did so without "articulat[ing] . . . a 'rational connection between the facts found and the choice made'" because the only justification is lack of sufficient volume of contracted rates—a problem the agency created for itself by defining "contracted rates" to exclude substantial volumes of contracts contrary to the statute. *Id.*

139. Accordingly, those elements of the Interim Final Rule Part I that govern QPA determinations for air ambulance services must be set aside. 5 U.S.C. § 706(2).

PRAYER FOR RELIEF

AAMS respectfully requests that the Court enter judgment in its favor and that the Court:

(a.) Vacate the following elements of the interim final rule entitled *Requirements Related to Surprise Billing; Part II*, 86 Fed. Reg. 55,980 (Oct. 7, 2021):

- Section 54.9816-8T(c)(4)(B)(ii)'s direction that "[t]he certified IDR entity must select the offer closest to the qualifying payment amount unless the certified IDR entity determines that credible information submitted by either party under paragraph (c)(4)(i) clearly demonstrates that the qualifying payment amount is materially different from the appropriate out-of-network rate, or if the offers are equally distant from the qualifying payment amount but in opposing directions. In these cases, the certified IDR entity must select the offer as the out-of-network rate that the certified IDR entity determines best represents the value of the qualified IDR item or services, which could be either offer."

(b.) Vacate the following elements of the interim final rule entitled *Requirements Related to Surprise Billing; Part I*, 86 Fed. Reg. 36,872 (July 13, 2021):

- Section 54.9816-6T(a)(1)'s direction that "[s]olely 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."
- Section 54.9816-6T(a)(7)(ii)'s provision that "[i]f 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)."

- Section 54.9816-6T(a)(12)'s provision that "except that, with respect to air ambulance services, all providers of air ambulance services are considered to be a single provider specialty."

(c.) Issue a declaratory judgment that these portions of the interim final rules were issued in violation of the Administrative Procedure Act;

(d.) Enjoin Defendants from implementing, enforcing, or otherwise carrying out these portions of the interim final rules;

(e.) Award AAMS attorney's fees and costs; and

(f.) Award AAMS such other and further relief as the Court may deem just and proper.

Dated: November 16, 2021

Respectfully submitted,

/s/ *Sarah P. Hogarth*
Brian R. Stimson (petition for admission pending)
Sarah P. Hogarth (D.C. Bar. No. 1033884)
McDermott Will & Emery LLP
500 North Capitol Street NW
Washington, DC 20001
(202) 756-8000
bstimson@mwe.com
shogarth@mwe.com

Attorneys for Plaintiff
Association of Air Medical Services

Exhibit 1

Congress of the United States
U.S. House of Representatives
COMMITTEE ON WAYS AND MEANS
1102 LONGWORTH HOUSE OFFICE BUILDING
(202) 225-3625
Washington, D.C 20515-0348
http://waysandmeans.house.gov

October 4, 2021

The Honorable Xavier Becerra
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

The Honorable Martin Walsh
Secretary
U.S. Department of Labor
200 Constitution Avenue, NW
Washington, DC 20210

The Honorable Janet Yellen
Secretary
U.S. Department of the Treasury
1500 Pennsylvania Avenue, NW
Washington, DC 20220

Re: Implementation of the No Surprises Act

Dear Secretaries Becerra, Yellen, and Walsh:

We write regarding our concerns with respect to the implementation of the historic and bipartisan No Surprises Act by your Departments. We are concerned that the regulation published on September 30, 2021, as well as the decision to delay full implementation of the Advanced Explanation of Benefits (AEOB) and other patient protections, do not reflect the law that Congress passed. While this law represents one of the greatest consumer protection reforms in American history, its success depends on your Departments fulfilling Congressional intent and swiftly implementing all necessary provisions.

For far too long, patients received devastating surprise out-of-network medical bills and suffered from a lack of price transparency. Payers and providers put patients in the middle of their payment disputes. They kept patients in the dark about the cost of their care, then saddled them with insurmountable and unexpected charges. Congress stepped in to protect patients by ending the practice of surprise medical billing. In so doing, Congress sought to promote fairness in payment disputes between insurers and providers—carefully specifying all the various factors that should be considered during the independent dispute resolution (IDR) process. Your

Departments are also charged with ensuring that payers and providers work together to provide patients with transparent information that includes the patients' costs and the network status of their providers in the form of an AEOB.

The IDR process was subject to extensive Congressional consideration for nearly two years prior to the enactment of the No Surprises Act. The law incentivizes insurers and providers to act in good faith and resolve disputes amongst themselves while also recognizing that the parties may be unable to resolve their differences in certain instances. As a result, the law provides for an IDR process overseen by an independent and neutral arbiter who must consider a number of factors equally in deciding whether to select the provider or payer's offer. Such factors include median in-network rates, prior contracted rates during the previous four plan years, the relative market share of both parties involved, the provider's training and experience, the patient's acuity, the complexity of furnishing the item or service, and in the case of a provider that is a facility, its teaching status, case mix and scope of services, demonstrations of good faith efforts (or lack of good faith efforts) to enter into a network agreement, and other items. Congress deliberately crafted the law to avoid any one factor tipping the scales during the IDR process.

As you know, the Committees of jurisdiction worked through multiple proposals to end surprise billing throughout the 116th Congress. The compromise reflected in the No Surprises Act balanced the various approaches alongside the significant political and economic considerations at issue. Multiple proposals that ultimately did not become law relied on the median in-network rate as the benchmark for payment, with baseball-style arbitration designed as a backstop to, at most, result in a mere adjustment to the benchmark rate. In contrast, the legislation reported out of the Committee on Ways and Means, which was adopted in the No Surprises Act, authorizes IDR but does not preference in-network rates to determine the payment amount. The law Congress enacted directs the arbiter to consider all of the factors without giving preference or priority to any one factor—that is the express result of substantial negotiation and deliberation among those Committees of jurisdiction, and reflects Congress's intent to design an IDR process that does not become a de facto benchmark.

Despite the careful balance Congress designed for the IDR process, the September 30, 2021 interim final rule with comment strays from the No Surprises Act in favor of an approach that Congress *did not* enact in the final law and does so in a very concerning manner. The rule crafts a process that essentially tips the scale for the median contracted rate being the default appropriate payment amount. Under the interim final rule, the IDR entity is only allowed to deviate from the median amount where the parties present "credible information about additional circumstances [that] clearly demonstrates that the [median in-network rate] is materially different from the appropriate out-of-network rate." Such a standard affronts the provisions enacted into law, and we are concerned that this approach biases the IDR entity toward one factor (a median rate) as opposed to evaluating all factors equally as Congress intended.

In addition, we are concerned by the Administration's decision to delay the implementation of certain key transparency provisions slated to take effect on January 1, 2022. In guidance from August 2021, the Centers for Medicare and Medicaid Services delayed the compliance date for when consumers should receive a good faith estimate of the cost of services

through an AEOB despite the date specified by Congress. We are concerned that without a strict implementation deadline, payers and providers will not work toward expanding the current data transfer technology framework to ensure full compliance with the law. This provision was enacted to bring unprecedented transparency to patients about the cost of their health care, and delaying its implementation will leave patients vulnerable.

We understand that implementing the No Surprises Act to end the practice of surprise medical billing in a year is no small task, and that complexities exist as your individual Departments work together, but we must remain steadfast in ending this predatory practice. We request a written follow-up explaining how the regulation issued last week establishing the IDR process and designing a new test for how factors should be considered comports with the law Congress enacted. We are also requesting a timeline for full implementation that declares interim plans to build on current technology available to allow for implementation of these patient protections, specifically the AEOB and true and honest cost estimate, as soon as practicable. Finally, we ask that you revisit this interim final rule and consider adjustments that better align with the law Congress enacted.

Sincerely,

Richard E. Neal
Chairman
Committee on Ways and Means

Kevin Brady
Ranking Member
Committee on Ways and Means

Exhibit 2

Congress of the United States
House of Representatives
Washington, DC 20515

November 5, 2021

The Honorable Xavier Becerra
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

The Honorable Janet Yellen
Secretary
U.S. Department of the Treasury
1500 Pennsylvania Avenue NW
Washington, DC 20220

The Honorable Martin J. Walsh
Secretary
U.S. Department of Labor
200 Constitution Avenue NW
Washington, DC 20210

Dear Secretary Becerra, Secretary Yellen, and Secretary Walsh:

We write regarding the interim final rule (IFR) released on September 30 entitled "Requirements Related to Surprise Billing; Part II". The bipartisan No Surprises Act, passed by Congress in December 2020, was one of the most important patient protection bills in American history, but its success will depend on your departments following the letter of law in its implementation. We urge you to amend the IFR in order to align the law's implementation with the legislation Congress passed.

Congress passed the No Surprises Act after extensive bipartisan and bicameral deliberations to protect patients from surprise medical bills and create a balanced process to resolve payment disputes between insurance plans and health care providers. During these deliberations, multiple proposals were considered including a benchmark rate, an independent dispute resolution (IDR) process, and a hybrid. Following a comprehensive process that included hearings, markups, and extensive negotiations, Congress rejected a benchmark rate and determined the best path forward for patients was to authorize an open negotiation period coupled with a balanced IDR process.

The No Surprises Act specified an IDR process that takes patients out of the middle of payment disputes. It allows providers and payors to bring any relevant information to support their payment offers for consideration, except for billed charges and public payor information. Per this process, the certified IDR entity shall consider:

- Median in-network rates
- Provider training and quality of outcomes
- Market share of parties
- Patient acuity or complexity of services
- In the case that a provider is a facility: teaching status, case mix, and scope of services
- Demonstrations of previous good faith efforts to negotiate in-network rates
- Prior contract history between the two parties over the previous four years

The process laid out in the law expressly directs the certified IDR entity to consider each of these listed factors should they be submitted, capturing the unique circumstance of each billing dispute without causing any single piece of information to be the default one considered.

Unfortunately, the parameters of the IDR process in the IFR released on September 30 do not reflect the way the law was written, do not reflect a policy that could have passed Congress, and do not create a balanced process to settle payment disputes. The IFR directs IDR entities to begin with the assumption that the median in-network rate is the

appropriate payment amount prior to considering other factors. This directive establishes a de-facto benchmark rate, making the median in-network rate the default factor considered in the IDR process. This approach is contrary to statute and could incentivize insurance companies to set artificially low payment rates, which would narrow provider networks and jeopardize patient access to care – the exact opposite of the goal of the law. It could also have a broad impact on reimbursement for in-network services, which could exacerbate existing health disparities and patient access issues in rural and urban underserved communities.

We appreciate the complex nature of the patient protections that must be established and look forward to a final rule that accurately reflects Congress's multi-year bipartisan and bicameral work to pass this landmark legislation. Therefore, we urge you to revise the IFR to align with the law as written by specifying that the certified IDR entity should not default to the median in-network rate and should instead consider all of the factors outlined in the statute without disproportionately weighting one factor.

Thank you for your continued efforts on this important matter. We look forward to working with you to ensure the best outcomes for our patients and the health of our communities.

Sincerely,

Thomas R. Suozzi
Member of Congress

Brad R. Wenstrup, D.P.M.
Member of Congress

Raul Ruiz, M.D.
Member of Congress

Larry Bucshon, M.D.
Member of Congress

Additional Signatories

Alma S. Adams, Ph.D.
Colin Allred
Jodey C. Arrington
Cindy Axne
Ami Bera, M.D.
Jack Bergman
Andy Biggs
Dan Bishop
Sanford D. Bishop, Jr.
Mike Bost
Julia Brownley
Vern Buchanan
Tim Burchett
Michael C. Burgess, M.D.
Salud Carbajal
André Carson
Earl L. "Buddy" Carter, R.Ph.
Liz Cheney
Judy Chu
Steve Cohen
Tom Cole
J. Luis Correa
Jim Costa
Charlie Crist
Jason Crow
Sharice L. Davids
Danny K. Davis
Madeleine Dean
Suzan DelBene
Mark DeSaulnier
Neal P. Dunn, M.D.
Jake Ellzey
Tom Emmer
Adriano Espaillat
Ron Estes
Dwight Evans
Randy Feenstra
A. Drew Ferguson, IV
Brian Fitzpatrick
Chuck Fleischmann

John Garamendi
Andrew R. Garbarino
Louie Gohmert
Jimmy Gomez
Josh Gottheimer
Mark E. Green, M.D.
Glenn Grothman
Michael Guest
Josh Harder
Andy Harris, M.D.
Brian Higgins
J. French Hill
Ashley Hinson
Chrissy Houlahan
Richard Hudson
Ronny L. Jackson, M.D
Sheila Jackson Lee
Chris Jacobs
Dusty Johnson
Eddie Bernice Johnson
Henry C. “Hank” Johnson Jr.
John Joyce, M.D.
John Katko
Mike Kelly
Daniel T. Kildee
Derek Kilmer
Young Kim
Ron Kind
Raja Krishnamoorthi
Darin LaHood
Doug LaMalfa
Conor Lamb
Doug Lamborn
James R. Langevin
Jake LaTurner
Barbara Lee
Debbie Lesko
Julia Letlow
Mike Levin
Ted W. Lieu
Barry Loudermilk
Alan Lowenthal
Frank D. Lucas
Stephen F. Lynch
Nicole Malliotakis
Carolyn B. Maloney
Sean Patrick Maloney
Tracey Mann
Lucy McBath
James P. McGovern
David B. McKinley P.E
Peter Meijer
Grace Meng
Dan Meuser
Carol D. Miller
Mariannette J. Miller-Meeks, M.D.
Alex X. Mooney
Joseph D. Morelle
Frank J. Mrvan
Gregory F. Murphy, M.D.
Stephanie Murphy
Jerrold Nadler
Grace F. Napolitano
Dan Newhouse
Eleanor Holmes Norton
Devin Nunes
Jimmy Panetta
Bill Pascrell, Jr.
Ed Perlmutter
Dean Phillips
Bill Posey
Tom Reed
Guy Reschenthaler
Tom Rice
David Rouzer
Lucille Roybal-Allard
Bobby L. Rush
Tim Ryan
Linda T. Sánchez
Bradley S. Schneider
David Schweikert
Austin Scott
David Scott
Pete Sessions
Terri A. Sewell
Brad Sherman
Mike Simpson
Albio Sires
Christopher H. Smith
Jason Smith
Lloyd Smucker
Elise Stefanik
Eric Swalwell
Van Taylor
Mike Thompson
Rashida Tlaib
Ritchie Torres
Michael R. Turner
Jefferson Van Drew, D.M.D.
Beth Van Duyne
Nydia M. Velázquez
Jackie Walorski
Daniel Webster
Bruce Westerman
Robert J. Wittman
Steve Womack
John Yarmuth
Don Young

CC: Daniel Barry, Acting General Counsel, U.S. Department of Health and Human Services
Laurie Schaffer, Principal Deputy General Counsel, U.S. Department of the Treasury
Peter Constantine, Associate Solicitor for Legal Counsel, U.S. Department of Labor
Lynn Eisenberg, General Counsel, U.S. Office of Personnel Management

Exhibit 3

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 September 13, 2021.

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/cciio*), 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 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 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 billing for individuals enrolled in group health plans and group and individual health insurance coverage.

[1] The term ''group health plan'' includes both insured and self-insured group health plans.

[2] 26 CFR 54.9815–2719A(b); 29 CFR 2590.715–2719A(b); 45 CFR 147.138(b).

[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.*

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, 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 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

[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.

[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/do/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.

[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.

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 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 1973 [18] 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 1964 [20] 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.

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 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

[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.*

[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.

[21] 86 FR 7009 (Jan. 25, 2021).

[22] Public Law 116–260.

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 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 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

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

[24] 42 U.S.C. 1395dd.

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 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 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 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

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

[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/.*

[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).

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.

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.

[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.

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 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 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

[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).

[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).

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 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

[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.

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

[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.

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 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 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 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

[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.

[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).

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 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 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

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

[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).

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 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

[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.

[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-*

Continued

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 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 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 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

health-model; CMS. Maryland Total Cost of Care Model available at *https://innovation.cms.gov/innovation-models/md-tccm.*

[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 the 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.*

[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.

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.

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

[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.

[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.

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 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 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

[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.

[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.

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 QPAs 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 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 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 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

[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.*

[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.

[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), 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.*

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 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.

[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.*

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 program [58] 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 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

[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).

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 CPI–U 2022/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 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

[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.

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 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

[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.

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 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

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

[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.

[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.

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

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 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 an 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

[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

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acknowledge that there may be instances where a participant, beneficiary, or 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

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or in part due to the imposition of cost-sharing requirements is an ABD).

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 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

[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.

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 grandmothered 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 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, 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

[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.

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

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 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

[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.

[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.

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 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 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

[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.

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 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

[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.

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 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

[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.'').

[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%2Doverlapping%2C,and%20the%20U.S.%20Virgin%20Islands.*

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 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 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 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-

[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, A.R. 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.

[86] 42 U.S.C. 2000d *et seq.*

[87] 269 U.S.C. 794.

[88] 42 U.S.C. 12101 *et seq.*

[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.

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 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 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,

[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.

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 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.

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.

[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, 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/.*

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 Information [96]) 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 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

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

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 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

[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.

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

[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).

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 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 OPM[101] 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 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.

[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/do/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.*

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

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, 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.

BILLING CODE 4120–01–P

[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/.*

[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/.*

TABLE 1: Accounting Statement

<table>
<tr><td colspan="5">Benefits:</td></tr>
<tr><td colspan="5">Non-Quantified:
• 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.</td></tr>
<tr><td>Costs:</td><td>Estimate</td><td>Year Dollar</td><td>Discount Rate</td><td>Period Covered</td></tr>
<tr><td rowspan="2">Annualized Monetized ($/year)</td><td>$ 2,252.23 million</td><td>2021</td><td>7 percent</td><td>2021 – 2025</td></tr>
<tr><td>$ 2,177.12 million</td><td>2021</td><td>3 percent</td><td>2021 – 2025</td></tr>
<tr><td colspan="5">Quantitative:
• 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.</td></tr>
</table>

• 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: • 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.

BILLING CODE 4120–01–C

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 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 $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), 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

[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/.*

[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 E.C., Mello M.M., 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.

[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.

[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.

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 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. 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 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

[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.

[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.

[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.*

[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.

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 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.

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 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

[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.

[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.

[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.*

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 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 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, 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

[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.*

[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.*

[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.*

[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.*

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 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 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 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 media [163] 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

[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 (Pub. L. 2018, c. 32) Data Reporting. As of January 31, 2021. *https://www.state.nj.us/dobi/division_insurance/oonarbitration/data/210131report.html.*

[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. U.S.C.-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/.*

[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.

[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.*

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 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, 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 issuers [166] and 205

[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.*

[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.*

TPAs [167]—will be required to comply with these 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

Occupation:	Hourly wage rate	2021	
		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
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

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

[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.*

TABLE 3—ONGOING ANNUAL OPERATIONAL COSTS FOR ISSUERS AND TPAS STARTING IN 2022—Continued

Occupation:	Hourly wage rate	2022		2023 onwards	
		Time (hours)	Estimated labor cost	Time (hours)	Estimated labor cost
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 on-boarding 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 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 services [173] 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 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

[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-ascs-are-in-the-us#:~:text=Currently%2C%20there%20are%20more%20than,Healthcare's%20platform%20on%20surgery%20centers.*

[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.*

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 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-pockets 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

[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.

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.

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.

[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%2Doverlapping%2C,and%20the%20U.S.%20Virgin%20Islands.*

[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.*

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).

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))

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

[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.*

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 visits [184] 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 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-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.

[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/.*

[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.*

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 Washington [187] 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.

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

[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.*

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 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.

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

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

[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/.*

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 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 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

[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.*

[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 × 66% = 618,427 notices printed × $0.05 per page × ½ pages per notice = approximately $15,461.

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 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

[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.*

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 coverage [197] and that approximately 16 percent 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 email 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.

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	117,228,780
3 Year Average	17,309	1,632,707	2,086,326	79,482,349	183,634 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

[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.*

[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.*

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 web page, 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 visits [200] and 11,107,056 visits to health care facilities annually for surgical and non-surgical procedures [201] 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

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 web page, in a searchable manner, and to make the content available in an easily

[200] Agency for Healthcare Research and Quality, HCUP Fast Stats—Trends in Emergency Department Visits.

[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/.*

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 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 No.	Respondents	Responses	Burden per response (hours)	Total annual burden (hours)	Hourly labor cost of reporting	Total labor cost of reporting	Printing and materials cost	Total cost
45 CFR 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
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.

[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.*

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 website 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 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

[203] 2.5 million ERISA-covered plans × 16% grandfathered plans × (100% minus 5% newly non-grandfathered plans) × (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-ebsa-opr-ria-and-pra-burden-calculations-june-2019.pdf.*

[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.

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.
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

[206] 2022: 62.6 million ERISA-covered policyholders × 14% of covered employees in grandfathered plans × (100% minus 5% newly non-grandfathered plans) × (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.

[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.*

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 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 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 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).

[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/dhhsnvgov/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 × (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 participants with self-insured ERISA-covered plans) / 617 self-insured ERISA-covered plans = 9,724 participants per self-insured ERISA-covered plan.

[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 × 0.66 × $0.05 = $321.

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).

(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:

(CPI–U 2019/CPI–U 2018) × (CPI–U 2020/CPI–U 2019) × (CPI–U 2021/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 CPI–U present year/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 a 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

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:

(CPI–U 2019/CPI–U 2018) × (CPI–U 2020/CPI–U 2019) × (CPI–U 2021/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 CPI–U present year/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 a 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.

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 CPI–U present year/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 a 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 obtaning 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 on 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.

* * * * *

[FR Doc. 2021–14379 Filed 7–6–21; 4:15 pm]

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

Exhibit 4

OFFICE OF PERSONNEL MANAGEMENT

5 CFR Part 890

RIN 3206–AO29

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 54

[TD 9955]

RIN 1545–BQ05

DEPARTMENT OF LABOR

Employee Benefits Security Administration

29 CFR Parts 2510 and 2590

RIN 1210–AC00

DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Parts 147 and 149

[CMS–9908–IFC]

RIN 0938–AU62

Requirements Related to Surprise Billing; Part II

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 implement provisions of the No Surprises Act that provide for a Federal independent dispute resolution (IDR) (Federal IDR) process to permit group health plans and health insurance issuers offering group or individual health insurance coverage and nonparticipating providers, facilities, and providers of air ambulance services to determine the out-of-network rate for items and services that are emergency services, nonemergency services furnished by nonparticipating providers at participating facilities, and air ambulance services furnished by nonparticipating providers of air ambulance services, under certain circumstances. The Department of Health and Human Services (HHS), the Department of Labor (DOL), and the Department of the Treasury (collectively, the Departments) are issuing these interim final rules with largely parallel provisions that apply to group health plans and health insurance issuers offering group or individual health insurance coverage and certified IDR entities, providers, facilities, and providers of air ambulance services. In addition to the interim final rules issued jointly by the Departments, this document also includes interim final rules issued by the Office of Personnel Management (OPM) to clarify how certain No Surprises Act provisions apply to health benefits plans offered by carriers under the Federal Employees Health Benefits (FEHB) Act. In addition to the interim final rules issued jointly by the Departments and OPM, this document includes interim final rules issued by HHS that address good faith estimates of health care items and services for uninsured or self-pay individuals and the associated patient-provider dispute resolution process. The HHS-only interim final rules apply to selected dispute resolution (SDR) entities, providers, facilities, and providers of air ambulance services.

DATES:

Effective date: These regulations are effective on October 7, 2021.

Applicability date: Except as otherwise specified in this paragraph, the regulations issued jointly by the Departments of HHS, Labor, and the Treasury are generally applicable for plan or policy years beginning on or after January 1, 2022. The regulations regarding certification of IDR entities at 26 CFR 54.9816–8T(a) and (e), 29 CFR 2590.716–8(a) and (e), and 45 CFR 149.510(a) and (e) are applicable beginning on October 7, 2021. The OPM-only regulations that apply to health benefits plans are applicable to contract years beginning on or after January 1, 2022. The regulations issued by HHS alone that apply to health care providers, facilities, providers of air ambulance services, and SDR entities are applicable beginning on January 1, 2022, except that the regulations at 45 CFR 149.620(a) and (d) are applicable beginning on October 7, 2021.

Comment date: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on December 6, 2021.

ADDRESSES: Written comments may be submitted to the addresses specified below. Any comment that is submitted will be shared among the Departments. 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 RIN 1210–AB00. 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 two ways (please choose only one of the ways listed):

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

2. *By mail.* You may mail written comments to the following address ONLY: Office of Health Plan Standards and Compliance Assistance, Employee Benefits Security Administration, U.S. Department of Labor, 200 Constitution Avenue NW, Room N–5653, Washington, DC 20210, Attention: RIN 1210–AB00.

You may mail written comments regarding the HHS-only regulations to the following address: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention CMS–9908–IFC, P.O. Box 8010, Baltimore, MD 21244–8010. Attention: RIN 0938–AU62.

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

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; Elizabeth Schumacher or David Sydlik, Employee Benefits Security Administration, Department of Labor, at 202–693–8335; Deborah Bryant, Centers for Medicare & Medicaid Services, Department of Health and Human Services, at 301–492–4293.

Customer Service Information: Information from OPM on health benefits plans offered under the 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/agencies/ebsa*).

In addition, information from HHS on private health insurance coverage, coverage provided by non-Federal governmental group health plans, and requirements that apply to health care providers, health care facilities, and providers of air ambulance services can be found on the Centers for Medicare & Medicaid Services (CMS) website (*www.cms.gov/cciio*), 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. Preventing Surprise Medical Bills Under the Consolidated Appropriations Act, 2021

On December 27, 2020, the Consolidated Appropriations Act, 2021 (CAA), which includes the No Surprises Act, was enacted.[1] 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 bills arise most frequently. Surprise billing occurs when an individual receives an unexpected medical bill from a health care provider or facility after receiving 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.

The No Surprises Act added new provisions applicable to group health plans and health insurance issuers offering group or individual health insurance coverage in Subchapter B of chapter 100 of the Internal Revenue Code (Code), Part 7 of the Employee Retirement Income Security Act (ERISA), and Part D of title XXVII of the Public Health Service Act (PHS Act). Section 102 of the No Surprises Act added Code section 9816, ERISA section 716, and PHS Act section 2799A–1,[2] which contain limitations on cost sharing and requirements regarding the timing of initial payments for emergency services furnished by nonparticipating providers and emergency facilities, and for nonemergency services furnished by nonparticipating providers at certain participating health care facilities. Section 103 of the No Surprises Act amended Code section 9816, ERISA section 716, and PHS Act section 2799A–1 to establish a Federal IDR process that allows plans and issuers and nonparticipating providers and facilities to resolve disputes regarding out-of-network rates. Section 105 of the No Surprises Act created Code section 9817, ERISA section 717, and PHS Act section 2799A–2, which contain limitations on cost sharing and requirements for the timing of initial payments for nonparticipating providers of air ambulance services and allow plans and issuers and providers of air ambulance services to access the Federal IDR process described in Code section 9816, ERISA section 716, and PHS Act section 2799A–1. The No Surprises Act provisions that apply to health care providers and facilities and providers of air ambulance services, such as 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.

On July 13, 2021, the Departments of the Treasury, Labor, and Health and Human Services (Departments) and the Office of Personnel Management (OPM) published interim final rules with request for comments titled, *Requirements Related to Surprise Billing; Part I,* which generally apply to group health plans and health insurance issuers offering group or individual health insurance coverage (including grandfathered health plans) with respect to plan years (in the individual market, policy years) beginning on or after January 1, 2022; to carriers in the FEHB Program with respect to contract years beginning on or after January 1, 2022; and to health care providers and facilities, and providers of air ambulance services beginning on January 1, 2022 (July 2021 interim final rules).[3] The July 2021 interim final rules implement Code sections 9816(a)–(b) and 9817(a), ERISA sections 716(a)–(b) and 717(a), and PHS Act sections 2799A–1(a)–(b), 2799A–2(a), 2799A–7, 2799B–1, 2799B–2, 2799B–3, and 2799B–5 to protect consumers from surprise medical bills for emergency services, nonemergency services furnished by nonparticipating providers at participating facilities in certain circumstances, and air ambulance services furnished by nonparticipating providers of air ambulance services. Among other requirements, the July 2021 interim final rules require plans and issuers that provide or cover 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 to cover emergency services without any prior authorization; without regard to whether the health care provider furnishing the emergency services is a participating provider or the services are provided in a participating emergency facility; and without regard to any other term or condition of the plan or coverage other than the exclusion or coordination of benefits or a permitted affiliation or waiting period. With respect to emergency services furnished by nonparticipating providers or facilities, nonemergency services furnished by nonparticipating providers at certain participating facilities, and air ambulance services furnished by nonparticipating providers of air ambulance services, the July 2021 interim final rules generally limit cost sharing for out-of-network services to in-network levels, require such cost sharing to count toward any in-network deductibles and out-of-pocket maximums, and prohibit balance billing.

The July 2021 interim final rules also specify that consumer cost-sharing amounts for emergency services furnished by nonparticipating providers or facilities, and for nonemergency services furnished by nonparticipating providers at certain participating facilities, must be calculated based on one of the following amounts: (1) An amount determined by an applicable All-Payer Model Agreement under

[1] Public Law 116–260 (December 27, 2020).

[2] As discussed later in this preamble, section 102(d)(1) of the No Surprises Act amended the Federal Employees Health Benefits Act, 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 requirements described in section 9816 of the Code, section 716 of ERISA, and section 2799A–1 (as applicable) in the same manner as these provisions apply with respect to a group health plan or health insurance issuer offering group or individual health insurance coverage.

[3] 86 FR 36872 (July 13, 2021).

Social Security Act section 1115A; (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, the latter referred to as the qualifying payment amount (QPA). Cost-sharing amounts for air ambulance services provided by nonparticipating providers of air ambulance services must meet the same standards as would apply if the services were provided by a participating provider of air ambulance services and must be calculated using the lesser of the billed charges or the QPA.

Under the July 2021 interim final rules, balance billing for services subject to the requirements in those interim final rules generally is prohibited.[4] In general, the protections in the July 2021 interim final rules that limit cost sharing and prohibit balance billing do not apply to certain post-stabilization services, or to certain nonemergency services performed by nonparticipating providers at participating health care facilities, if the provider makes certain disclosures to the participant, beneficiary, or enrollee, and obtains the individual's consent to waive balance billing protections. However, this exception to the prohibition on balance billing is narrow. In particular, it is not available in certain circumstances where surprise bills are likely to occur, such as for ancillary services provided by nonparticipating providers in connection with nonemergency care in a participating health care facility. The July 2021 interim final rules also include a number of other specific requirements regarding notice and consent that must be met in order for a provider or facility to be permitted to balance bill a participant, beneficiary, or enrollee for items and services that would otherwise be subject to the prohibition on balance billing.

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. These interim final rules build upon the protections in the July 2021 interim final rules and implement the Federal IDR provisions under Code sections 9816(c) and 9817(b), ERISA sections 716(c) and 717(b), and PHS Act sections 2799A–1(c) and 2799A–2(b). OPM is also issuing regulations in phases to implement 5 U.S.C. 8902(p).

The Departments and OPM also published a notice of proposed rulemaking on September 16, 2021, titled *Requirements Related to Air Ambulance Services, Agent and Broker Disclosures, and Provider Enforcement.*[5] The proposed rule would, if finalized, implement reporting requirements for air ambulance claims data; 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) of title II of Division BB of the CAA); 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. Later this year, the Departments intend to undertake rulemaking to implement reporting requirements related to pharmacy benefits and prescription drug costs (section 204 of title II of Division BB of the CAA).

The provisions of the No Surprises Act that are applicable to group health plans and health insurance issuers offering group or individual health insurance coverage in the Code, ERISA, and the PHS Act apply to grandfathered health plans. Section 1251 of the Affordable Care Act provides that grandfathered health plans are not subject to certain provisions of the Code, ERISA, and the PHS Act, as added by the Affordable Care Act, for as long as they maintain their status as grandfathered health plans.[6] For example, grandfathered health plans are neither subject to the requirement to cover certain preventive services without cost sharing under PHS Act section 2713 nor to the annual limitation on cost sharing set forth under PHS Act section 2707(b). If a plan or coverage were to relinquish its grandfathered status, it would be required to comply with both provisions, in addition to several other requirements. However, the CAA does not include an exception for grandfathered health plans that is comparable to section 1251 of the Affordable Care Act. Furthermore, section 102(d)(2) of the No Surprises Act amended section 1251(a) of the Affordable Care Act to clarify that the new and recodified patient protections provisions of the No Surprises Act, including those related to choice of health care professional, apply to grandfathered health plans. Therefore, not only do the provisions of these interim final rules and the provisions of the July 2021 interim final rules that apply to group health plans and issuers of group or individual health insurance coverage apply to grandfathered plans, so do the other provisions applicable to group health plans and issuers of group or individual health insurance coverage in titles I and II of Division BB of the CAA.

B. PHS Act Section 2719 and Scope of Claims Eligible for External Review

PHS Act section 2719, as added by the Affordable Care Act, applies to group health plans that are not grandfathered health plans and health insurance issuers offering non-grandfathered coverage in the group and individual markets, and sets forth standards for plans and issuers regarding both internal claims and appeals and external review. With respect to external review, PHS Act section 2719 provides for both state external review processes and a Federal external review process that applies in the absence of an applicable state process that meets the requirements of section 2719. Non-grandfathered group health plans that are not self-insured plans (as self-insured plans are not subject to state insurance regulations) and health insurance issuers offering non-grandfathered group or individual health insurance coverage must comply with an applicable state external review process if that process includes, at a minimum, the consumer protections set forth in the Uniform Health Carrier External Review Model Act issued by the National Association of Insurance Commissioners (the NAIC Uniform Model Act). If a state's external review process does not meet the minimum consumer protection standards set forth in the NAIC Uniform Model Act (or if a plan is self-insured and not subject to state insurance regulation), group health plans and health insurance issuers in the group and individual markets in that state are required to implement an effective external review process that meets minimum standards established by the Departments through rulemaking.

The Departments issued interim final regulations to implement PHS Act section 2719, including the provisions related to external review, in 2010.[7] An

[4] 45 CFR 149.410(a), 149.420(a) and 149.440(a).

[5] 86 FR 51730 (Sept. 16, 2021).

[6] For a list of the market reform provisions applicable to grandfathered health plans under title XXVII of the PHS Act that the Affordable Care Act added or amended and that were incorporated into ERISA and the Code, visit *https://www.dol.gov/sites/dolgov/files/EBSA/laws-and-regulations/laws/affordable-care-act/for-employers-and-advisers/grandfathered-health-plans-provisions-summary-chart.pdf.*

[7] 75 FR 43329 (July 23, 2010).

amendment to the interim final rules was issued in 2011.[8] In 2015, the Departments issued final rules to finalize the interim final regulations.[9] Among other things, the 2015 final rules address the scope of claims eligible for external review.[10] State external review processes that meet the minimum standards must provide for the external review of adverse benefit determinations that are based on requirements for medical necessity, appropriateness, health care setting, level of care, or effectiveness of a covered benefit. The Federal external review process must be available for any adverse benefit determination by a plan or issuer that involves medical judgment, as well as rescissions. Section 110 of the No Surprises Act directs the Departments, in applying section 2719(b) of the PHS Act, to require the external review process to apply with respect to any adverse determination by a plan or issuer under Code section 9816 or 9817, ERISA section 716 or 717, or PHS Act section 2799A–1 or 2799A–2.

C. Protecting Uninsured Individuals Through Transparency and Patient-Provider Dispute Resolution

On July 9, 2021, President Biden signed Executive Order 14036, Promoting Competition in the American Economy in order to promote the interests of American workers, businesses, and consumers.[11] The executive order acknowledges that robust competition is critical to providing consumers with more choices, better service, and lower prices and directs the Secretary of HHS to support existing price transparency initiatives for hospitals, other providers, and insurers along with any new price transparency initiatives or changes made necessary by the No Surprises Act or any other statues. Consistent with Executive Order 14036, these interim final rules implement provisions of the No Surprises Act that will provide individuals with more pricing information prior to seeking care, allowing them to shop for the care that is best for them and increase competition in the health care market.

The No Surprises Act also adds a new Part E of title XXVII of the PHS Act establishing requirements applicable to health care providers, providers of air ambulance services, and health care facilities. Section 112 of the No Surprises Act adds PHS Act sections 2799B–6 and 2799B–7. PHS Act section 2799B–6 requires providers and facilities to furnish a good faith estimate of expected charges upon request or upon scheduling an item or service. Providers and facilities are required to inquire if an individual is enrolled in a group health plan, group or individual health insurance coverage, an FEHB plan,[12] or a Federal health care program, and, if enrolled in a group health plan, or group or individual health insurance coverage, or a health benefits plan under chapter 89 of title 5,[13] whether the individual is seeking to have a claim for such item or service submitted to such plan or coverage. In the case that the individual is enrolled in such a plan or coverage (and is seeking to have a claim for such an item or services submitted to such plan or coverage), PHS Act section 2799B–6(2)(A) requires that the provider or facility furnish the good faith estimate to the individual's plan or issuer of such coverage to inform the advanced explanation of benefits that plans and issuers are required to provide a participant, beneficiary, enrollee, or FEHB covered individual under Code section 9816(f), ERISA section 716(f), PHS Act section 2799A–1(f), and 5 U.S.C. 8902(p). In the case that the individual requesting a good faith estimate for an item or service or seeking to schedule an item or service to be furnished who is not enrolled in a plan or coverage, or is not seeking to file a claim with such plan or coverage (self-pay), PHS Act section 2799B–6(2)(B) and these interim final rules at 45 CFR 149.610 require providers and facilities to furnish the good faith estimate to the individual.

These interim final rules do not include requirements regarding PHS Act section 2799B–6(2)(A), which require providers and facilities to furnish good faith estimates to plans or issuers. Under Code section 9816(f), ERISA section 716(f), and PHS Act section 2799A–1(f) and 5 U.S.C. 8902(p), plans and issuers are required to include the good faith estimates in an advanced explanation of benefits provided to participants, beneficiaries, enrollees, and FEHB covered individuals. As stated in the August 20, 2021, FAQs issued by the Departments, the Departments have received feedback from the public about the challenges of developing the technical infrastructure necessary for providers and facilities to transmit to plans and issuers starting January 1, 2022, the good faith estimates required under PHS Act section 2799B–6, which plans and issuers must then include in the advanced explanation of benefits. Accordingly, until rulemaking to fully implement this requirement to provide such a good faith estimate to an individual's plan or coverage is adopted and applicable, HHS will defer enforcement of the requirement that providers and facilities provide good faith estimate information for individuals enrolled in a health plan or coverage and seeking to submit a claim for scheduled items or services to their plan or coverage. Additionally, stakeholders have requested that the Departments delay the applicability date of Code section 9816(f), ERISA section 716(f), and PHS Act section 2799A–1(f) until the Departments have established standards for the data transfer between providers and facilities and plans and issuers and have given enough time for plans and issuers and providers and facilities to build the infrastructure necessary to support the transfers. The Departments agree that compliance with this section is likely not possible by January 1, 2022, and therefore intend to undertake notice and comment rulemaking in the future to implement this provision, including establishing appropriate data transfer standards. Until such time, the Departments will defer enforcement of the requirement that plans and issuers must provide an advanced explanation of benefits. HHS will consider whether additional interim solutions for insured consumers are feasible. The Departments note that any rulemaking to fully implement Code section 9816(f), ERISA section 716(f), and PHS Act sections 2799A–1(f) and 2799B–6(2)(A) will include a prospective applicability date that provides plans, issuers, providers, and facilities with a reasonable amount of time to comply with new requirements. HHS encourages states that are primary enforcers of these requirements with regard to providers and issuers to take a similar enforcement approach, and

[8] 76 FR 37207 (June 10, 2011).

[9] 80 FR 72191 (Nov. 18, 2015).

[10] 26 CFR 54.9815–2719(d)(1); 29 CFR 2590.715–2719(d)(1); 45 CFR 147.136(d)(1).

[11] 86 FR 36987 (Jul 9, 2021).

[12] HHS interprets the requirements described in PHS Act section 2799B–6 to apply with respect to FEHB covered individuals as they would to other individuals enrolled in a group health plan, group or individual health insurance coverage offered by a health insurance issuer. Although PHS Act section 2799B–6 does not reference health benefits plans under chapter 89 of title 5, the definition of ''uninsured individual'' at PHS Act section 2799B–7 does include individuals who do not have benefits under these health benefits plans, and these sections work together to provide protections for the uninsured (or self-pay) population. Moreover, the requirement for the provision of an advance explanation of benefits required by Code section 9816(f), ERISA section 716(f), and PHS Act section 2799A–(1)(f), as well as 5 U.S.C. 8902(p) cannot be accomplished by a FEHB carrier unless it receives a good faith estimate from a provider in accordance with PHS Act section 2799B–6(2)(A).

[13] A health benefits plan offered under chapter 89 of title 5, United States Code is also known as an FEHB plan.

will not determine that a state is failing to substantially enforce these requirements if it takes such an approach.

Nonetheless, providers and facilities will be subject to enforcement action for failure to provide a good faith estimate to individuals not enrolled in a plan or coverage, or not seeking to have a claim for such item or services submitted to such plan or issuer of such coverage, as specified under these interim final rules. HHS seeks comment on this approach.

On November 12, 2020, the Departments issued the Transparency in Coverage final rules,[14] which require group health plans and health insurance issuers of group or individual health insurance coverage to make price comparison information available to participants, beneficiaries, and enrollees through an internet-based self-service tool and in paper form, upon request. This information must be available for plan years—or in the individual market, for policy years—beginning on or after January 1, 2023 with respect to 500 specified items and services, and with respect to all covered items and services, for plan or policy years beginning on or after January 1, 2024. The Departments are of the view that the disclosure requirements to participants, beneficiaries, and enrollees under the Transparency in Coverage final rules, and those required under Code section 9816(f), ERISA section 716(f), and PHS Act section 2799A–1(f), are substantially similar and therefore the Departments seek comment on whether there are ways to leverage the Transparency in Coverage requirements, including whether there are ways for plans and issuers to provide the information required in the Transparency in Coverage final rules to participants, beneficiaries, and enrollees during plan or policy years beginning in 2022. The Departments also seek comment on whether it would be feasible for providers and facilities to provide an estimate or range of estimated costs for insured consumers upon request for 2022.

Section 112 of the No Surprises Act also adds PHS Act section 2799B–7, which directs the Secretary of HHS to establish a process under which uninsured (or self-pay) individuals can avail themselves of a patient-provider dispute resolution process if their billed charges after receiving an item or service are substantially in excess of the expected charges listed in the good faith estimate furnished by the provider or facility, pursuant to PHS Act section 2799B–6. Under PHS Act section 2799B–7, an uninsured (or self-pay) individual means, with respect to an item or service, an individual who does not have benefits for such item or service under a group health plan, group or individual health insurance coverage offered by a health insurance issuer, Federal health care program (as defined in section 1128B(f) of the Social Security Act), or a health benefits plan under chapter 89 of title 5, United States Code (or an individual who has benefits for such item or service under a group health plan or individual or group health insurance coverage offered by a health insurance issuer, but does not seek to have a claim for such item or service submitted to such plan or coverage).

II. Executive Summary

A. Departments of the Treasury, Labor, and HHS: Federal IDR Process and External Review

In order to implement the Federal IDR provisions under Code sections 9816(c) and 9817(b), ERISA sections 716(c) and 717(b), and PHS Act sections 2799A–1(c) and 2799A–2(b), as added by sections 103 and 105 of the No Surprises Act, these interim final rules establish a Federal IDR process that nonparticipating providers or facilities, nonparticipating providers of air ambulance services, and group health plans and health insurance issuers in the group and individual market may use following the end of an unsuccessful open negotiation period to determine the out-of-network rate for certain services. More specifically, the Federal IDR provisions may be used to determine the out-of-network rate for certain emergency services, nonemergency items and services furnished by nonparticipating providers at participating health care facilities, and air ambulance services furnished by nonparticipating providers of air ambulance services where an All-Payer Model Agreement or specified state law does not apply.

Under Code sections 9816(c)(1)(A) and 9817(b)(1)(A), ERISA sections 716(c)(1)(A) and 717(b)(1)(A), PHS Act sections 2799A–1(c)(1)(A) and 2799A–2(b)(1)(A), and these interim final rules, upon receiving an initial payment or notice of denial of payment from a plan or issuer with respect to such items or services, such provider or facility or provider of air ambulance services (as applicable) or plan or issuer (as applicable) may initiate an open negotiation period within 30 business days beginning on the date the provider or facility receives the initial payment or notice of denial of payment. The open negotiation period may continue for up to 30 business days beginning on the date that either party first initiates the open negotiation period. The parties may discontinue the negotiation if they agree on an out-of-network rate before the last day of the 30-business-day open negotiation period. If the parties cannot agree on an out-of-network rate, they must exhaust the 30-business-day open negotiation period before initiating the Federal IDR process. Either party may initiate the Federal IDR process during the 4-business-day period beginning on the 31st business day after the start of the open negotiation period. The parties may select a certified IDR entity, or if the parties do not select a certified IDR entity, the Departments will do so. The No Surprises Act and these interim final rules specify that the certified IDR entity selected cannot be a party to the determination or an employee or agent of such a party, or have a material familial, financial, or professional relationship with such party.

In resolving the disputes through the Federal IDR process, the No Surprises Act and these interim final rules provide that each party must submit to the certified IDR entity an offer for a payment amount for the qualified IDR item or service in dispute and other information related to the offer as requested by the certified IDR entity within 10 business days of selection of the certified IDR entity and may submit additional information for the certified IDR entity to consider. In making a determination of which payment offer to select, these interim final rules specify that the certified IDR entity must begin with the presumption that the QPA is the appropriate out-of-network rate for the qualified IDR item or service under consideration. These interim final rules further provide that the certified IDR entity must select the offer closest to the QPA unless the certified IDR entity determines that credible information submitted by either party clearly demonstrates that the QPA is materially different from the appropriate out-of-network rate, based on the additional factors set forth in Code sections 9816(c)(5)(C)(ii) and 9817(b)(5)(C)(ii), ERISA sections 716(c)(5)(C)(ii) and 717(b)(5)(C)(ii), and PHS Act sections 2799A–1(c)(5)(C)(ii) and 2799A–2(b)(5)(C)(ii). The certified IDR entity may not consider usual and customary charges, the amount that would have been billed (including billed charges that are directed to the plan or issuer) if the protections of 45 CFR 149.410,

[14] 26 CFR 54.9815–2715A2(b), 29 CFR 2590.715–2715A2(b), and 45 CFR 147.211(b).

149.420, or 149.440 [15] (as applicable) had not applied, or any public payor payment or reimbursement rates.[16] As discussed more fully in section III.D.4.ii. of this preamble, this approach is consistent with the No Surprises Act's emphasis on the QPA, both as the basis of the surprise billing protections also included in the statute and implemented by the July 2021 interim final rules and as the sole factor identified without any qualification by the statute.[17] The Departments are of the view that implementing the Federal IDR process in this manner encourages predictable outcomes, which will reduce the use of the Federal IDR process over time and the associated administrative fees born by the parties, while providing equitable and clear standards for when payment amounts may deviate from the QPA, as appropriate.

The No Surprises Act and these interim final rules also set forth requirements for certification of IDR entities by the Departments. To become certified IDR entities, IDR entities must provide written documentation demonstrating that they meet the eligibility criteria, including having sufficient expertise and staffing to conduct determinations on a timely basis, being free of conflicts of interest, being accredited by a nationally recognized and relevant accrediting body (such as URAC) or otherwise ensuring that IDR entity personnel possess the requisite training to conduct payment determinations (for example, providing documentation that personnel employed by the IDR entity have completed arbitration training by the American Arbitration Association (AAA), the American Health Law Association (AHLA), or a similar organization), ensuring policies and procedures are in place to maintain confidentiality of individually identifiable health information, providing a fixed fee for single determinations and a separate fee for batched determinations, having a procedure in place to retain certified IDR entity fees and retain and remit administrative fees, meeting appropriate indicators of fiscal integrity and stability, evidencing its ability to collect and transmit the information required to be reported to the Departments, and properly carrying out the requirements of the Federal IDR process in accordance with the law. These interim final rules also establish a process whereby members of the public, providers, facilities, providers of air ambulance services, plans, or issuers may petition for the denial or revocation of certification of an IDR entity. Finally, these interim final rules require the collection of information related to the Federal IDR process from certified IDR entities in order to allow the Departments to quarterly publish information on IDR payment determinations.

The Departments are also establishing a Federal IDR portal to administer the Federal IDR process. The Departments' Federal IDR portal will be available at *https://www.nsa-idr.cms.gov* and will be used throughout the Federal IDR process to maximize efficiency and reduce burden. As discussed throughout this preamble, the Federal IDR portal may be used to satisfy various requirements under these interim final rules, including provision of notices, Federal IDR initiation, submission of an application to be a certified IDR entity, as well as satisfying reporting requirements.

These interim final rules also amend final regulations issued by the Departments in 2015 related to external review in order to implement section 110 of the No Surprises Act. Section 110 requires that ''[i]n applying the provisions of section 2719(b) of the [PHS Act] to group health plans and health insurance issuers offering group or individual health insurance coverage, the Secretary of [HHS], Secretary of Labor, and Secretary of the Treasury, shall require, beginning not later than January 1, 2022, the external review process described in paragraph (1) of such section to apply with respect to any adverse determination by such a plan or issuer under Code section 9816 or 9817, ERISA section 716 or 717, or PHS Act section 2799A–1 or 2799A–2, including with respect to whether an item or service that is the subject to such a determination is an item or service to which such respective section applies.'' Accordingly, these interim final rules amend the final regulations regarding external review in two ways. First, the scope of adverse benefit determinations eligible for external review is amended to ensure that issues related to compliance with the specified provisions of the No Surprises Act fall within that scope. Several examples are also added to provide greater clarity to stakeholders regarding the expanded scope. Second, applicability provisions are amended to require that grandfathered health plans, which generally are exempt from requirements related to external review, must nonetheless provide for external review of adverse benefit determinations for claims subject to the cost-sharing and surprise billing protections in the No Surprises Act. The Departments seek comment on all aspects of these interim final rules.

B. Office of Personnel Management: Federal IDR Process for FEHB Carriers

The OPM interim final rules amend existing 5 CFR 890.114(a) to include references to the Treasury, DOL, and HHS interim final rules to clarify that pursuant to 5 U.S.C. 8902(p), FEHB carriers are also subject to the Federal IDR process set forth in those regulations with respect to an item or service eligible for determination through open negotiation or the Federal IDR process furnished by a FEHB carrier offering a health benefits plan in the same manner as those 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 FEHB carrier's contract. Through new 5 CFR 890.114(d), OPM adopts the Departments' interim final rules as conformed by terms unique to the FEHB Program. In 5 CFR 890.114(d), OPM adopts the Departments' rules as necessary to properly integrate with existing FEHB Program structure and sets forth circumstances in which OPM will enforce these rules as applied to FEHB carriers. The OPM interim final rules require FEHB carrier notice to the OPM Director (herein, the Director) of an FEHB carrier's notice of initiation, or receipt of a provider's notice of initiation, of the Federal IDR process. The Director will coordinate with the Departments in matters regarding FEHB

[15] The July 2021 interim final rules prohibit nonparticipating emergency facilities and nonparticipating providers furnishing emergency services from billing participants, beneficiaries, or enrollees for payment amounts that exceed the cost-sharing requirement for those items or services. The July 2021 interim final rules also generally prohibit nonparticipating providers furnishing nonemergency items and services at participating facilities from balance billing participants, beneficiaries, or enrollees for those items or services. In addition, the July 2021 interim final rules prohibit nonparticipating providers of air ambulance services furnishing air ambulance services for which benefits are available under a group health plan or group or individual health insurance coverage from balance billing participants, beneficiaries, or enrollees for those items or services.

[16] Public payor payment and reimbursement rates include reimbursement rates under the Medicare program under title XVIII of the Social Security Act, under the Medicaid program under title XIX of such Act, under the Children's Health Insurance Program under title XXI of such Act, under the TRICARE program under chapter 55 of title 10, United States Code, and under chapter 17 of title 38, United States Code.

[17] The No Surprises Act limits the certified IDR entity's consideration of additional factors by prohibiting the certified IDR entity from considering certain other factors, such as usual and customary charges and billed charges, in making a payment determination.

carriers requiring resolution under the Federal IDR process and with respect to oversight of certified IDR entities' reports regarding FEHB carriers. As discussed in the July 2021 interim final rules, all out-of-network rate determinations regarding IDR items or services eligible for determination through open negotiation or the Federal IDR process under the No Surprises Act with respect to FEHB plans or carriers that are not resolved by open negotiation are subject to the Federal IDR process unless OPM contracts with FEHB carriers include terms that adopt state law as governing for this purpose.

C. Department of HHS: Protections for the Uninsured

To ensure that uninsured (or self-pay) individuals are also afforded protections against surprise health care costs, the No Surprises Act includes provisions that require providers and facilities to furnish good faith estimates to uninsured (or self-pay) individuals upon their request and at the time of scheduling the item or service. In order to implement these provisions under PHS Act sections 2799B–6(1) and 2799B–6(2)(B), HHS is adding 45 CFR 149.610 to establish requirements for providers and facilities to specifically inquire about an individual's health coverage status and requirements for providing a good faith estimate to uninsured (or self-pay) individuals. These interim final rules define uninsured (or self-pay) individuals to include those who do not have benefits for an item or service under a group health plan, group or individual health insurance coverage offered by a health insurance issuer, a Federal health care program (as defined in section 1128B(f) of the Social Security Act), or a health benefits plan under chapter 89 of title 5, United States Code, or an individual who has benefits for such item or service under a group health plan or individual or group health insurance coverage offered by a health insurance issuer, but who does not seek to have a claim for such item or service submitted to such plan or coverage. PHS Act section 2799B–6, added by section 112 of the No Surprises Act, does not specifically define a Federal health care program and also does not reference health benefits plans under chapter 89 of title 5. However, PHS Act section 2799B–7, which was also added by section 112 of the No Surprises Act, and which provides protections related to the good faith estimate required under PHS Act section 2799B–6, defines an uninsured individual to include individuals not enrolled in a Federal health care program (as defined in section 1128B(f) of the Social Security Act) and individuals not enrolled in health benefits plans under chapter 89 of title 5. To align these two related sections, HHS is adopting the definition of an uninsured (or self-pay) individual at PHS Act section 2799B–7 for the purposes of the interim final rules at 45 CFR 149.610 which implements PHS Act section 2799B–6(1) and 2799B–6(2)(B) and 45 CFR 149.620 which implements PHS Act section 2799B–7.

The definition of uninsured (or self-pay) individuals in these interim final rules includes individuals enrolled in individual or group health insurance coverage offered by a health insurance issuer, or a health benefits plan under chapter 89 of title 5, but not seeking to have a claim for such item or service submitted to such plan or coverage. These individuals are often referred to as self-pay individuals, therefore these interim final rules include the term self-pay when discussing uninsured individuals.

Under PHS Act section 2791(b)(5), short-term, limited-duration insurance is excluded from the definition of individual health insurance coverage. Therefore, for purposes of 45 CFR 149.610 and 45 CFR 149.620, uninsured (or self-pay) individuals include individuals who are enrolled in short-term, limited-duration insurance and not also enrolled in a group health plan, group or individual health insurance coverage offered by a health insurance issuer, Federal health care program (as defined in section 1128B(f) of the Social Security Act), or a health benefits plan under chapter 89 of title 5, United States Code. Thus, providers and facilities will be required to provide to such individuals a good faith estimate and such individuals will be able to avail themselves of the patient-provider dispute resolution process, where applicable.

PHS Act section 2799B–6(2) and these interim final rules specify that a provider or facility must provide a notification (in clear and understandable language) of the good faith estimate of the expected charges for furnishing the items or services listed on the good faith estimate (including any items or services that are reasonably expected to be provided in conjunction with such scheduled or requested items or services and such items or services reasonably expected to be so provided by another health care provider or health care facility), with the expected billing and diagnostic codes for any such items or services.

As discussed in section I.C. of this preamble, requirements to implement PHS Act section 2799B–6(2)(A) are not included in these interim final rules given the challenges of developing the technical infrastructure necessary to transmit such data from providers and facilities to plans and issuers. The requirements in these interim final rules apply only to good faith estimate notifications for uninsured (or self-pay) individuals as described in PHS Act section 2799B–6(2)(B) and in these interim final rules. HHS acknowledges that PHS Act section 2799B–6 also requires providers and facilities to make certain disclosures to an individual's plan or coverage if the individual is enrolled in such a plan or coverage and is seeking to have a claim for such items or services submitted to such plan or coverage. Specifically, section 2799B–6(2)(A) requires a provider or facility to provide such a plan or issuer notification of the good faith estimate of expected charges for furnishing an item or service on the same terms as provided to individuals.

Health care providers and health care facilities are required under PHS Act section 2799B–6 to furnish a notification of the good faith estimate of expected charges to an uninsured (or self-pay) individual who schedules an item or service, and to an individual who has not yet scheduled an item or service, but requests a good faith estimate. PHS Act section 2799B–6 requires providers and facilities to furnish a good faith estimate to an uninsured (or self-pay) individual who schedules an item or service at least 3 business days before the date such item or service is to be so furnished, not later than 1 business day after the date of such scheduling (or, in the case of such an item or service scheduled at least 10 business days before the date such item or service is to be so furnished (or if requested by the uninsured (or self-pay) individual), not later than 3 business days after the date of such scheduling or such request). As further discussed in section VI of this preamble, in instances where an uninsured (or self-pay) individual requests a good faith estimate of expected charges, but the item or service has not been scheduled, these interim final rules require that the treating provider furnish a good faith estimate to the uninsured (or self-pay) individual, within 3 business days of such request. For example, if an uninsured (or self-pay) individual schedules an item or service on Monday, January 3 to be provided on Thursday, January 6, the provider and facility must furnish a good faith estimate no later than Tuesday, January 4. If scheduling occurs on Monday, January 3 for items or services to be

provided on Thursday, January 13, the provider and facility must furnish a good faith estimate no later than Thursday, January 6. If an uninsured (or self-pay) individual requests a good faith estimate on Monday, January 3 for items or services not yet scheduled, the provider and facility must furnish the good faith estimate no later than Thursday, January 6.

These interim final rules include definitions relating to good faith estimates of expected charges for uninsured (or self-pay) individuals for scheduled items or services and upon request. These interim final rules also include requirements for providers and facilities regarding the contents of the good faith estimates and the manner in which good faith estimates must be provided.

PHS Act section 2799B–7 provides further protections for the uninsured (or self-pay) individual by requiring the Secretary of HHS to establish a process (in this section referred to as patient-provider dispute resolution) under which an uninsured (or self-pay) individual who received from a provider or facility a good faith estimate of the expected charges, and who, after being furnished the item or service, is billed an amount that is substantially in excess of the expected charges in the good faith estimate, may seek a determination from a certified dispute resolution entity of the amount to be paid to the provider or facility.

HHS is adding new 45 CFR 149.620 to implement this patient-provider dispute resolution process, including specific definitions related to the process. HHS is also codifying provisions related to eligibility for the patient-provider dispute resolution process, and selection of an SDR entity. HHS clarifies that while SDR entities provide a similar function and must meet similar requirements as certified IDR entities, SDR entities are specific to the patient-provider dispute resolution process. These interim final rules also codify requirements related to the determination of payment amounts by SDR entities, fees associated with the patient-provider dispute resolution process, certification of SDR entities, and deferral to state-established patient-provider dispute resolution processes that meet certain minimum Federal standards.

III. Overview of the Interim Final Rules Regarding the Federal Independent Dispute Resolution Process for Plans, Issuers, Providers, Facilities, and Providers of Air Ambulance Services—Departments of the Treasury, Labor, and HHS

A. Definitions

Code section 9816, ERISA section 716, and PHS Act sections 2799A–1 and 2799A–2 include defined terms that are specific to the law's requirements and implementation.[18] The definitions in 26 CFR 54.9816–3T, 29 CFR 2590.716–3, and 45 CFR 149.30 apply to these interim final rules; these interim final rules also define additional terms specific to the Federal IDR process. Under these interim final rules, ''batched items and services'' means multiple qualified IDR items or services that are considered jointly as part of one payment determination by a certified IDR entity for purposes of the Federal IDR process. For a qualified IDR item or service to be included as a batched item or service, the qualified IDR item or service must satisfy the criteria for batching set forth in 26 CFR 54.9816–8T(c)(3), 29 CFR 2590.716–8(c)(3), and 45 CFR 149.510(c)(3). ''Certified IDR entity'' means an entity responsible for conducting determinations under 26 CFR 54.9816–8T(c), 29 CFR 2590.716–8(c), and 45 CFR 149.510(c) that meets the certification criteria specified in 26 CFR 54.9816–8T(e), 29 CFR 2590.716–8(e), and 45 CFR 149.510(e) and that has been certified by the Departments. Separately, ''IDR entity'' means an entity that may apply or has applied for certification to conduct determinations under 26 CFR 54.9816–8T(c), 29 CFR 2590.716–8(c), and 45 CFR 149.510(c) and currently is not certified by the Departments pursuant to 26 CFR 54.9816–8T(e), 29 CFR 2590.716–8(e), and 45 CFR 149.510(e). If a certified IDR entity's certification has expired or has been revoked as a result of the process described in 26 CFR 54.9816–8T(e)(6), 29 CFR 2590.716–8(e)(6), and 45 CFR 149.510(e)(6), upon the date of the expiration or revocation, the formerly-certified IDR entity will be referred to as an IDR entity.

These interim final rules also define certain terms related to conflict-of-interest standards applicable to certified IDR entities. Stakeholders have emphasized the importance of ensuring a broad conflict-of-interest standard in order to avoid the risk of biased IDR payment determinations (or the appearance of biased IDR payment determinations). In general, a ''conflict of interest'' means, with respect to a party to a payment determination, a certified IDR entity, a material relationship, status, or condition of the party, or certified IDR entity that impacts the ability of a certified IDR entity to make an unbiased and impartial payment determination. For purposes of these interim final rules, a conflict of interest exists when a certified IDR entity is a group health plan; a health insurance issuer offering group health insurance coverage, individual health insurance coverage or short-term, limited-duration insurance; an FEHB carrier; or a provider, a facility,[19] or a provider of air ambulance services. While the statute does not specify that the IDR entity must not be a health insurance issuer offering short-term, limited-duration insurance, the Departments have determined that such entities should not be eligible for certification, due to their similarity to health insurance issuers offering group and individual health insurance coverage and their inherent interest as issuers in keeping reimbursement rates for providers, facilities, and providers of air ambulance services low. A conflict of interest also exists when a certified IDR entity is an affiliate or a subsidiary of a group health plan; a health insurance issuer offering group health insurance coverage, individual health insurance coverage or short-term, limited-duration insurance; an FEHB carrier; or provider, facility, or provider of air ambulance services. A conflict of interest also exists when a certified IDR

[18] To implement these interim final rules regarding the Federal IDR process under the PHS Act, HHS is amending 45 part CFR 149 by adding new Subparts F and G. Additionally, the Departments are amending 26 CFR 54.9816–1T and 54.9816–2T, 29 CFR 2590.716–1 and 2590.716–2 and 45 CFR 149.10 and 149.20 to expand the scope and applicability of this part to include IDR entities and the Federal IDR process. HHS is also amending 45 CFR 149.10 and 149.20 to expand the scope and applicability of this part to include SDR entities, the good faith estimate requirements, and patient-provider dispute resolution process.

[19] Similar to the July 2021 interim final rules, the term ''facility'' indicates a facility that furnishes health care services that is subject to the surprise billing protections of the No Surprises Act, such as a hospital (including a hospital's emergency department), urgent care center, or ambulatory surgical center. For purposes of good faith estimates under 45 CFR 149.610 and the Patient-Provider dispute resolution process in 45 CFR 149.620 ''facility'' includes an institution (such as a hospital or hospital outpatient department, critical access hospital, ambulatory surgical center, rural health center, federally qualified health center, laboratory, or imaging center) in any state in which state or applicable local law provides for the licensing of such an institution, that is licensed as such an institution pursuant to such law or is approved by the agency of such state or locality responsible for licensing such institution as meeting the standards established for such licensing.

entity is an affiliate or subsidiary of a professional or trade association representing group health plans; health insurance issuers offering group health insurance coverage, individual health insurance coverage or short-term, limited-duration insurance; FEHB carriers; or providers, facilities, or providers of air ambulance services. Additionally, a conflict of interest exists when a certified IDR entity has, or any personnel assigned to a determination have a material familial, financial, or professional relationship with a party to the payment determination being disputed, or with any officer, director, or management employee of the plan, issuer or carrier offering a health benefits plan under 5 U.S.C. 8902; the plan administrator, plan fiduciaries, or plan, issuer, or carrier's employees; the health care provider, the health care provider's group or practice association; the provider of air ambulance services, the provider of air ambulance services' group or practice association, or the facility that is a party to the dispute. The Departments are of the view that an officer, director, or management employee of the plan issuer, or carrier offering a health benefits plan under 5 U.S.C. 8902; the plan administrator, plan fiduciaries, or plan, issuer or carrier employees; the health care provider, the health care provider's group or practice association; the provider of air ambulance services, the provider of air ambulance services' group or practice association, or the facility that is a party to the dispute are individuals who could have significant involvement with the dispute. Relationships with these individuals could therefore improperly affect the certified IDR entities' ability to be impartial.

These interim final rules also define what constitutes a material familial relationship, a material financial relationship, or material professional relationship with a party to the payment determination. In developing these definitions, the Departments looked to states' conflict-of-interest standards for external review and arbitrations of surprise billing claims. These state standards typically use terms that are similar to those used in Code section 9816(c)(4)(F)(i)(II), ERISA section 716(c)(4)(F)(i)(II), and PHS Act section 2799A–1(c)(4)(F)(i)(II).[20] By adopting definitions that largely mirror these state standards, the Departments seek to ensure that the definitions are workable and increase the likelihood that IDR entities may be familiar with these standards, if they have performed services in these states. Accordingly, these interim final rules provide that the term ''material familial relationship'' means any relationship as a spouse, domestic partner, child, parent, sibling, spouse's or domestic partner's parent, spouse's or domestic partner's sibling, spouse's or domestic partner's child, child's parent, child's spouse or domestic partner, or sibling's spouse or domestic partner. ''Material financial relationship'' means any financial interest of more than five percent of total annual revenue or total annual income of a certified IDR entity or an officer, director, or manager thereof, or of a reviewer or reviewing physician employed or engaged by a certified IDR entity to conduct or participate in any payment determination under the Federal IDR process. Under the definition of ''material financial relationship,'' annual revenue and annual income do not include mediation fees received by mediators who are also arbitrators, provided that the mediator acts in the capacity of a mediator and does not represent a party in the mediation. Finally, with respect to terms related to the conflict-of-interest standards, ''material professional relationship'' means any physician-patient relationship, any partnership or employment relationship or affiliation, any shareholder or similar ownership interest in a professional corporation, partnership, or other similar entity, or any independent contractor arrangement that constitutes a material financial relationship with any expert used by the certified IDR entity or any officer or director of the certified IDR entity. The Departments solicit comment on whether the defined terms related to the conflict-of-interest standards should include threshold requirements to further define the level of relationship that would rise to the level of a conflict of interest.

Additionally, under these interim final rules, the Departments define certain terms related to confidentiality, information security, and privacy requirements that apply to an IDR entity seeking certification under these interim final rules. Code section 9816(c)(4)(A)(v), ERISA section 716(c)(4)(A)(v), and PHS Act section 2799A–1(c)(4)(A)(v) require certified IDR entities to maintain the confidentiality of individually identifiable health information (IIHI) obtained while making payment determinations and engaging in other activities related to the Federal IDR process. In establishing definitions for these terms, the Departments looked to existing Federal standards, particularly the Health Insurance Portability and Accountability Act of 1996 (HIPAA), the Health Information Technology for Economic and Clinical Health (HITECH) Act, and the privacy, security, and breach notification standards under 45 CFR part 160 A and subparts A, C, D, and E of part 164, because the Departments are of the view that these provisions are industry standards. The Departments have modified these standards in some cases to fit the circumstances of IDR entities.

These interim final rules define ''Individually identifiable health information (IIHI)'' to mean any information, including demographic data, that relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual; and that identifies the individual; or with respect to which there is a reasonable basis to believe the information can be used to identify the individual.[21] Finally, these interim final rules define ''Unsecured IIHI'' to mean IIHI that is not rendered unusable, unreadable, or indecipherable to unauthorized persons through the use of a technology or methodology specified by the Departments. For technologies and methodologies approved for this purpose, certified IDR entities should refer to the HHS Guidance to Render Unsecured Protected Health Information Unusable, Unreadable, or Indecipherable to Unauthorized Individuals.[22]

These interim final rules provide that the term ''breach'' means the acquisition, access, use, or disclosure of IIHI in a manner not permitted under 26 CFR 54.9816–8T(e)(2)(v), 29 CFR 2590.716–8(e)(2)(v), and 45 CFR 149.510(e)(2)(v) that compromises the security or privacy of the IIHI. Under these interim final rules, a breach excludes any unintentional acquisition, access, or use of IIHI by personnel, including a contractor or subcontractor, acting under the authority of a certified IDR entity, if the acquisition, access, or use was made in good faith and within the scope of authority and does not result in further use or disclosure in a

[20] *See e.g.,* WAC 284–43A–010; N.Y. Comp. Codes R. & Regs. tit. 11 section 410.2.

[21] Note that this definition is broader than the definition of IIHI set forth in the Health Insurance Portability and Accountability Act (HIPAA) Rules at 45 CFR 160.103.

[22] HHS Office for Civil Rights, ''Guidance to Render Unsecured Protected Health Information Unusable, Unreadable, or Indecipherable to Unauthorized Individuals,'' available at *https://www.hhs.gov/guidance/document/guidance-render-unsecured-protected-health-information-unusable-unreadable-or.*

manner not permitted under 26 CFR 54.9816–8T(e)(2)(v), 29 CFR 2590.716–8(e)(2)(v), and 45 CFR 149.510(e)(2)(v). Also excluded is any inadvertent disclosure by a person who is authorized to access IIHI as personnel of a certified IDR entity to another person authorized to access IIHI as personnel of the same certified IDR entity (including a contractor or subcontractor of the certified IDR entity), and the information received as a result of such disclosure is not further used or disclosed in a manner not permitted under 26 CFR 54.9816–8T(e)(2)(v), 29 CFR 2590.716–8(e)(2)(v), and 45 CFR 149.510(e)(2)(v). Finally, also excluded is a disclosure of IIHI when a certified IDR entity has a good faith belief that an unauthorized person to whom the disclosure was made would not reasonably have been able to retain such information. For example, if, while conducting an IDR payment determination, a certified IDR entity sends paperwork containing IIHI to the wrong address and the paperwork is returned by the post office, unopened, as undeliverable, the certified IDR entity can conclude that the entity at the improper address could not reasonably have retained the information. The definition of breach additionally provides that an acquisition, access, use, or disclosure of IIHI in a manner not permitted under 26 CFR 54.9816–8T(e)(2)(v), 29 CFR 2590.716–8(e)(2)(v), and 45 CFR 149.510(e)(2)(v) is presumed to be a breach unless the certified IDR entity demonstrates that there is a low probability that the security or privacy of the IIHI has been compromised based on a risk assessment of at least the following factors: (1) The nature and extent of the IIHI involved, including the types of identifiers and the likelihood of re-identification; (2) the unauthorized person who used the IIHI or to whom the disclosure was made; (3) whether the IIHI was actually acquired or viewed; and (4) the extent to which the risk to the IIHI has been mitigated.

Additionally, ''qualified IDR item or service'' means an item or service that is either an emergency service furnished by a nonparticipating provider or nonparticipating emergency facility subject to the protections of 26 CFR 54.9816–4T, 29 CFR 2590.716–4, or 45 CFR 149.110, for which the conditions of 45 CFR 149.410(b) (regarding receipt of notice of surprise billing protections and providing consent to waive them) are not met. The term also means an item or service furnished by a nonparticipating provider at a participating health care facility subject to the requirements of 26 CFR 54.9816–5T, 29 CFR 2590.716–5, and 45 CFR 149.120, for which the conditions of 149.420(c)–(i) (regarding receipt of notice of surprise billing protections and providing consent to waive them) are not met, for which the provider or facility (as applicable) or plan or issuer submits a valid Notice of IDR Initiation initiating the Federal IDR process. For the Notice of IDR Initiation to be valid, the open negotiation period under 26 CFR 54.9816–8T(b)(1), 29 CFR 2590.716–8(b)(1), and 45 CFR 149.510(b)(1) must have lapsed, and an agreement on the payment amount must not have been reached. The term qualified IDR item or service includes air ambulance services provided by nonparticipating providers of air ambulance services subject to the protections of 26 CFR 54.9817–1T, 29 CFR 2590.717–1, and 45 CFR 149.130, as these services are defined in 26 CFR 54.9816–3T, 29 CFR 2590.716–3, and 45 CFR 149.30, for which the open negotiation period under 26 CFR 54.9816–8T(b)(1), 29 CFR 2590.716–8(b)(1), and 45 CFR 149.510(b)(1) has lapsed, and no agreement on the payment amount has been reached.

The term ''qualified IDR item or service'' does not include items and services for which the out-of-network rate is determined by an All-Payer Model Agreement under section 1115A of the Social Security Act, or by reference to a specified state law. Additionally, this term does not include items or services submitted by the initiating party that are subject to the 90-calendar-day suspension period under 26 CFR 54.9816–8T(c)(4)(vii)(B), 29 CFR 2590.716–8(c)(4)(vii)(B), and 45 CFR 149.510(c)(4)(vii)(B). However, the term may include items or services that are subject to the 90-calendar-day suspension period if they are submitted during the subsequent 30-business-day period, as allowed under these interim final rules. The Departments solicit comment on these definitions, including whether other terms should be defined.

B. The Term ''Days''

The No Surprises Act specifies a number of time periods that providers, facilities, providers of air ambulance services, plans, issuers, certified IDR entities, and the Departments must abide by throughout the course of the Federal IDR process, including time periods for initiation of the Federal IDR process, selection of a certified IDR entity, submission of documents, and payment determinations. The statute is largely silent on whether the term ''days'' used in these provisions means business days or calendar days. However, in certain provisions, the No Surprises Act specifies the use of calendar days or business days, indicating that where the statute is silent the Departments may choose either meaning. The Departments received feedback from stakeholders that meeting various deadlines under the Federal IDR process may be challenging (for example, depending on a certified IDR entity's case load or the number of claims that a provider or facility batches together) and that, if possible, additional time should be provided for the parties and the certified IDR entity to meet these deadlines. The Departments are of the view that in order to provide parties with the most time permitted under the statute to meet the various deadlines under the Federal IDR process as set forth in the No Surprises Act, business days should be used, unless there is a reason to use calendar days. For example, these interim final rules provide that calendar days are used for the timing requirement for the non-prevailing party to make payment after the certified IDR entity issues a written determination, as well as the requirement barring the initiation of the Federal IDR process for a payment dispute that concerns the same or similar qualified IDR item or service that was the subject of the initial notification during the 90-calendar-day period following the initial determination discussed later in this preamble. In these instances, the Departments are of the view that once a decision has been rendered, these interim final rules should not unduly delay the payment entitled under that decision. Moreover, in terms of the 90-day suspension period, the Departments are of the view that using a business day standard here has the potential to create an unnecessary barrier to accessing the Federal IDR process.

Furthermore, the Departments are of the view that using business days will avoid issues that may arise if deadlines were to fall on weekends or Federal holidays. Therefore, business days (Monday through Friday, not including Federal holidays) instead of calendar days are used throughout these interim final rules for the Federal IDR process unless otherwise indicated, regardless of whether a nonparticipating provider or facility, or a plan or issuer's business typically operates on weekend days.

C. Open Negotiation and Initiation of the Federal IDR Process

Code section 9816(c)(1)(A), ERISA section 716(c)(1)(A), PHS Act section 2799A–1(c)(1)(A), and these interim final rules provide that with respect to an emergency service, a nonemergency

item or service furnished by a nonparticipating provider at a participating facility subject to the surprise billing protections for which the notice and consent exceptions do not apply, and for which the out-of-network rate is not determined by reference to an All-Payer Model Agreement under section 1115A of the Social Security Act or specified state law as defined in 26 CFR 54.9816–3T, 29 CFR 2590.716–3, and 45 CFR 149.30, the provider or facility, or plan or issuer, may engage in open negotiations to determine the total out-of-network rate (including any cost sharing). If the parties fail to reach an agreement through open negotiation, they may initiate the Federal IDR process. Code section 9817(b), ERISA section 717(b), and PHS Act section 2799A–2(b) provide that out-of-network rates for air ambulance services may be determined through open negotiation or an IDR process that is largely identical to the process provided for in Code section 9816(c), ERISA section 716(c), and PHS Act section 2799A–1(c), provided the out-of-network rate is not determined by reference to an All-Payer Model Agreement under section 1115A of the Social Security Act or specified state law as defined in 26 CFR 54.9816–3T, 29 CFR 2590.716–3, and 45 CFR 149.30. Therefore, where applicable, providers of air ambulance services are included in the preamble and regulatory language text describing open negotiations and the Federal IDR process. The primary distinctions between air ambulance services and other health care services apply in how the certified IDR entity should select an offer and in the obligations on the certified IDR entity regarding reporting of information relating to the Federal IDR process.

1. Open Negotiation

The open negotiation period may be initiated by any party during the 30-business-day period beginning on the day the nonparticipating provider, facility, or nonparticipating provider of air ambulance services receives either an initial payment or a notice of denial of payment for an item or service.[23] If the provider, facility, or provider of air ambulance services accepts such initial payment as the total payment, that initial payment combined with the cost-sharing amount for the item or service is the out-of-network rate, as defined in 26 CFR 54.9816–3T, 29 CFR 2590.716–3, and 45 CFR 149.30. Under the July 2021 interim final rules, the plan or issuer must provide in writing, with each initial payment or notice of denial of payment, certain information, including a statement that if the provider, facility, or provider of air ambulance services, as applicable, wishes to initiate a 30-business-day open negotiation period for purposes of determining the out-of-network rate, the provider, facility, or provider of air ambulance services may contact the appropriate person or office to initiate open negotiation, and that if the 30-business-day open negotiation period does not result in an agreement on the out-of-network rate, generally, the provider, facility, or provider of air ambulance services may initiate the Federal IDR process. The plan or issuer must also provide 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 the item or service.

In order for a plan, issuer, provider, facility, or provider of air ambulance services to know when it is a party to an open negotiation period and which items or services are subject to negotiation, these interim final rules require that the party initiating the open negotiation must provide written notice to the other party of its intent to negotiate, referred to as an open negotiation notice. The open negotiation notice must include information sufficient to identify the items or services subject to negotiation, including the date the item or service was furnished, the service code, the initial payment amount or notice of denial of payment, as applicable, an offer for the out-of-network rate, and contact information of the party sending the open negotiation notice. The open negotiation notice must be sent within 30 business days of the initial payment or notice of denial of payment from the plan or issuer regarding such item or service and must be provided in writing. The party sending the open negotiation notice may satisfy this requirement by providing the notice to the opposing party electronically (such as by email) if the following two conditions are satisfied: (1) The party sending the open negotiation notice has a good faith belief that the electronic method is readily accessible to the other party; and (2) the notice is provided in paper form free of charge upon request. For example, if a provider sends an open negotiation notice to the email address identified by the group health plan or issuer in the notice of denial or initial payment, such electronic delivery would satisfy this requirement (as long as the provider also sends the notice in paper form free of charge upon request). Similarly, if a provider, facility, or provider of air ambulance services submits a claim electronically, this could provide the plan or issuer with a good faith belief that the electronic method is readily accessible to the other party.

The 30-business-day open negotiation period begins on the day on which the open negotiation notice is first sent by a party. The Departments expect that most open negotiation notices will be sent electronically, and that, in general, the date the notice is sent will also be the date the notice is received. Furthermore, given that the parties have already made initial contact (namely that the provider or facility has transmitted a bill to the plan or issuer, and the plan or issuer has sent a notice of denial or initial payment to the provider or facility), the Departments anticipate that the parties should be able to provide effective notice without problems, and encourage the parties to take reasonable measures to ensure that actual notice is provided, such as confirming that the email address is accurate. The Departments caution that if the open negotiation notice is not properly provided to the other party (and no reasonable measures have been taken to ensure actual notice has been provided), the Departments may determine that the 30-business-day open negotiation period has not begun. In such case, any subsequent payment determination from a certified IDR entity may be unenforceable due to the failure of the party sending the open negotiation notice to meet the open negotiation requirement of these interim final rules. Therefore, the Departments encourage parties submitting open negotiation notices to take steps to confirm the other party's contact information and confirm receipt by the other party, through approaches such as read receipts, especially where a party does not initially respond to an open negotiation notice. The Departments solicit comment on whether there are any challenges or additional clarifications needed to ensure the parties are afforded the full open negotiation period, including whether there are any challenges regarding designating the date the notice is sent as the commencement date of the open negotiation period.

To facilitate communication between parties and compliance with this notice requirement, the Departments are concurrently issuing a standard notice

[23] As clarified in the July 2021 interim final rules, the 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, prior to the beginning of any open negotiations or initiation of the Federal IDR process.

that the parties must use to satisfy the open negotiation notice requirement.

Negotiation during the open negotiation period will occur without the involvement of the Departments or a certified IDR entity. The Departments note that this requirement for a 30-business-day open negotiation period prior to initiating the Federal IDR process does not preclude the parties from reaching an agreement in fewer than 30 business days. However, in the event the parties do not reach an agreement, the parties must still exhaust the 30-business-day open negotiation period before either party may initiate the Federal IDR process. The Departments encourage parties to negotiate in good faith during this time period to reach an agreement on the out-of-network rate. To the extent parties reach agreement during this period, they can avoid the administrative costs associated with the Federal IDR process.

2. Initiating the Federal IDR Process and the Notice of IDR Initiation

Code section 9816(c)(1)(B), ERISA section 716(c)(1)(B), PHS Act section 2799A–1(c)(1)(B), and these interim final rules provide that with respect to items or services that were subject to open negotiation, if the parties have not reached an agreed-upon amount for the out-of-network rate by the last day of the open negotiation period, either party may initiate the Federal IDR process during the 4-business-day period beginning on the 31st business day after the start of the open negotiation period. A party may not initiate the Federal IDR process if, with respect to an item or service, the party knows or reasonably should have known that the provider or facility provided notice and obtained consent from a participant, beneficiary, or enrollee to waive surprise billing protections consistent with PHS Act sections 2799B–1(a) and 2799B–2(a) and the implementing regulations at 45 CFR 149.410(b) and 149.420(c)–(i).

To initiate the Federal IDR process, the initiating party must submit a notice to the other party and to the Departments (Notice of IDR Initiation) through the Federal IDR portal. The Notice of IDR Initiation must include: (1) Information sufficient to identify the qualified IDR items or services (and whether the qualified IDR items or services are designated as batched items and services), including the dates and location of the items or services, the type of qualified IDR items or services (such as emergency services, post-stabilization services, professional services, hospital-based services), corresponding service and place-of-service codes, the amount of cost sharing allowed and the amount of the initial payment made by the plan or issuer for the qualified IDR items or services, if applicable; (2) the names and contact information of the parties involved, including email addresses, phone numbers, and mailing addresses; (3) the state where the qualified IDR items or services were furnished; (4) the commencement date of the open negotiation period; (5) the initiating party's preferred certified IDR entity; (6) an attestation that the items or services are qualified IDR items and services within the scope of the Federal IDR process; (7) the QPA; (8) information about the QPA as described in 26 CFR 54.9816–6T(d), 29 CFR 2590.716–6(d), and 45 CFR 149.140(d); and (9) general information describing the Federal IDR process. This general information will help ensure that the non-initiating party is informed about the process and is familiar with the next steps. Such general information should include a description of the scope of the Federal IDR process and key deadlines in the Federal IDR process, including the dates to initiate the Federal IDR process, how to select a certified IDR entity, and the process for selecting an offer. The Departments have developed a form that parties must use to satisfy this requirement to provide general information describing the Federal IDR process.

As with the open negotiation notice, the initiating party may provide the Notice of IDR Initiation to the opposing party electronically (such as by email) if the following two conditions are satisfied: (1) The initiating party has a good faith belief that the electronic method is readily accessible by the other party; and (2) the notice is provided in paper form free of charge upon request.

In addition to furnishing notice to the non-initiating party, the initiating party must also furnish the Notice of IDR Initiation to the Departments on the same day the notice is furnished to the non-initiating party. The initiating party must provide its Notice of IDR Initiation through the Departments' Federal IDR portal. Moreover, IDR entities, certified IDR entities and disputing parties will be required to use the Federal IDR portal to perform certain functions related to the Federal IDR process. The Federal IDR portal will be used to facilitate and support IDR entity certification, the initiation of the Federal IDR process, the selection of certified IDR entities, the submission of supporting documentation to certified IDR entities, and the submission of certified IDR entity reporting metrics, as required by these interim final rules.

Under Code section 9816(c)(1)(B), ERISA section 716(c)(1)(B), and PHS Act section 2799A–1(c)(1)(B), the date of initiation of the Federal IDR process will be the date of the submission or such other date specified by the Departments that is not later than the date of receipt of the Notice of IDR Initiation by both the other party and the Departments. Consistent with the flexibility provided by the statute to specify an alternate date of initiation, these interim final rules specify that the initiation date of the Federal IDR process is the date of receipt of the Notice of IDR Initiation by the Departments. As noted, since the Departments will monitor the Federal IDR portal, submitting the Notice of IDR Initiation through the Federal IDR portal will provide a clear date on which the Notice of IDR Initiation has been received by the Departments. This approach will better enable the Departments to meet the statutory requirement to select a certified IDR entity within 6 business days of the initiation of the IDR process in instances in which the parties have not jointly selected a certified IDR entity. The Departments will acknowledge and confirm the initiation date with both parties upon receipt of the Notice of IDR Initiation. Given that the Departments expect most of these notices to be provided electronically, and that the parties will have been in continuous contact by this point in the process (through the submission of the initial bill, the remittance of the initial payment of the claim or notice of denial of payment, the submission of the open negotiation notice, and negotiations during the open negotiation period), the Departments expect minimal delay between when the Departments are notified through the portal and when the opposing party is notified (either by the initiating party or the Departments). The Departments solicit comment on both the content of the Notice of IDR Initiation as well as the manner for providing the notices as set forth under these interim final rules.

D. Federal IDR Process Following Initiation

1. Selection of Certified IDR Entity

Under Code section 9816(c)(4)(F), ERISA section 716(c)(4)(F), and PHS Act section 2799A–1(c)(4)(F), the plan or issuer and the nonparticipating provider, nonparticipating emergency facility, or nonparticipating provider of air ambulance services (as applicable) that are parties to the Federal IDR process may jointly select a certified IDR entity no later than 3 business days

following the date of the IDR initiation. As stated above, in initiating the Federal IDR process, the initiating party will indicate its preferred certified IDR entity in the Notice of IDR Initiation. Under these interim final rules, the party in receipt of the Notice of IDR Initiation may agree or object to the selection of the preferred certified IDR entity identified in the Notice of IDR Initiation. If the non-initiating party in receipt of the Notice of IDR Initiation fails to object within 3 business days of the date of initiation of the Federal IDR process, the preferred certified IDR entity identified in the Notice of IDR Initiation will be the selected certified IDR entity, provided that the certified IDR entity does not have a conflict of interest. If the party in receipt of the Notice of IDR Initiation timely objects, that party must timely notify the initiating party of the objection, including an explanation of the reason for objecting, and propose an alternative certified IDR entity. The initiating party must then agree or object to the alternative certified IDR entity. In order to jointly select a certified IDR entity, the plan or issuer and the nonparticipating provider, nonparticipating emergency facility, or nonparticipating provider of air ambulance services must agree on a certified IDR entity not later than 3 business days after the date of initiation of the Federal IDR process. Due to the short timeframe for this selection, the Departments anticipate that communication between the parties regarding certified IDR entity selection will typically be conducted through electronic mail to the email addresses used to send and receive the Notice of IDR Initiation. The Departments anticipate that most users of the Federal IDR process will be providers, facilities, providers of air ambulance services, plans, and issuers, which are likely to use electronic communications regularly. If both parties agree on and select a certified IDR entity, or fail to agree upon a certified IDR entity within the specified timeframe, the initiating party must notify the Departments by electronically submitting the notice of the certified IDR entity selection or failure to select (as applicable), no later than 1 business day after the end of the 3-business-day period (or in other words, 4 business days after the date of initiation of the Federal IDR process) through the Federal IDR portal. In addition, in instances where the non-initiating party believes that the Federal IDR process is not applicable, the non-initiating party must notify the Departments through the Federal IDR portal within the same timeframe that the notice of selection (or failure to select) is required and provide information regarding the lack of applicability. Based upon this information and any additional information requested by the selected certified IDR entity, the selected certified IDR entity will determine whether the Federal IDR process is applicable. The Departments seek comment on this approach and whether any challenges exist in relying solely upon electronic notifications.

The Departments will make available on the Federal IDR portal a list of certified IDR entities among which parties to the Federal IDR process may select, including basic information about the certified IDR entities, such as contact information, certified IDR entity numbers (unique identification numbers assigned to each certified IDR entity by the Departments), websites, and service areas. The Departments seek comment on this approach, including whether additional information about the certified IDR entities should be made public, and whether any challenges exist in relying solely upon electronic notifications.

Under these interim final rules, the selected certified IDR entity must not have a conflict of interest as defined in 26 CFR 54.9816–8T(a)(2), 29 CFR 2590.716–8(a)(2), and 45 CFR 149.510(a)(2). The selected certified IDR entity must also ensure that assignment of personnel to the dispute and decisions regarding hiring, compensation, termination, promotion, or other similar matters related to personnel assigned to the dispute are not made based upon the likelihood that the assigned personnel will support a particular party or type of party (that is, provider, facility, provider of air ambulance services, plan, or issuer) to the determination being disputed other than as outlined under 26 CFR 54.9816–8T(c)(4)(iii), 29 CFR 2590.716–8(c)(4)(iii), and 45 CFR 149.510(c)(4)(iii). Also, as agents of the certified IDR entity, personnel responsible for handling individual payment determinations must comply with the certification requirements of these interim final rules as set forth by their principal, the certified IDR entity, in its procedures. Therefore, the personnel assigned to disputes by the certified IDR entity must not have a conflict of interest, as defined by 26 CFR 54.9816–8T(a)(2), 29 CFR 2590.716–8(a)(2), and 45 CFR 149.510(a)(2). In addition, any personnel assigned to the matter must not have been a party to the determination being disputed or an employee or agent of such a party within the 1 year immediately preceding the dispute resolution assignment, similar to the ''revolving door'' laws [24] laid out in 18 U.S.C. 207(b), 207(c), and 207(e). Under 18 U.S.C. 207(b), 207(c), and 207(e), former officers or employees of the executive branch, including independent agencies, are prohibited from aiding or advising on matters with which they were involved while in the executive branch for 1 year. These interim final rules adopt the same 1-year timeframe by prohibiting former employees' or agents' involvement in dispute resolution processes involving former employers for 1 year. The Departments are of the view that this approach provides a reasonable and appropriate standard for preventing conflicts of interest. Although 18 U.S.C. 207(b), 207(c), and 207(e) are typically used in reference to trade or treaty negotiations, the 1-year prohibition is also a standard applied generally to employees of the executive and legislative branches and independent agencies. These statutes represent conflict-of-interest standards that the Departments view as reasonable and appropriate for developing standards for preventing conflicts of interest involving certified IDR entities that are resolving disputes in the Federal IDR process. Certified IDR entities are expected to ensure staff compliance with the standards of these interim final rules, and as such, attestations of no conflict of interest at the organization level are intended also to represent the absence of conflicts of interest among the employees and agents of the certified IDR entity.

The Departments anticipate that certified IDR entities will likely be limited to organizations with sufficient staff who have arbitration and health care claims experience, including entities currently providing services for external review or state IDR determinations. To further ensure that personnel assigned to any determination in the Federal IDR process do not have a conflict of interest, the Departments have included additional safeguards for personnel, as well as an additional requirement that the certified IDR entity have procedures in place to ensure adherence by personnel with these additional safeguards. Accordingly, at the time of application for certification, the IDR entity must attest that it has procedures in place to ensure that no conflicts of interest exist or will exist, as set forth in the discussion of

[24] Maskell, J., Post-Employment, ''Revolving Door,'' Laws for Federal Personnel. Congressional Research Service. 2014. *https://fas.org/sgp/crs/misc/R42728.pdf.*

certification requirements later in this preamble. As an additional requirement, certified IDR entities will have had to submit, as part of their application to be certified IDR entities, policies and procedures for conducting ongoing audits for conflicts of interest, to ensure that should any arise, the certified IDR entity procedures in place to inform the Departments of the conflict of interest and mitigate the risk by reassigning the dispute to other personnel in the event that any personnel previously assigned have a conflict of interest.

If the parties have agreed on a certified IDR entity, the notice of the certified IDR entity selection must include the following information: (1) The name of the certified IDR entity; (2) the certified IDR entity number; and (3) an attestation by both parties (or by the initiating party if the other party has not responded) that the selected certified IDR entity does not have a conflict of interest. The attestation must be submitted based on conducting a conflicts of interest check using information available (or accessible using reasonable means) to the parties (or the initiating party if the other party has not responded) at the time of the selection.

As stated earlier in this preamble, upon receipt of notification that the parties failed to agree on a certified IDR entity, the Departments will select a certified IDR entity. In such instances, the Departments will randomly select a certified IDR entity that charges a fee within the allowed range provided for in guidance and defined further in section III.D.4.viii of this preamble. If there are insufficient certified IDR entities that charge a fee within the allowed range available to adjudicate the payment determination, the Departments will randomly select a certified IDR entity that has received approval to charge a fee outside of the allowed range. The Departments will make the random selection not later than 6 business days after the date of initiation of the Federal IDR process, and will notify the parties of the selection. The Departments considered alternative approaches to randomly selecting a certified IDR entity, including whether the Departments should consider the specific fee of the certified IDR entity or look to other factors, such as how often the certified IDR entity chooses the amount closest to the QPA. Following consideration of various approaches, the Departments have chosen to utilize a random selection method to select a certified IDR entity that charges a fee within the allowed range (or has received approval from the Departments to charge a fee outside of the allowed range, if there are insufficient certified IDR entities that charge a fee within the allowed range available) and that does not have a conflict of interest with either party. The Departments are of the view that this approach will help ensure that requests for IDR and workload associated with making determinations for such requests are appropriately distributed across the certified IDR entities, will result in an efficient and timely assignment of a certified IDR entity to payment determinations, and will protect against bias in the types of cases a certified IDR entity reviews while encouraging certified IDR entities to charge reasonable fees for their services. Additionally, the Departments are of the view that this approach will provide predictability to the parties regarding the fees they will be expected to pay if they do not select the certified IDR entity. The Departments seek comment on this approach, including whether the random selection method should be limited only to certified IDR entities that charge a fee within the allowed range. The Departments may issue future guidance regarding whether entities that have received approval from the Departments to charge a fee outside of the allowed range may be selected by the Departments under the random selection method.

After selection by the parties (including when the initiating party selects a certified IDR entity and the other party does not object), or by the Departments, the certified IDR entity must also review its selection to ensure that it meets the requirements of 26 CFR 54.9816–8T(c)(1)(ii), 29 CFR 2590.716–8(c)(1)(ii), and 45 CFR 149.510(c)(1)(ii) related to potential conflicts of interest. If the selected certified IDR entity meets these requirements, the certified IDR entity must attest to meeting these requirements. If the certified IDR entity is unable to attest that it meets these requirements, the certified IDR entity must notify the Departments through the Federal IDR portal within 3 business days, after which the Departments will notify the parties. Upon notification, the parties will have 3 business days to select another certified IDR entity under the process described in 26 CFR 54.9816–8T(c)(1), 29 CFR 2590.716–8(c)(1), or 45 CFR 149.510(c)(1). If the parties notify the Departments that they have not agreed on a certified IDR entity, the Departments may randomly select another certified IDR entity.

The certified IDR entity must also review the information submitted by the parties to determine whether the Federal IDR process applies, including whether an All-Payer Model Agreement or specified state law applies. If the Federal IDR process does not apply, the certified IDR entity must notify the Departments and the parties within 3 business days of making this determination.

2. Authority To Continue Negotiation

Code sections 9816(c)(2)(B) and 9817(b)(2)(B), ERISA sections 716(c)(2)(B) and 717(b)(2)(B), PHS Act sections 2799A–1(c)(2)(B) and 2799A–2(b)(2)(B), and these interim final rules provide that, in instances in which the parties agree on an amount for a qualified IDR item or service after the Federal IDR process is initiated but prior to a determination by a certified IDR entity, the agreed-upon amount will be treated as the out-of-network rate and will be treated as resolving the dispute. If the parties to the Federal IDR process agree on an out-of-network rate for a qualified IDR item or service after providing to the Departments the Notice of IDR Initiation, but before the certified IDR entity has made its payment determination, the initiating party must notify the Departments and the certified IDR entity (if selected) by electronically submitting notification of such agreement through the Federal IDR portal as soon as possible but no later than 3 business days after the date of the agreement. As is the case in instances where the parties do not come to an agreement before the certified IDR entity selects the amount submitted by one of the parties, the amount by which this agreed-upon out-of-network rate exceeds the cost-sharing amount for the qualified IDR item or service is the total plan or coverage payment.[25] The plan or issuer must pay the balance of the total plan or coverage amount of the agreed-upon out-of-network rate (with any initial payment made counted towards the total plan or coverage payment) to the nonparticipating provider, nonparticipating emergency facility, or nonparticipating provider of air ambulance services not later than 30 business days after the agreement is reached. As noted in section III.D.4.viii of this preamble regarding costs of the Federal IDR process, when there is an agreement after initiation and a certified IDR entity is selected but prior to a determination by the certified IDR entity, each party must pay half of the certified IDR entity fee, unless the parties agree otherwise on a method for allocating the applicable fee. In no instance may either party seek

[25] *See* 26 CFR 54.9816–4T, 54.9816–5T, and 54.9817–1T; 29 CFR 2590.716–4, 2590.716–5, and 2590.717–1; and 45 CFR 149.110, 149.120, and 149.130.

additional payment from the participant or beneficiary, including in instances in which the out-of-network rate exceeds the QPA. When an agreement is reached, either before or after a certified IDR entity is selected, notification to the Departments must include the out-of-network rate (that is, the total payment amount, including both cost sharing and the total plan or coverage payment) and signatures from an authorized signatory for each party.

3. Treatment of Batched Items and Services

Code section 9816(c)(3), ERISA section 716(c)(3), and PHS Act section 2799A–1(c)(3) direct the Departments to specify criteria under which multiple qualified IDR items and services may be considered jointly as part of one payment determination (batching). Under these interim final rules, multiple claims for qualified IDR items and services may be submitted and considered jointly as part of one payment determination by a certified IDR entity (batched items and services) only if certain conditions are met. Batched items and services submitted and considered jointly as part of one payment determination under 26 CFR 54.9816–8T(c)(3)(i), 29 CFR 2590.716–8(c)(3)(i), 45 CFR 149.510(c)(3)(i) are subject to the fee for batched determinations under these interim final rules.

First, the qualified IDR items and services must be billed by the same provider or group of providers or facility or same provider of air ambulance services. Items and services are billed by the same provider or group of providers or facility or same provider of air ambulance services if the items or services are billed with the same National Provider Identifier (NPI) or Taxpayer Identification Number (TIN).

Second, the payment for the items and services would be made by the same group health plan or health insurance issuer.

Third, the qualified IDR items and services must be the same or similar items or services. The definition of a same or similar item or service in these interim final rules is consistent with the definition under the July 2021 interim final rules. The Departments defined a same or similar item or service in 26 CFR 54.9816–6T(a)(13), 29 CFR 2590.716–6(a)(13), and 45 CFR 149.140(a)(13) as those items and services that are billed under the same service code, or a comparable code under a different procedural code system, and the Departments defined the service codes as the code that describes an item or service using Current Procedural Terminology (CPT), Healthcare Common Procedure Coding System (HCPCS), or Diagnosis-Related Group (DRG) codes.

Finally, all the qualified IDR items and services must have been furnished within the same 30-business-day period, or the 90-calendar-day suspension period described later in this preamble. Therefore, if items or services are furnished within the 90-calendar-day suspension period and meet the other applicable requirements, they may be submitted and considered jointly as part of one payment determination by a certified IDR entity, once the suspension period has ended. Under Code section 9816(c)(9), ERISA section 716(c)(9), and PHS Act section 2799A–1(c)(9), the Departments may provide an alternative period to the aforementioned 30-business-day period as determined by the Departments for certain circumstances, such as low-volume items and services. The Departments are using this authority to ensure that items and services delivered during the 90-calendar-day suspension period are eligible for the Federal IDR process and may be included in the same batch.

The Departments are of the view that the approach set forth to allow for batching of multiple qualified IDR items and services will avoid combinations of unrelated claims, providers, facilities, providers of air ambulance services and plans and issuers in a single dispute that could unnecessarily complicate an IDR payment determination and create inefficiencies in the Federal IDR process. The Departments solicit comment on this approach and whether there is a need to prescribe an alternative period for other qualified IDR items and services different from the 30-business-day period discussed earlier in the discussion of the batching requirements and what circumstances should be considered in defining any alternative period.

Additionally, in some cases, a plan or issuer may pay a provider, facility, or provider of air ambulance services a single payment for multiple services an individual received during an episode of care (bundling). In the case of qualified IDR items or services that are billed by a provider, facility, or provider of air ambulance services as part of a bundled arrangement, or where a plan or issuer makes an initial payment as a bundled payment (or specifies that a denial of payment is made on a bundled payment basis), these interim final rules provide that those qualified items or services may be submitted and considered as part of one payment determination by a certified IDR entity (and is subject to the fee for single determinations under 26 CFR 54.9816–8T(c)(3)(ii), 29 CFR 2590.716–8(c)(3)(ii), 45 CFR 149.510(c)(3)(ii)).

The Departments recognize that certain batched items and services may have different QPAs. For example, if a determination includes multiple batched claims for Service A furnished by Provider B to individuals covered by Issuer C, with some individuals covered by plans in the individual market and others covered by plans in the large group market, there likely would be two different QPAs for the certified IDR entity to consider—one QPA for the services furnished to individuals enrolled in individual market coverage, and one QPA for individuals with large group market coverage. As discussed elsewhere in this preamble, when this is the case, the parties must provide the relevant information for each QPA, and the certified IDR entity must consider each QPA for each item or service separately. However, since batched items and services involve the same or similar medical procedure, batching is likely to reduce redundant IDR proceedings as well as streamline the certified IDR entity's decision-making, as some of the considerations relate to factors not specific to the individual encounter.

The Departments seek comment on all aspects of the criteria for batching claims and bundling, including whether additional conditions should be added to limit batching or whether the conditions should be amended to facilitate broader batching of qualified IDR items and services. The Departments also seek comment on how frequently nonparticipating providers, nonparticipating emergency facilities, or nonparticipating providers of air ambulance services will be reimbursed through a bundled payment and whether allowing items or services included in a bundled payment by a provider or facility to be treated as one payment determination could be used to circumvent the batching requirements by not requiring precise consideration of what specific claims within the batch should be arbitrated and which claims should not, thereby resulting in potential overuse of the Federal IDR process in a manner that creates inefficiencies.

4. Payment Determination

i. Submission of Offers

Code section 9816(c)(5)(B), ERISA section 716(c)(5)(B), and PHS Act section 2799A–1(c)(5)(B) provide that, not later than 10 days after the date of selection of the certified IDR entity with respect to a determination for a

qualified IDR item or service, the plan or issuer and the nonparticipating provider, nonparticipating emergency facility, or provider of air ambulance services must each submit to the certified IDR entity an offer for a payment amount for such qualified IDR item or service. Under these interim final rules, the offer must be submitted not later than 10 business days after the selection of the certified IDR entity and must be expressed as both a dollar amount and the corresponding percentage of the QPA represented by that dollar amount, to facilitate the certified IDR entity reporting the offer as a percentage of the QPA to the Departments. Where batched items and services have different QPAs, the parties should provide these different QPAs and may provide different offers for these batched items and services, provided that the same offer should apply for all items and services with the same QPA.

Parties to the Federal IDR process must also submit information requested by the certified IDR entity relating to the offer. The Departments intend for the Federal IDR portal to collect this information as part of the offer submission process, such that certified IDR entities will not have to directly request this information. Providers and facilities must also indicate the size of their practices and facilities at the time the information is submitted. This will enable certified IDR entities to report on the size of the provider practices and facilities, as required under 26 CFR 54.9816–8T(f)(1)(ii), 29 CFR 2590.716–8(f)(1)(ii), and 45 CFR 149.510(f)(1)(ii). Specifically, the provider must specify whether the provider practice or organization has fewer than 20 employees, 20 to 50 employees, 51 to 100 employees, 101 to 500 employees, or more than 500 employees. For facilities, the facility must specify whether the facility has 50 or fewer employees, 51 to 100 employees, 101 to 500 employees, or more than 500 employees. Providers and facilities must also provide information on the practice specialty or type, respectively (if applicable). Similarly, plans and issuers must provide the coverage area of the plan or issuer, the relevant geographic region for purposes of the QPA, and, for group health plans, whether they are fully-insured, or partially or fully self-insured.[26] FEHB carriers must identify if a particular item or service relates to FEHB plans. The information such as practice or facility size, coverage area, geographic region, and whether a plan is fully-insured or partially or fully self-insured is required to be submitted as part of an offer so that the certified IDR entities can report this information to the Departments. This information will inform the reports required from the Departments under Code section 9816(c)(7), ERISA section 716(c)(7), and PHS Act section 2799A–1(c)(7). Both parties must submit any other information requested by the certified IDR entity relating to such offer. In addition, parties may submit any information relating to the offer, except that the information may not include information that relates to usual and customary charges, billed amounts, and public payor rates as discussed later in this preamble.

With regard to the number of employees of a provider or facility, the Departments understand that hospitals and facilities may use a variety of methods for staffing, such as through contracting with physicians' practices or foundations whose physicians or medical staff are not considered employees of the hospital or facility. The Departments seek comment on whether additional guidance is needed to account for these situations in the reporting of provider and facility size.

ii. Selection of Offer for Qualified IDR Items or Services That Are Not Air Ambulance Services

These interim final rules provide that, not later than 30 business days after the selection of the certified IDR entity, the certified IDR entity must select one of the offers submitted by the plan or issuer and the provider or facility to be the out-of-network rate for the qualified IDR item or service. For each qualified IDR item or service, the amount by which this out-of-network rate exceeds the cost-sharing amount for the qualified IDR item or service is the total plan or coverage payment (with any initial payment made counted towards the total plan or coverage payment). In selecting the offer, the certified IDR entity must presume that the QPA is an appropriate payment amount but must also consider the additional circumstances, following the requirements of 26 CFR 54.9816–8T(c)(4)(iii)(B) through (D), 29 CFR 2590.716–8(c)(4)(iii)(B) through (D), and 45 CFR 149.510(c)(4)(iii)(B) through (D), only if the information is submitted by the parties. However, to be considered by the certified IDR entity, information submitted by the parties must be credible and relate to the offer submitted by either party, and must not include information on the prohibited factors described in 26 CFR 54.9816–8T(c)(4)(v), 29 CFR 2590.716–8(c)(4)(v), or 45 CFR 149.510(c)(4)(v). After considering the QPA, additional information requested by the certified IDR entity from the parties, and all of the credible information that the parties submit that is consistent with the requirements in 26 CFR 54.9816–8T(c)(4)(i)(A), 29 CFR 2590.716–8(c)(4)(i)(A), or 45 CFR 149.510(c)(4)(i)(A), the certified IDR entity must select the offer closest to the QPA, unless the credible information submitted by the parties clearly demonstrates that the QPA is materially different from the appropriate out-of-network rate, based on the additional circumstances allowed under 26 CFR 54.9816–8T(c)(4)(iii)(B) through (D), 29 CFR 2590.716–8(c)(4)(iii)(B) through (D), or 45 CFR 149.510(c)(4)(iii)(B) through (D) with respect to the qualified IDR item or service. In these cases, or when the offers are equally distant from the QPA but in opposing directions, the certified IDR entity must select the offer that the certified IDR entity determines best represents the value of the items or services, which could be either party's offer.

These interim final rules define information as credible if upon critical analysis the information is worthy of belief and is trustworthy. These interim final rules also specify that a material difference exists where there is substantial likelihood that a reasonable person with the training and qualifications of a certified IDR entity making a payment determination would consider the information important in determining the out of network rate and view the information as showing that the QPA is not the appropriate out-of-network rate under such additional circumstances.

If the certified IDR entity determines that credible information about additional circumstances clearly demonstrates that the QPA is materially different from the appropriate out-of-network rate, the certified IDR entity must select the offer that the certified IDR entity determines best represents the appropriate out-of-network rate for the qualified IDR items or services, which could be either party's offer. Not later than 30 business days after the selection of the certified IDR entity, the certified IDR entity must also notify the plan or issuer and the provider or facility of the selection of the offer, and provide the written decision required under 26 CFR 54.9816–8T(c)(4)(vi), 29 CFR 2590.716–8(c)(4)(vi), and 45 CFR 149.510(c)(4)(vi).

[26] Pursuant to OPM contracts with FEHB carriers under 5 U.S.C. Ch. 89, 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.

The Departments are of the view that the best interpretation of Code section 9816, ERISA section 716, and PHS Act section 2799A–1 is that when selecting an offer, a certified IDR entity must look first to the QPA, as it represents a reasonable market-based payment for relevant items and services, and then to other considerations. This presumption that the QPA is the appropriate out-of-network rate can be rebutted by presentation of credible information about additional circumstances, following the requirements of 26 CFR 54.9816–8T(c)(4)(iii)(B) through (D), 29 CFR 2590.716–8(c)(4)(iii)(B) through (D), and 45 CFR 149.510(c)(4)(iii)(B) through (D), that clearly demonstrate that the QPA is materially different from the appropriate out-of-network rate. The statutory text lists the QPA as the first factor that the certified IDR entity must consider in determining which offer to select. The ''additional circumstances'' that the certified IDR entity must consider if relevant, credible information is provided are described in a separate paragraph, and the certified IDR entity's consideration of additional circumstances is subject to a prohibition on considering certain factors. Additionally, whereas the statute provides relatively limited guidance on how to consider or define these additional circumstances, the statute sets out detailed rules for calculating the QPA, suggesting that an accurate and clear calculation of the QPA is integral to the application of consumer cost sharing and to the certified IDR entity's determination of the out-of-network rate. For example, the statute includes a requirement that when plans and issuers do not have sufficient information to calculate their own median contracted rates, they utilize a database free of conflicts of interest.[27] Plans and issuers must also provide specific information on how the QPA is calculated to nonparticipating providers and facilities, ensuring that they are aware of how this amount is calculated.[28] Plans and issuers are also subject to audit requirements that will be enforced by the Departments to ensure that they follow these rules.[29] Cost sharing for participants, beneficiaries, and enrollees for items and services will be based on the recognized amount, which will generally be the QPA for services eligible for the Federal IDR process, indicating that the QPA is a reasonable out-of-network rate. The Departments are also required to report how payment determinations compare to the corresponding QPA, reflecting that the QPA is a benchmark for determining the appropriate out-of-network rate.[30] Taken together, these statutory elements reflect the importance the No Surprises Act assigns to the QPA in the Federal IDR process, and show that the statute contemplates that typically the QPA will be a reasonable out-of-network rate.

The Departments are also of the view that policy considerations support the approach taken under these interim final rules regarding which offer a certified IDR entity must select. Generally, the QPA should reflect standard market rates arrived at through typical contract negotiations and should therefore be a reasonable out-of-network rate under most circumstances. The QPA is generally based on the median of contracted rates, and these contracted rates are established through arms-length negotiations between providers and facilities and plans and issuers (or their service providers). Anchoring the determination of the out-of-network rate to the QPA will increase the predictability of IDR outcomes, which may encourage parties to reach an agreement outside of the Federal IDR process to avoid the administrative costs, and will aid in reducing prices that may have been inflated due to the practice of surprise billing prior to the No Surprises Act. Finally, anchoring the determination to the QPA will help limit the indirect impact on participants, beneficiaries, and enrollees that would occur from higher out-of-network rates if plans and issuers were to pass higher costs on to individuals in the form of increases in premiums.

Accordingly, the certified IDR entity must begin with the presumption that the QPA is the appropriate out-of-network rate for the qualified IDR item or service under consideration. Therefore, in determining which offer to select, these interim final rules provide that the certified IDR entity must select the offer closest to the QPA, unless credible information presented by the parties rebuts that presumption and clearly demonstrates the QPA is materially different from the appropriate out-of-network rate, as discussed earlier in this section of the preamble.

The Departments clarify that it is not the role of the certified IDR entity to determine whether the QPA has been calculated by the plan or issuer correctly, to make determinations of medical necessity, or review denials of coverage.[31] Rather, the certified IDR entity is responsible for considering only the information presented by the parties to determine whether either party has presented credible information regarding additional circumstances, following the requirements set forth in paragraphs 26 CFR 54.9816–8T(c)(4)(iii)(B) through (D), 29 CFR 2590.716–8(c)(4)(iii)(B) through (D), and 45 CFR 149.510(c)(4)(iii)(B) through (D), demonstrating that the QPA is materially different from the appropriate out-of-network rate, in order to rebut the presumption that the QPA is the appropriate out-of-network rate. For batched items and services, the certified IDR entity may select different offers, from either or both parties, when the QPAs for the qualified IDR items or services within the batch are different. The certified IDR entity may do so even if it does not select the offer closest to the QPA for a particular qualified IDR item or service due to the factors listed later in this section of the preamble, and instead selects the offer closest to the QPA for other qualified IDR items and services within the batch.

In the Departments' view, the requirements set forth in these interim final rules regarding which offer a certified IDR entity must select, based on the presumption that the QPA is the appropriate payment amount and on the parties' ability to rebut that presumption, will help promote efficiency and predictability in the Federal IDR process, and will increase the likelihood that a certified IDR entity will generally select the offer closest to the QPA. While the QPA is the presumptive factor, the Departments are of the view that a clear standard indicating how a certified IDR entity may select an offer that is not closest to the QPA is necessary to help ensure consistency in how different certified IDR entities evaluate offers, which will help ensure that the Federal IDR process yields predictable outcomes and reduces administrative costs. Establishing a standard framework for certified IDR entities to evaluate factors furthers the intent of these interim final

[27] Code section 9816(a)(2), (3)(E); ERISA section 716(a)(2), (3)(E), and PHS Act section 2799A–1(a)(2), (3)(E); 26 CFR 54.9816–6T, 29 CFR 2590.716–6, and 45 CFR 149.140.

[28] *Id.*

[29] 86 FR 36872, 36899 (July 13, 2021).

[30] Code section 9816(c)(7)(A)(v), (B)(iii) and (iv); ERISA section 716(c)(7)(A)(v), (B)(iii) and (iv); and PHS Act section 2799A–1(c)(7)(A)(v), (B)(iii) and (iv).

[31] However, if either the certified IDR entity or one of the parties believes the QPA has not been calculated in accordance with the requirements in 26 CFR 54.9816–6T, 29 CFR 2590.716–6, or 45 CFR 149.140, the Departments encourage the certified IDR entity or the provider or facility to notify the applicable state or federal authority, or submit a complaint against the plan or issuer as set forth in 26 CFR 54.9816–7T, 29 CFR 2590.716–7, or 45 CFR 149.150, as applicable.

rules to create equity and consistency in the Federal IDR process and aligns with other policies set forth in these interim final rules, such as the conflict-of-interest standards and the certification standards for IDR entities. Ensuring that all certified IDR entities apply the same standards will help ensure that the Federal IDR process is appropriately predictable, fair, and equitable.

Although these interim final rules establish the QPA as the presumptive factor, these interim final rules and the underlying statute also specify additional circumstances that certified IDR entities must consider in selecting an offer, if a party submits information about the additional circumstance that the certified IDR entity determines is credible. These interim final rules also require that the parties provide certain information to the certified IDR entity, described previously in this preamble, regarding practice size, practice specialty or type; information about the plan or issuer's coverage area; information about the QPA; and, if applicable, information showing that the Federal IDR process is inapplicable to the dispute. In addition, the certified IDR entity may request additional information relating to the parties' offers and must consider credible information submitted to determine if it demonstrates that the QPA is materially different from the appropriate out-of-network rate (unless the information relates to a factor that the certified IDR entity is prohibited from considering).

Regarding those factors, first, to the extent credible information is submitted by a party, the certified IDR entity must consider whether the credible information about the level of training, experience, and quality and outcome measurements (such as those endorsed by the consensus-based entity authorized under section 1890 of the Social Security Act) of the provider or facility that furnished the qualified IDR item or service clearly demonstrates that the QPA is materially different from the appropriate out-of-network rate for the qualified IDR item or service. In order for a certified IDR entity to consider this additional information submitted by a party, the credible information must clearly demonstrate that the QPA failed to take into account that the experience or level of training of a provider was necessary for providing the qualified IDR item or service to the patient or that the experience or training made an impact on the care that was provided. The Departments are of the view that qualified IDR items or services should not necessitate an out-of-network rate higher than the offer closest to the QPA, simply based on the level of experience or training of a provider, as this would lead to an increase in prices without a valid reason and does not align with the goals of the No Surprises Act. For instance, the out-of-network payment amount for the simple repair of a superficial wound (CPT codes 12001–12007) in most cases would not necessitate a rate higher than the QPA just because a provider has 30 years of experience versus 10 years of experience. Alternatively, if the plan's or issuer's contracted rates included risk-sharing, bonus, penalty, or other incentive-based or retrospective payments that were excluded for purposes of calculating the QPA for the items and services as required by the July 2021 interim final rules, a party may provide evidence as to why the provider's or facility's quality or outcome measures support an out-of-network rate that is different from the QPA and the certified IDR entity should consider whether this requires selecting an out-of-network rate that is higher (in the case of a bonus) or lower (in the case of a penalty) than the offer closest to the QPA.

Second, to the extent credible information is submitted by a party, the certified IDR entity must consider whether the credible information about the market share held by the nonparticipating provider or facility or the plan (including, for self-insured plans, the market share of their third-party administrator (TPA) in instances where the self-insured plan relies on the TPA's networks) or issuer in the geographic region in which the qualified IDR item or service was provided, clearly demonstrates that the QPA is materially different from the appropriate out-of-network rate for the qualified IDR item or service. Research suggests that the market dominance of a provider or facility, or that of a plan or issuer, can drive reimbursement rates up or down in a given region.[32] For instance, a plan or issuer having the majority of the market share in a geographic region may signal a QPA that is unreasonably low, as plans and issuers with a large market share may drive down rates,[33] in which case an out-of-network rate higher than the offer closest to the QPA may be appropriate. Alternatively, a provider having the majority of the market share in a geographic region may signal a QPA that is unreasonably high, as providers with a large market share may drive up rates, in which case an out-of-network rate lower than the offer closest to the QPA may be appropriate.

Third, to the extent credible information is submitted by a party, the certified IDR entity must consider whether the credible information about patient acuity or the complexity of furnishing the qualified IDR item or service to the participant, beneficiary, or enrollee clearly demonstrates that the QPA is materially different from the appropriate out-of-network rate for the qualified IDR item or service. In many cases, because the plan or issuer is required to calculate the QPA using median contracted rates for service codes, as well as modifiers, if applicable, and because service codes and modifiers reflect patient acuity and the complexity of the service provided,[34] these factors will already be reflected in the QPA. Therefore, the Departments anticipate that there would only be rare instances in which the QPA would not adequately account for the acuity of the patient or complexity of the service. For example, if the complexity of a case is an outlier such that the time or intensity of care exceeds what is typical for a service code, the certified IDR entity may conclude that the QPA does not adequately take the factor into account. Similarly, the QPA for a qualified IDR item or service may be considered too high for items or services that become less complex or are furnished more frequently over time, such as items for which the QPA reflects reimbursement for a product with a patent that expires after 2019, in instances where the QPA is based off the median of the contracted rates from 2019. A certified IDR entity may also conclude that the QPA does not adequately account for patient acuity, or the complexity of furnishing the qualified IDR item or service in instances where the parties disagree on what service code or modifier accurately describes the qualified IDR item or service. For instance, the Departments are aware that some plans and issuers review claims and alter the service code or modifier submitted by the provider or facility to another service code or modifier that the plan or issuer determines to be more appropriate (a practice commonly referred to as ''downcoding'' when the adjustment

[32] Schwartz, K., Lopez, E., Rae, M., Neuman, T. What We Know About Provider Consolidation. Kaiser Family Foundation. September 2020. *https://www.kff.org/health-costs/issue-brief/what-we-know-about-provider-consolidation/.*

[33] See Richard M. Scheffler and Daniel R. Arnold. ''Insurer Market Power Lowers Prices in Numerous Concentrated Provider Markets.'' Health Affairs. 2017 36:9, 1539–1546; Glenn Melnick, Yu-Chu Shen and Vivian Wu. ''The Increased Concentration Of Health Plan Markets Can Benefit Consumers Through Lower Hospital Prices.'' Health Affairs 30, no. 9.

[34] *https://www.medicalbillingandcoding.org/cpt-modifiers/.*

results in lower reimbursement).[35] If a plan or issuer has altered the service code or modifier(s) for a submitted claim and applies a QPA that uses a different service code or modifier(s) than the service code or modifier(s) submitted by the provider or facility, the provider or facility could submit credible information to the certified IDR entity demonstrating that the QPA applied by the plan or issuer to the claim is based on a service code or modifier that did not properly encompass patient acuity, the complexity of furnishing the qualified IDR item or service. If the certified IDR entity agrees that either of the parties have presented credible information that clearly demonstrates that the QPA is materially different from the appropriate out-of-network rate, and adequately takes into account the considerations allowed under 26 CFR 54.9816–8T(c)(4)(iii)(B) through (D), 29 CFR 2590.716–8(c)(4)(iii)(B) through (D), and 45 CFR 149.510(c)(4)(iii)(B) through (D), then it could select either offer, but must select the offer that the certified IDR entity determines best represents the value of the qualified IDR item or service.[36]

Fourth, to the extent credible information is submitted by a party, the certified IDR entity must also consider whether the credible information about the teaching status, case mix, and scope of services of the nonparticipating facility, clearly demonstrates that the QPA is materially different from the appropriate out-of-network rate for the qualified IDR item or service. Similar to the other factors, it is the view of the Departments that the QPA, which is intended to reflect the market-driven rate, should be considered the prevailing rate unless a party provides credible information that the characteristic of the teaching status, case mix, or scope of services of the nonparticipating facility was in some way critical to the delivery of the qualified IDR item or service, and not adequately accounted for in the QPA, thereby rebutting the presumption that the QPA is the appropriate out-of-network rate. For example, a certified IDR entity could consider the trauma level of a hospital when the dispute involves trauma care or qualified IDR items or services that could not be performed at a lower-level hospital, but only to the extent the QPA does not otherwise reflect this factor. The Departments seek comment on whether additional requirements should be considered to address any potentially abusive scenarios, including scenarios in which parties could potentially distort information that informs the enumerated considerations, such as overestimating the teaching experience of providers at the facility or upcoding the costs for items or services, and seek comment on the potential for gaming of the Federal IDR process.

Fifth, to the extent credible information is submitted by a party, the certified IDR entity must also consider whether the credible information about any demonstrations of good faith efforts (or lack thereof) made by the nonparticipating provider, nonparticipating facility, or nonparticipating provider of air ambulance services or the plan or issuer, as applicable, to enter into network agreements and, if applicable, contracted rates between the provider or facility and the plan or issuer, as applicable during the previous 4 plan years, clearly demonstrates that the QPA is materially different from the appropriate out-of-network rate for the qualified IDR item or service. For example, a certified IDR entity must consider what the contracted rate might have been had the good faith negotiations resulted in the nonparticipating provider, facility, or provider of air ambulance services being in-network, if a party is able to provide related credible information of good faith efforts or the lack thereof.

Beyond these enumerated factors, the certified IDR entity must also generally consider additional information submitted by a party, provided the information is credible and relates to the offer submitted by either party. The certified IDR entity is not permitted to consider that information if it includes information on factors described in 26 CFR 54.9816–8T(c)(4)(v), 29 CFR 2590.716–8(c)(4)(v), and 45 CFR 149.510(c)(4)(v). This prohibition is discussed further in the next section of this preamble.

The Departments intend to provide additional guidance to certified IDR entities as necessary to clarify how the allowable factors should be considered and seek comment on this approach, including the appropriateness and scope of the factors previously discussed.

iii. Selection of Offer for Qualified IDR Services That Are Air Ambulance Services

The process for a certified IDR entity to select an offer in a dispute related to qualified IDR services that are air ambulance services is essentially the same as the process applicable to disputes related to qualified IDR items or services that are not air ambulance services. As with disputes related to qualified IDR items or services that are not air ambulance services, in determining which offer to select, these interim final rules provide that the certified IDR entity must consider the QPA for the applicable year for the qualified IDR services that are air ambulance services. However, Code section 9817(b)(5)(C), ERISA section 717(b)(5)(C), PHS Act section 2799A–2(b)(5)(C), and these interim final rules specify additional circumstances, in addition to the QPA, that the certified IDR entity must also consider in making the determination for air ambulance services, to the extent the parties provide credible information on such criteria. As with qualified IDR items or services, the certified IDR entity should only consider this information to the extent the certified IDR entity determines that either party submitted credible information that clearly demonstrates that the QPA is materially different from the appropriate out-of-network rate. If a party presents credible information clearly demonstrating that the QPA is materially different from the appropriate out-of-network rate, the certified IDR entity must consider the additional circumstances.

To the extent credible information is submitted by a party, the certified IDR entity must consider whether credible information about the quality and outcomes measurements of the provider of air ambulance services that furnished the services clearly demonstrates that the QPA is materially different from the appropriate out-of-network rate. Additionally, to the extent credible

[35] The Departments clarify that the July 2021 interim final rules do not require the plan or issuer to calculate the participant's, beneficiary's, or enrollee's cost sharing using a QPA for the service code submitted by the provider or facility. The plan or issuer could instead calculate the participant's, beneficiary's, or enrollee's cost sharing using a QPA for the service code that the plan or issuer determined was more appropriate. However, the QPA methodology under 26 CFR 54.9816–6T, 29 CFR 2590.716–6, and 45 CFR 149.140 requires plans and issuers to calculate the median contracted rate for an item or service using contracted rates for the same or similar item or service. A plan or issuer would be considered out of compliance with these requirements if the plan or issuer calculated a QPA using a service code that does not reasonably reflect the furnished item or service.

[36] The Departments note that in instances in which the certified IDR entity selects an offer based on a determination that a service code other than the one upon which the QPA was based more accurately describes the qualified IDR item or service, neither the plan or issuer nor provider or facility is permitted to adjust the participant's, beneficiary's, or enrollee's cost-sharing amount. The cost-sharing amount remains the same as originally calculated in accordance with 26 CFR 54.9816–4T(b)(3)(ii) and (iii), 29 CFR 2590.716–4(b)(3)(ii) and (iii), and 45 CFR 149.110(b)(3)(ii) and (iii); 26 CFR 54.9816–5T(c)(1) and (2), 29 CFR 2590.717–1(c)(1) and (2), and 45 CFR 149.120(c)(1) and (2); or 26 CFR 54.9817–1T(b)(1) and (2), 29 CFR 2590.717–1(b)(1) and (2), and 45 CFR 149.130(b)(1) and (2).

information is submitted by a party, the certified IDR entity must consider whether credible information about the acuity of the condition of the participant, beneficiary, or enrollee receiving the services, or the complexity of providing the services to the participant, beneficiary, or enrollee, clearly demonstrates that the QPA is materially different from the appropriate out-of-network rate. Further, to the extent credible information is submitted by a party, the certified IDR entity must consider credible information submitted by a party about whether the level of training, experience, and quality of medical personnel that furnished the air ambulance services clearly demonstrates that the QPA is materially different from the appropriate out-of-network rate for the air ambulance services. To the extent a party submits any such credible information, the certified IDR entity must also consider whether credible information about the ambulance vehicle type, including the clinical capability level of the vehicle, clearly demonstrates that the QPA is materially different from the appropriate out-of-network rate for the air ambulance services. In considering the ambulance vehicle type, the certified IDR entity may not consider whether the air ambulance is fixed wing or rotary wing, because the QPA will reflect this difference, as different service codes are used to bill for air ambulance services depending on whether fixed wing or rotary wing vehicles are used. Instead, the certified IDR entity should consider air ambulance vehicle type only to the extent that it is not already taken into account by the QPA.

To the extent a party submits any such credible information, the certified IDR entity must also consider whether credible information about the population density of the point of pick-up (as defined in 42 CFR 414.605) for the air ambulance (such as urban, suburban, rural, or frontier [37]), clearly demonstrates that the QPA is materially different from the appropriate out-of-network rate for a particular air ambulance service. Under the July 2021 interim final rules, the QPA is calculated by reference to the geographic region, which for air ambulance services distinguishes between one region containing all metropolitan statistical areas (as described by the U.S. Office of Management and Budget (OMB) and published by the U.S. Census Bureau) in a 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). If these geographic regions do not provide sufficient information, the QPA is calculated in reference to Census divisions, with one region consisting of all metropolitan statistical areas in each Census division, and one region consisting of all other portions of the Census division, determined at the point of pick-up. Therefore, the QPA for these geographic regions may already reflect the population density of the pick-up location. Nevertheless, in certain circumstances, the QPA for air ambulance services may not adequately capture the population density, due to additional distinctions, such as between metropolitan areas within a state, or between rural and frontier areas. To the extent that there is credible information about additional circumstances clearly demonstrating that the QPA is materially different from the appropriate out-of-network rate for a particular air ambulance service, the certified IDR entity must consider these distinctions.

Finally, to the extent credible information is submitted by a party, the certified IDR entity must consider whether credible information about demonstrations of good faith efforts (or lack thereof) made by the nonparticipating provider of air ambulance services or the plan or issuer to enter into network agreements, as well as contracted rates between the provider and the plan or issuer, as applicable, during the previous 4 plan years, clearly demonstrate that the QPA is materially different from the appropriate out-of-network rate for such air ambulance services.

As with qualified IDR items or services that are not air ambulance services, the certified IDR entity must begin with the presumption that the amount closest to the QPA is the appropriate out-of-network rate for the air ambulance service under consideration and select the offer closest to the QPA, unless credible information submitted by the parties clearly demonstrates that the QPA is materially different from the appropriate out-of-network rate, or unless the offers are equally distant from the QPA but in opposing directions. In those cases, the certified IDR entity must select the offer that the certified IDR entity determines best represents the value of the qualified IDR items or services, which could be either party's offer.

iv. Prohibition on Consideration of Certain Factors

Code section 9816(c)(5)(D), ERISA section 716(c)(5)(D), PHS Act section 2799A–1(c)(5)(D), and these interim final rules provide that the certified IDR entity may not consider certain factors in determining which offer is the out-of-network rate. First, the certified IDR entity may not consider usual and customary charges. This term, also known as usual, customary and reasonable charges, refers to the amount providers in a geographic area usually charge for the same or similar medical service.[38] This provision also prohibits consideration of payment or reimbursement rates expressed as a proportion of usual and customary charges. Second, certified IDR entities cannot consider the amount that would have been billed to either a plan or issuer, or a participant, beneficiary, or enrollee by a provider, facility, or provider of air ambulance services if the provider, facility, or provider of air ambulance services were not subject to a prohibition on balance billing. The Departments recognize that 45 CFR 149.410, 149.420, and 149.440 prohibit providers, facilities, and providers of air ambulance services from billing participants, beneficiaries, or enrollees for the full charge for items and services to which these provisions apply, but do not limit the amount that may be billed to the plan or issuer. However, the Departments are of the view that the intent of Code section 9816(c)(5)(D), ERISA section 716(c)(5)(D), and PHS Act section 2799A–1(c)(5)(D) is to prohibit the certified IDR entity from considering the billed charge for a qualified IDR item or service. Therefore, the Departments interpret this prohibition to include consideration of billed charges to the plan or issuer for the qualified IDR item or service. Finally, certified IDR entities must not consider payment or reimbursement rates payable by a public payor, in whole or in part, for items and services furnished by the providers, facilities, or providers of air ambulance services. This prohibition includes payments or reimbursement rates under the Medicare program under title XVIII of the Social Security Act, the Medicaid program under title XIX of the Social Security Act, the Children's Health Insurance Program under title XXI of the Social

[37] For these purposes, the term ''frontier'' should be understood as including those ZIP codes where the point of pick-up is in a rural area determined to be in the lowest 25 percent of rural population arrayed by population density (also known as super rural ZIP codes for purposes of determining ground ambulance base rates). *See* 42 CFR 414.610(c)(5)(ii) and 42 CFR 414.626(c)(1)(ii).

[38] See Uniform Glossary of Coverage and Medical Terms, available at *https://www.dol.gov/sites/dolgov/files/EBSA/laws-and-regulations/laws/affordable-care-act/for-employers-and-advisers/sbc-uniform-glossary-of-coverage-and-medical-terms-new.pdf* and *https://www.cms.gov/CCIIO/Resources/Forms-Reports-and-Other-Resources/Downloads/Uniform-Glossary-01-2020.pdf*.

Security Act, and the TRICARE program under chapter 55 of title 10, United States Code, chapter 17 of title 38, United States Code. This prohibition also applies to payment rates for demonstration projects under section 1115 of the Social Security Act, as these are payment or reimbursement rates payable by a public payor. This provision prohibits consideration of payment or reimbursement rates expressed as a proportion of rates payable by public payors. Thus, the certified IDR entity must not consider, for example, which offer is closest to 150 percent of the Medicare reimbursement rate for a certain item or service.[39] The Departments solicit comment regarding whether any additional guidance or clarification is needed on these prohibited factors.

v. Written Decision

Once the certified IDR entity has made a determination, the certified IDR entity must provide the underlying rationale for its determination in a written decision submitted to the parties and the Departments. The certified IDR entity must submit the decision and the underlying rationale through the Federal IDR portal in a form and manner specified by the Departments in guidance. This rationale will inform the reports required from the Departments under Code section 9816(c)(7), ERISA section 716(c)(7), and PHS Act section 2799A–1(c)(7), and will assist in ensuring that the certified IDR entities comply with the requirements of this process, including the requirements of 26 CFR 54.9816–8T(c)(4)(iii), 29 CFR 2590.716–8(c)(4)(iii), and 45 CFR 149.510(c)(4)(iii). If a certified IDR entity does not choose the offer closest to the QPA, the written decision's rationale must include a detailed explanation of the additional considerations relied upon, whether the information about those considerations submitted by the parties was credible, and the basis upon which the certified IDR entity determined that the credible information demonstrated that the QPA is materially different from the appropriate out-of-network rate.

[39] The Departments recognize that contracted rates are frequently based off a percentage of the Medicare payment rate. The Departments clarify that even in instances where the QPA is calculated using contracted rates that are expressed as a proportion of rates payable by a public payor (or other prohibited considerations), the certified IDR entity is required to consider the QPA. In the Departments' view, this does not constitute consideration of the payment or reimbursement rate payable by a public payor.

v. Effect of Determination

Code section 9816(c)(5)(E), ERISA section 716(c)(5)(E), PHS Act section 2799A–1(c)(5)(E), and these interim final rules provide that a determination made by a certified IDR entity is binding upon all parties involved, in the absence of fraud or evidence of intentional misrepresentation of material facts to the certified IDR entity by any party regarding the claim. A certified IDR entity's determination is not subject to judicial review, except as set forth in 9 U.S.C. 10(a)(1)–(4).[40]

Under Code section 9816(c)(5)(E)(ii), ERISA section 716(c)(5)(E)(ii), PHS Act section 2799A–1(c)(5)(E)(ii), and these interim final rules, when a certified IDR entity makes a determination, the party that submitted the initial Notice of IDR Initiation may not submit a subsequent Notice of IDR Initiation involving the same other party with respect to a claim that is the same as or similar to a qualified IDR item or service that was the subject of the initial determination during the 90-calendar-day period following the initial determination. The Departments interpret the 90-day period in the statute to refer to 90 calendar days. The Departments are of the view that this interpretation balances the statutory intent to provide for a ''cooling-off'' period between disputes that relate to the same or similar items or services while ensuring that the initiating party is able to resolve outstanding payment disputes through the Federal IDR process as soon as permitted under the statute. The Departments interpret the statutory phrase of ''such item or service'' in this context to refer to the same or similar item or service, in order to maintain consistency with the statutory provisions related to the QPA and the provisions allowing batching of items and services. Additionally, such an interpretation clarifies the meaning of the statutory provisions at Code section 9816(c)(5)(E)(iii), ERISA section 716(c)(5)(E)(iii), and PHS Act section 2799A–1(c)(5)(E)(iii), which allow subsequent submission of such an item or service only if the open negotiation period ended during such a 90-day period (as the open negotiation period for the particular item or service under dispute would have already ended). For claims for the same or similar item or service for which the end of the open negotiation period occurs during the 90-calendar-day suspension period, after the end of the 90-calendar-day suspension period, either party may initiate the Federal IDR process for the items and services affected by the suspension. For these items or services, the initiating party must submit the Notice of IDR Initiation within 30 business days following the end of the 90-calendar-day suspension period, as opposed to the standard 4-business-day period following the end of the open negotiation period. The 30-business-day period begins on the day after the last day of the 90-calendar-day period.

The plan or issuer must make any additional payment, if applicable, of the amount of the offer selected by the certified IDR entity directly to the provider, facility, or provider of air ambulance services not later than 30 calendar days after the determination by the certified IDR entity. This amount will be the offer selected, reduced by the sum of any initial payment the plan or issuer has paid to the provider, facility, or provider of air ambulance services and any cost sharing paid or owed by the participant, beneficiary, or enrollee to the provider, facility, or provider of air ambulance services. If the offer selected by the certified IDR entity is less than the sum of the initial payment and any cost sharing paid by the participant, beneficiary, or enrollee, the provider, facility, or provider of air ambulance services will be liable to the plan or issuer for the difference. This difference must be paid directly to the plan or issuer not later than 30 calendar days after the determination by the certified IDR entity. The Departments note that this determination of the out-of-network rate does not change the participant's, beneficiary's, or enrollee's cost sharing, which is based on the recognized amount. The cost-sharing amount remains the same as originally calculated in accordance with 26 CFR 54.9816–4T(b)(3)(ii) and (iii), 29 CFR 2590.716–4(b)(3)(ii) and (iii), and 45 CFR 149.110(b)(3)(ii) and (iii); 26 CFR 54.9816–5T(c)(1) and (2), 29 CFR 2590.716–5(c)(1) and (2), and 45 CFR 149.120(c)(1) and (2); or 26 CFR 54.9817–1T(b)(1) and (2), 29 CFR 2590.717–1(b)(1) and (2), and 45 CFR 149.130(b)(1) and (2).

vi. Recordkeeping Requirement

These interim final rules require that the certified IDR entity must maintain records of relevant documentation associated with any Federal IDR process determination for 6 years. The 6-year

[40] Subparagraphs (1) through (4) of 9 U.S.C. 10(a) provide that courts may vacate an arbitration: where the award was procured by corruption, fraud, or undue means; where there was evident partiality or corruption in the arbitrators; where the arbitrators were guilty of misconduct in refusing to postpone the hearing, in refusing to hear evidence pertinent and material to the controversy; or of any other misbehavior prejudicing the rights of the parties; or where the arbitrators exceeded their powers, or so imperfectly executed them that a mutual, final, and definite award was not made.

recordkeeping requirement is similar to other recordkeeping requirements under the Code, ERISA, and the PHS Act. For example, independent review organizations involved in the Federal external review process under 26 CFR 54.9815–2719, 29 CFR 2590.715–2719, and 45 CFR 147.136 must retain records for 6 years. This recordkeeping requirement will help ensure that state and Federal oversight agencies are able to audit past determinations of certified IDR entities and that parties are able to obtain records of the determinations. Certified IDR entities must make these records available for examination by all parties to the dispute, except when disclosure would violate state or Federal privacy laws and regulations, as well as to state or Federal oversight agencies upon request for oversight purposes.

vii. Costs of the Federal IDR Process and Payment

At the time that a certified IDR entity is selected by both of the parties or by the Departments, each party to a determination must pay to the certified IDR entity the administrative fee due to the Departments for participating in the Federal IDR process. At the time of submission of the offer by each party to a determination, the certified IDR entity fee must be paid to the certified IDR entity. Each party will be able to view the certified IDR entity fees and administrative fees in the Federal IDR portal when engaging in the certified IDR entity selection process. As discussed later in this preamble, certified IDR entities must set the certified IDR entity fee within a pre-determined range (or as otherwise approved by the Departments) specified by the Departments through guidance. The Departments anticipate issuing this guidance annually. For a discussion of the considerations the Departments will review when setting the certified IDR entity fee range, see section III.D.5 of this preamble.

These interim final rules require each party to pay the entire certified IDR entity fee at the time the parties provide their offer under 26 CFR 54.9816–8T(c)(4)(i), 29 CFR 2590.716–8(c)(4)(i), and 45 CFR 149.510(c)(4)(i). Certified IDR entities are required to hold these funds in a trust or escrow account until the certified IDR entity makes a determination of the out-of-network rate, or in instances in which the parties agree on an out-of-network rate, until the Departments notify the certified IDR entity that it may remit the funds as specified in these interim final rules. The certified IDR entity may (but is not required to) accrue interest on the funds. The certified IDR entity is not required to remit any accrued interest to any other party. Within 30 business days of making the determination, the certified IDR entity must refund to the prevailing party the amount the party submitted for the certified IDR entity fee. The certified IDR entity will retain the certified IDR entity fee submitted by the non-prevailing party, as the non-prevailing party is required to pay the certified IDR entity fee. In the case of batched determinations, the certified IDR entity may make different payment determinations for each qualified IDR item or service under dispute. In these cases, the party with fewest determinations in its favor is considered the non-prevailing party and is responsible for paying the certified IDR entity fee. In the event that each party prevails in an equal number of determinations, the certified IDR entity fee will be split evenly between the parties. The Departments are of the view that this approach reduces the administrative burden of fee collections and ensures payment of certified IDR entities. This approach also eliminates any concerns that certified IDR entities will make determinations based on which party is more likely to pay the certified IDR entity fee. The Departments may issue additional guidance if abusive situations or other issues related to the payment of the administrative fee or the certified IDR entity fee arise. The Departments also solicit comment on whether additional requirements, including procedures to offset against or make adjustments to amounts owed under a payment determination, are necessary to ensure payment or collection of the administrative fee and the certified IDR entity fee.

If the parties negotiate an out-of-network rate before the certified IDR entity makes a determination, the certified IDR entity is required to return half of each party's payment for the certified IDR entity fee, unless directed otherwise by both parties to distribute the total amount of that refund in different shares.

Under Code section 9816(c)(8), ERISA section 716(c)(8), PHS Act section 2799A–1(c)(8), and these interim final rules, each party to a determination must pay an administrative fee for participating in the Federal IDR process. The statute further indicates that the administrative fee must be paid to the Departments at the time and in the manner specified by the Departments. These interim final rules require each party to pay the administrative fee to the certified IDR entity at the time the certified IDR entity is selected, regardless of whether that certified IDR entity was selected by the parties or by the Departments. Having the certified IDR entity collect both the administrative fee and the certified IDR entity fee will help ensure efficiency by streamlining the process and will facilitate administrative convenience for the parties and the Departments. These interim final rules also specify that the administrative fee is non-refundable, even in instances where the parties negotiate an out-of-network rate before the certified IDR entity makes a determination or where the certified IDR entity determines that the case does not qualify for the Federal IDR process. Code section 9816(c)(8)(B), ERISA section 716(c)(8)(B), and PHS Act section 2799A–1(c)(8)(B) specify that the administrative fee is established such that the total amount of fees is approximately equal to the amount of expenditures estimated by the Departments in carrying out the Federal IDR process. Because the Departments expect that a large part of the expenditures in carrying out the Federal IDR process will come from the initiation of the Federal IDR process, the Departments will have incurred expenditures in instances in which the parties reach an agreement before the certified IDR entity makes a determination or in which the certified IDR entity determines that the case does not qualify for the Federal IDR process, and thus, it is appropriate that the parties should still be expected to pay the fee.

As explained in the following section on certification, the certified IDR entity must remit the administrative fee to the Departments at the time and in the manner specified in guidance. The administrative fee amount will be established in guidance published by the Departments in a manner so that the total administrative fees collected by the certified IDR entities and remitted to the Departments during a calendar year are approximately equal to the estimated amount of expenditures by the Departments for that calendar year in carrying out the Federal IDR process. In setting the administrative fee, the Departments will consider the estimated costs for the Departments to administer the Federal IDR process for the following calendar year, including the staffing and contracting costs related to certifying and providing oversight to certified IDR entities; the costs of developing and publishing reports as required under Code sections 9816 and 9817, ERISA sections 716 and 717, and PHS Act sections 2799A–1 and 2799A–2; the costs of collecting the administrative fees from certified IDR

entities; and the cost of maintaining the Federal IDR portal. In future years, such projected costs will be informed by the actual costs incurred by the Departments to date to administer the Federal IDR process. The Departments expect that certain resources related to the Federal IDR process will also be used for the patient-provider dispute resolution process, such as the Federal IDR portal, certain staffing, and contracts. In setting the administrative fee, the Departments will consider the expected volume for the Federal IDR process and the patient-provider dispute resolution process and apportion the IDR administrative fee such that it reflects the appropriate usage of the Federal IDR process by providers, facilities, providers of air ambulance services, plans, and issuers.

5. Certification of IDR Entities

Under Code section 9816(c)(4), ERISA section 716(c)(4), and PHS Act section 2799A–1(c)(4), an IDR entity must meet certain standards and be certified by the Departments to be selected for the Federal IDR process. Consistent with these provisions, these interim final rules provide that an IDR entity must provide through the Federal IDR portal written documentation to the Departments that demonstrates the entity satisfies certain standards and procedures outlined in these interim final rules and set forth in guidance issued by the Departments. Specifically, the Departments will indicate through guidance the types of documentation that should be submitted for each certification standard, in what manner they should be submitted, and how the documentation will be reviewed for certification. An IDR entity that satisfies the standards in the interim final rules and guidance issued by the Departments will be provided a certified IDR entity number and will be certified for a 5-year period, subject to the petition and revocation process, discussed later in this preamble.[41] Once certified, the certified IDR entity must continue to satisfy these requirements.

IDR entities will be expected, as part of their application for certification, to submit general information about their organization, including contact information, Taxpayer Identification Number (TIN), and website information, as well as the service area in which the IDR entity intends to conduct payment determinations under the Federal IDR process. IDR entities may choose to apply to operate in all states or self-limit to a particular subset of states. Further, anyone submitting the application for certification must have the legal and financial authority to bind the IDR entity. An IDR entity that the Departments certify must enter into an agreement with the Departments. That agreement will include specified provisions encompassed by these interim final rules, including, but not limited to, the requirements applicable to certified IDR entities when making payment determinations as well as the requirements regarding certification and revocation (such as specifications for wind down activities and reallocation of certified IDR entity fees, where warranted).

In order to be certified, an IDR entity must possess (directly or through contracts or other arrangements) and demonstrate sufficient arbitration and claims administration of health care services, managed care, billing, coding, medical, and legal expertise. With regard to medical expertise, where the payment determination depends on the patient acuity or the complexity of furnishing the qualified IDR item or service, or the level of training, experience, and quality and outcome measurements of the provider or facility that furnished the qualified IDR item or service, the IDR entity should have available medical expertise with the appropriate training and experience in the field of medicine involved in the qualified IDR item or service. Additionally, the IDR entity must employ (directly or through contracts or other arrangements) sufficient personnel to make determinations within the 30 business days allowed for such determinations. To satisfy this standard, the written documentation the IDR entity submits must include a description of its organizational structure and capabilities, including an organizational chart and the credentials, responsibilities, and number of personnel employed to make determinations. The Departments considered requiring IDR entities to have personnel (either hired directly or through a contract) with air space law knowledge for making determinations related to air ambulance cases, but are concerned that such a requirement may limit the number of eligible entities and increase the likelihood of conflicts of interests in air ambulance cases. The Departments seek comment on whether IDR entities should be required to have air space law knowledge for IDR entity certification to make determinations for air ambulance cases.

Next, an IDR entity must also maintain a current accreditation from a nationally recognized and relevant accreditation organization, such as URAC, or ensure that its personnel otherwise possess the requisite training to conduct payment determinations (for example, providing documentation that personnel employed by the IDR entity have completed arbitration training by the AAA, the AHLA, or a similar organization). This requirement will ensure the IDR entity has the operational ability to perform its primary functions as set forth in the No Surprises Act and these interim final rules. States have imposed similar requirements on independent review organizations for external review processes under PHS Act section 2719 (which is incorporated by reference into Code section 9815 and ERISA section 715), or for their state IDR processes. Similar to independent review organizations, certified IDR entity personnel should have the skills and training necessary to conduct unbiased and impartial determinations between plans or issuers and providers, facilities, or providers of air ambulance services, and similar billing, coding, and medical expertise. The Departments expect that many of the organizations with current experience in arbitration or dispute resolution will already have such accreditation and will employ personnel with relevant experience. The Departments seek comment on whether any additional accreditation or training standards would meet this requirement, including whether additional flexibility is needed to help encourage innovation in the provision of IDR services and new entrants as IDR entities that may be certified for the Federal IDR process.

Additionally, as a condition of certification, the IDR entity must have a process to ensure that no conflicts of interest exist between the parties and the personnel the certified IDR entity assigns to each dispute, and to screen for any material relationships between the parties and the personnel assigned to each dispute. This process will allow certified IDR entities to comply with the requirements of 26 CFR 54.9816–8T(c)(1)(ii), 29 CFR 2590.716–8(c)(1)(ii), and 45 CFR 149.510(c)(1)(ii).

While conducting the Federal IDR process, a certified IDR entity will be entrusted with IIHI. Code section 9816(c)(4)(A)(v), ERISA section 716(c)(4)(A)(v), and PHS Act section 2799A–1(c)(4)(A)(v) require a certified IDR entity to maintain the confidentiality of IIHI obtained in the course of conducting payment determinations. This IIHI is often protected under Federal and state law, but certain laws, such as the privacy and security regulations promulgated

[41] As discussed in the section on Economic Impact and Paperwork Burden, the Departments estimate there will be 50 IDR entities that will seek certification by the Departments.

under HIPAA, as amended, may not apply to IIHI when it is held by a certified IDR entity.

Therefore, these interim final rules specify that a certified IDR entity must provide written documentation to the Departments that demonstrates that the certified IDR entity satisfies, among other things, the confidentiality standards set forth in 26 CFR 54.9816–8T(e)(2)(v), 29 CFR 2590.716–8(e)(2)(v), and 45 CFR 149.510(e)(2)(v). These provisions include standards for certified IDR entities to maintain the confidentiality of IIHI obtained in the course of conducting the Federal IDR process. Because IIHI is sensitive, private information about consumers and their health, including information that is identifiable to a particular individual, IIHI warrants strong protection by the parties that will be handling this information. Therefore, the Departments are of the view that certified IDR entities must have procedures in place to protect consumers from improper storage, use, handling, or transmission of this information. The confidentiality standards in these interim final rules are informed by the privacy, security, and breach notification regulations issued under HIPAA and the HITECH Act, because the Departments are of the view that these provisions are industry standards.[42] Drawing from those standards for these interim final rules promotes continuity in the way consumer information is protected and secured throughout systems involved in health care. The Departments have drawn mainly from relevant HIPAA standards because these are the predominant federal standards that apply to identifiable consumer health information, when possessed by some of the parties to the Federal IDR process. Therefore the Departments are of the view that these standards are the most appropriate privacy standards for certified IDR entities. The Departments have tailored these requirements to the particular functions of certified IDR entities to ensure that they have clear, workable, and appropriate standards to implement.

These interim final rules set forth the confidentiality requirements applicable to certified IDR entities and include provisions regarding privacy, security, and breach notification. The Departments begin by discussing the general privacy requirement in 26 CFR 54.9816–8T(e)(2)(v)(A), 29 CFR 2590.716–8(e)(2)(v)(A), and 45 CFR 149.510(e)(2)(v)(A) that specify that a certified IDR entity may create, collect, handle, disclose, transmit, access, maintain, store, and/or use IIHI only to perform two categories of activities, described in 26 CFR 54.9816–8T(e)(2)(v)(A)(*1*) through (*2*), 29 CFR 2590.716–8(e)(2)(v)(A)(*1*) through (*2*), and 45 CFR 149.510(e)(2)(v)(A)(*1*) through (*2*): (1) To perform the certified IDR entity's required duties under these sections of the interim final rules; and (2) to perform functions related to carrying out additional obligations as may be required under applicable Federal or state laws or regulations.

Additionally, certified IDR entities are required to maintain the security of the IIHI they obtain by ensuring the confidentiality of all IIHI they create, obtain, maintain, store, and transmit; protecting against any reasonably anticipated threats or hazards to the security of this information; protecting against any reasonably anticipated unauthorized uses or disclosures of this information; and by ensuring compliance by any of their personnel, including their contractors and subcontractors (as applicable), assigned to a payment determination. To satisfy this requirement, certified IDR entities are required to have policies and procedures in place to properly use and disclose IIHI, identify when IIHI should be destroyed or disposed of, properly store and maintain confidentiality of IIHI that is accessed or stored electronically, and identify the steps the certified IDR entities will take in the event of a breach regarding IIHI. The Departments based these requirements on the similar rule applicable to HIPAA covered entities under 45 CFR 164.306(a)(1), but because the rule for HIPAA covered entities applies specifically with regard to electronic protected health information (PHI), the requirements in these interim final rules specify that certified IDR entities must ensure the confidentiality of all IIHI they create, obtain, maintain, store, or transmit in accordance with Code section 9816(c)(4)(A)(v), ERISA section 716(c)(4)(A)(v), and PHS Act section 2799A–1(c)(4)(A)(v). A certified IDR entity's responsibility to comply with these confidentiality requirements shall survive revocation of the IDR entity's certification for any reason, and IDR entities must comply with the record retention and disposal requirements described in these interim final rules.

The Departments also require certified IDR entities to securely destroy or dispose of IIHI in an appropriate and reasonable manner 6 years from either the date of its creation or the first date on which the certified IDR entity had access to it, whichever is earlier. In determining what is appropriate and reasonable, certified IDR entities should assess potential risks to participant, beneficiary, or enrollee privacy, as well as consider such issues as the form, type, and amount of IIHI to be disposed. The Departments are of the view that 6 years is a reasonable timeframe for destruction of such information since relevant business procedures should be complete well before this deadline, including IDR payment determinations and certified IDR entity compliance with the Departments' audits as applicable. Furthermore, the 6-year timeframe matches the record retention requirements for certified IDR entities under these interim final rules as well as other record retention requirements under ERISA. These standards are also similar to HIPAA Security Rule requirements[43] under 45 CFR 164.310(d)(2)(i) and (ii), except that the Departments have tailored the requirements in section 26 CFR 54.9816–8T(e)(2)(v)(B)(*4*), 29 CFR 2590.716–8(e)(2)(v)(B)(*4*), and 45 CFR 149.510(e)(2)(v)(B)(*4*) to apply to IIHI.

Next, the Departments require certified IDR entities to develop and utilize secure electronic interfaces when transmitting IIHI electronically, including through data transmission with the Federal IDR portal, and between disputing parties during the Federal IDR process and the certified IDR entity. In addition, the Departments are of the view that certified IDR entities must have in place requirements for their personnel, including their contractors and subcontractors (as applicable), similar to those required under HIPAA Rules to make sure IIHI is only handled by appropriate staff who are trained to handle IIHI, and that proper protocol is followed if a breach of IIHI occurs.

Finally, 26 CFR 54.9816–8T(e)(2)(v)(D), 29 CFR 2590.716–8(e)(2)(v)(D), and 45 CFR 14.510(e)(2)(v)(D) require that all confidentiality requirements applicable to certified IDR entities also apply to certified IDR entities' contractors and subcontractors with access to IIHI performing any duties related to the Federal IDR process. For example, if a breach rises to the level of requiring a breach notification, the contractor or subcontractors must notify the certified IDR entity to inform it of the risk assessment results, and the certified IDR entity must notify the provider, facility,

[42] 45 CFR part 160 subpart A and subparts A, C, D, and E of part 164.

[43] U.S. Dept. of Health and Human Servs., Office for Civil Rights, ''The HIPAA Privacy and Security Rules: Frequently Asked Questions About the Disposal of Protected Health Information,'' available at *https://www.hhs.gov/sites/default/files/disposalfaqs.pdf.*

or provider of air ambulance services; plan and issuer; the Departments; and each individual whose unsecured IIHI has been, or is reasonably believed to have been, subject to the breach, to the extent possible, as required by these interim final rules.

In addition to the privacy and security requirements discussed in this section of this preamble, these interim final rules contain breach notification requirements, similar to the HIPAA breach notification standards (the ''HIPAA Notification Rule'') at 45 CFR 164.402 and 164.404, to address steps that a certified IDR entity must take following the discovery of a breach of unsecured IIHI as defined in these interim final rules. The Departments are of the view that adopting breach notification standards similar to the HIPAA breach notification standards for certified IDR entities provides important protections for IIHI. For purposes of these interim final rules, the Departments made changes from the HIPAA breach notification standards to account for IIHI and certified IDR entities, as opposed to PHI and covered entities, in accordance with Code section 9816(c)(4)(C), ERISA section 716(c)(4)(C), and PHS Act section 2799A–1(c)(4)(C). The Departments require a certified IDR entity, upon discovery of a potential breach of unsecured IIHI, to conduct a risk assessment to determine the probability that the security or privacy of IIHI has been compromised based on at least the nature and extent of the IIHI involved, including the types of identifiers and the likelihood of re-identification; the unauthorized person who used the IIHI or to whom the disclosure was made; whether the IIHI was actually acquired or viewed; and the extent to which the risk to the IIHI has been mitigated. The Departments also require a breach to be treated as discovered by the certified IDR entity as of the first day on which such breach is known to the certified IDR entity or, by exercising reasonable diligence, should have been known to the certified IDR entity. A certified IDR entity shall be deemed to have knowledge of a breach if the breach is known, or by exercising reasonable diligence should have been known, to any person, other than the person committing the breach, who is an employee, officer, or other agent of the certified IDR entity.

The Departments are also including requirements for timing, content, and method of providing the breach notification in these interim final rules. Under these provisions, a certified IDR entity must provide notification without unreasonable delay and in no case later than 60 calendar days after the discovery of the breach. The Departments are of the view that 60 calendar days provides sufficient time for a certified IDR entity to discover a potential breach, conduct a risk assessment, and send notification as required in these interim final rules, in line with the requirements in 45 CFR 164.404 that allow up to 60 calendar days for such a notification to be sent. Since a condition for IDR entity certification involves submission of policies and procedures to: Properly create, obtain, maintain, store, or transmit IIHI in accordance with Code section 9816(c)(4)(A)(v), ERISA section 716(c)(4)(A)(v), and PHS Act section 2799A–1(c)(4)(A)(v); monitor, periodically assess, and update the security controls and related system risks to ensure the continued effectiveness of these controls; and guard against, detect, and report malicious software, the Departments are of the view that 60 calendar days are sufficient for proper identification, risk assessment, and notification of a breach.

When a certified IDR entity sends a breach notification, the content must include similar information as that required under 45 CFR 164.404, but focused on IIHI. Certified IDR entities must include, to the extent possible, the identification of each individual whose unsecured IIHI has been, or is reasonably believed by the certified IDR entity to have been, subject to the breach; a brief description of the breach, including the date of the breach and the date of the discovery of the breach, if known; a description of the types of unsecured IIHI that were involved in the breach (for example, whether full name, Social Security number, date of birth, home address, account number, diagnosis, disability code, or other types of information were involved); a brief description of what the certified IDR entity is doing to investigate the breach, to mitigate harm to the affected parties, and to protect against any further breaches; and contact procedures for individuals to ask questions or learn additional information, which must include a toll-free telephone number, email address, website, or postal address. The Departments are of the view that this level of detail is necessary for full transparency for those who are potentially affected by such a breach.

Finally, a certified IDR entity must submit such notification in written form (in clear and understandable language) either on paper, electronically through the Federal IDR portal, or by email to the Departments; the plan, issuer or FEHB carrier; the provider, facility, or provider of air ambulance services; and, when possible, each individual whose unsecured protected IIHI has been, or is reasonably believed by the certified IDR entity to have been, subject to the breach. The Departments understand that a certified IDR entity may not have access to contact information for each individual whose unsecured protected IIHI has been, or is reasonably believed by the certified IDR entity to have been, subject to a breach. In these cases, IDR entities must work with issuers, plans, providers, and facilities to ensure that these individuals are appropriately notified.

The Departments seek comment on the confidentiality requirements enumerated in 26 CFR 54.9816–8T(e)(2)(v), 29 CFR 2590.716–8(e)(2)(v), and 45 CFR 149.510(e)(2)(v), which are based on certain provisions of the HIPAA Rules, and whether any additional or different protections are warranted.

Additionally, the certified IDR entity must ensure the fiscal integrity and stability of its organization. In order to meet this standard, the IDR entity must demonstrate that it has a system of safeguards and controls in place to prevent and detect improper financial activities by its employees and agents and to assure fiscal integrity and accountability for all fees received and held. To demonstrate financial stability, IDR entities must also submit 3 years of financial statements, or other documentation that demonstrates fiscal stability as directed by the Departments if 3 years of financial statements are unavailable. This financial disclosure requirement is informed by similar requirements under the Sarbanes-Oxley Act.[44] The Departments are of the view that, because the Sarbanes-Oxley Act represents the primary standard for corporate disclosure of financial information, it is appropriate to mirror its standard as a means of ensuring certified IDR entity compliance with the statutory requirements related to fiscal integrity. The Departments are also of the view that the disclosure of these financial statements will enable the Departments to assess whether the IDR entity is financially viable and capable of maintaining its operations, independent of any future revenue earned under the Federal IDR process as a certified IDR entity.

As a condition of certification, an IDR entity must indicate to the Departments the fees it intends to charge for payment determinations, which are limited to a fixed fee amount for single

[44] Public Law 107–204, available at *https://www.govinfo.gov/content/pkg/PLAW-107publ204/html/PLAW-107publ204.htm.*

determinations (including determinations for bundled arrangements) and a separate fixed fee amount for batched determinations under paragraph (c)(3)(i) of these interim final rules. These fixed fees must be within a range set forth in guidance by the Departments, unless the IDR entity receives written approval from the Departments for a fee outside that range. The Departments are of the view that setting a range of permitted flat amounts, including a lower and upper limit, will permit certified IDR entities to charge a reasonable certified IDR entity fee for IDR payment determinations, while also making IDR costs clear to parties in advance of the Federal IDR process. Setting a minimum and a maximum rate will mitigate potential concerns regarding overuse of the Federal IDR process due to low fees and potential concerns regarding overcharging by certified IDR entities. For batched items and services, setting a separate range that is higher to account for the potential for a larger number of claims and increased complexity will help ensure that certified IDR entities are compensated adequately for their services. The certified IDR entity may update its fees and seek approval from the Departments to charge a flat rate beyond the upper or lower limits for fees annually, as provided in guidance.

The Departments considered whether to allow certified IDR entities to set their fees without limitations and also considered imposing anti-abuse provisions to prevent certified IDR entities from charging unreasonable amounts, while also taking into account the statutory intent to discourage the overuse of the Federal IDR process and incentivize IDR entity participation in the process. The Departments are of the view, however, that requiring certified IDR entities to set fees within fixed ranges will reduce the potential for excessive certified IDR entity fees that could result in inflated health care and insurance costs that could ultimately be passed on to consumers. The Departments are also setting a lower bound for certified IDR entity fees to ensure that certified IDR entity fees do not lead to the overuse of the Federal IDR process, thereby encouraging parties to exhaust other paths to agreement, such as open negotiation, before entering the Federal IDR process.

In setting the allowable certified IDR entity fee range, the Departments will consider current IDR entity fees for state-managed IDR processes that are similar to the Federal IDR process. Based on the Departments' research on existing IDR processes in states that have implemented similar surprise billing legislation, IDR entity fees generally range from $300–$600 per payment determination.[45] The Departments acknowledge that in some states, individual arbitrators charge as little as $270 and as much as $6,000 per arbitration.[46] However, the Departments are of the view that such drastic ranges of IDR entity fees risk inflating costs of care that could ultimately be passed on to consumers.

The Departments will also consider the anticipated time and resources needed for certified IDR entities to meet the requirements of these interim final rules, such as the time and resources needed to obtain certification, making payment determinations (including determining whether the dispute belongs in the Federal IDR process), data reporting, and audits. The Departments will also consider factors such as the anticipated volume of payment determinations under the Federal IDR process and adequacy of the Federal IDR process capacity to efficiently handle the volume of IDR initiations and payment determinations. The Departments will review and update the allowable fee range annually based on these factors and the impact of inflation and other cost increases. The Departments seek comment on these factors and any additional factors that should be considered when determining the range for allowable certified IDR entity fees.

The certified IDR entity may not charge a fee that is beyond the upper or lower limits for fees set forth in annual guidance published by the Departments as approved fixed fees, unless the IDR entity or certified IDR entity requests and can provide justification for the higher or lower fee, and the Departments provide written approval for the certified IDR entity to charge a fee beyond the upper or lower limits for fees set forth in guidance. For example, if the IDR entity or certified IDR entity is able to show that, due to matters the Department has not considered, the cost of making determinations under 26 CFR 54.9816–8T(c)(4), 29 CFR 2590.716–8(c)(4), and 45 CFR 149.510(c)(4) will be higher than the upper limit for fees set forth in guidance, the certified IDR entity may charge a higher fee for determinations in that calendar year with the Departments' written approval in accordance with 26 CFR 54.9816–8T(e)(2)(vii), 29 CFR 2590.716–8(e)(2)(vii), 45 CFR 149.510(e)(2)(vii). Certified IDR entities will not be permitted to vary their fees from any approved higher fees during the year for which such higher fees were approved.

Specifically, in order for the certified IDR entity to receive the Departments' written approval to charge a fee beyond the upper or lower bounds for fees as set forth in guidance, the IDR entity or certified IDR entity must submit a written proposal that includes: (1) The alternative flat fee the IDR entity or certified IDR entity believes is appropriate; (2) a description of the circumstances that require the alternative flat fee; and (3) a description of how the alternative flat fee will be used to mitigate such circumstances. A fee other than the higher (or lower) fee previously approved, including one outside the allowable range, will be permitted only upon the Departments' written approval to charge the fee documented in the IDR entity's or certified IDR entity's written proposal. The Federal IDR portal will provide the functionality for IDR entities and certified IDR entities to request a fixed fee beyond the lower and upper limits set forth in guidance. As discussed earlier in this preamble, in instances where the disputing parties do not select a certified IDR entity, the Departments will select a certified IDR entity that charges a fee within the allowed range as provided for in guidance by the Departments. Only if there are insufficient certified IDR entities that charge a fee within the allowed range available to make the payment determination will the Departments select a certified IDR entity that charges a fee that has been approved by the Department but that is outside the allowed range.

A certified IDR entity must also have procedures in place to retain the certified IDR entity fees paid by both parties at the initiation of the Federal IDR process in a trust or escrow account separate from other funds and to return the certified IDR entity fees paid by the prevailing party of an IDR payment determination, or a portion of the fees paid by both parties should they agree on an out-of-network rate through ongoing open negotiations, within 30 business days of the determination, as specified in these interim final rules. The certified IDR entity may (but is not required to) accrue interest on the funds held in a trust or escrow account and is not required to include accrued interest with the returned fee. Additionally, the IDR entity must also have a procedure in place to retain the administrative fee

[45] Hoadley, J., and Maanasa, K. ''How States are Using Independent Dispute Resolution to Resolve Out-of-Network Payment in Surprise Billing,'' To the Point 9blog), Commonwealth Funds, Feb. 27, 2020. *https://doi.org/10.26099/pqt4-vy24.*

[46] *https://www.kff.org/private-insurance/fact-sheet/surprise-medical-bills-new-protections-for-consumers-take-effect-in-2022/amp/.*

required under 26 CFR 54.9816–8T(e)(2)(ix), 29 CFR 2590.716–8(e)(2)(ix), and 45 CFR 149.510(e)(2)(ix), and to remit it to the Departments in accordance with the timeframe and procedures set forth in guidance.

As a condition of certification, the IDR entity must show that it is able to conduct the Federal IDR process as required under these interim final rules. As part of this requirement, the IDR entity must have processes and procedures in place to ensure that it will not make a determination under the Federal IDR process with respect to which the certified IDR entity would not be eligible for selection due to a conflict of interest.

Therefore, in order to be certified, an IDR entity must provide written documentation that shows the IDR entity satisfies certain standards related to conflicts of interest. Under 26 CFR 54.9816–8T(e)(3)(i), 29 CFR 2590.716–8(e)(3)(i), and 45 CFR 149.510(e)(3)(i) the IDR entity must attest that it does not have a conflict of interest as defined in 26 CFR 54.9816–8T(a)(2)(iv), 29 CFR 2590.716–8(a)(2)(iv), and 45 CFR 149.510(a)(2)(iv). Additionally, to be certified, an IDR entity must demonstrate that it has procedures in place to ensure that the specific personnel assigned to a payment determination do not have conflicts of interest regarding any party to the dispute within the 1 year immediately preceding an assignment of dispute determination. This requirement is similar to the requirements set forth in 18 U.S.C. 207(b) and, as discussed earlier in this section of the preamble, provides a reasonable and appropriate standard for preventing conflicts of interest.[47]

Finally, to preserve the integrity of the Federal IDR process, following certification, if a certified IDR entity, at any time acquires control of, becomes controlled by, or comes under common control with any entity described in paragraphs 26 CFR 54.9816–8T(e)(3)(i), 29 CFR 2590.716–8(e)(3)(i), and 45 CFR 149.510(e)(3)(i), the certified IDR entity must notify the Departments in writing no later than 3 business days after the acquisition or exercise of control. As the certified IDR entity would no longer meet the certification criteria, it will have its certification revoked under the processes set forth in 26 CFR 54.9816–8T(e)(6), 29 CFR 2590.716–8(e)(6), and 45 CFR 149.510(e)(6) (including the prohibition on accepting new payment determinations). The Departments seek comment on whether any additional protections are necessary.

Certified IDR entities must also adhere to audit standards set forth in these interim final rules and by the Departments in guidance to ensure that certified IDR entities are adhering to the requirements of these interim final rules, including those regarding certification as a certified IDR entity and those outlining how entities must conduct payment determinations as defined in Code section 9816(c), ERISA section 716(c), and PHS Act section 2799A–1(c). To ensure adherence, the Departments intend to perform audits on a select number of certified IDR entities. Certified IDR entities may be randomly selected by the Departments for an audit or selected based upon stakeholder complaints (including those received in connection with a petition for revocation of certification) received by the Departments. Resulting findings may be used for revocation of certification or in re-certification decisions made by the Departments.

Finally, the IDR entity must collect and provide the information required to be reported to the Departments under 26 CFR 54.9816–8T(f), 29 CFR 2590.716–8(f), and 45 CFR 149.510(f) and report such information about the Federal IDR process on a timely basis to the Departments in the form and manner provided by the Departments in guidance.

6. Petition for Denial or Revocation of IDR Entity Certification

An individual, provider, facility, provider of air ambulance services, plan, or issuer may petition for the denial of a certification of an IDR entity or a revocation of a certification of a certified IDR entity for failure to meet the requirements of Code section 9816(c), ERISA section 716(c), PHS Act section 2799A–1(c), or these interim final rules, through the Federal IDR portal in the form and manner set forth in guidance to be issued by the Departments. The petitioner must submit a written petition to the Departments that identifies the IDR entity seeking certification or the certified IDR entity that is the subject of the petition and outlines the reasons for the petition. The petition must also specify whether the petition seeks denial or revocation of a certification and must be signed by the petitioner. The petitioner may use the standard petition notice issued by the Departments and submit any supporting documentation for consideration by the Departments. The Departments will make public the list of IDR entities seeking certification, as well as the list of certified IDR entities, to help facilitate the petition process. Petitioners submitting a petition for denial of a certification will have 5 business days from the announcement that an IDR entity is seeking certification to submit the written petition. This 5-business-day period is applicable until the Departments issue guidance outlining a different period for petitions for a denial of certification.

The Departments will acknowledge receipt of the petition within 10 business days of receipt. If, after review, the Departments find that the petition adequately shows a failure to comply with the requirements of Code section 9816(c), ERISA section 716(c), PHS Act section 2799A–1(c), or these interim final rules, the Departments shall notify the IDR entity seeking certification or the certified IDR entity by providing a de-identified copy of the petition. Following this notification, the IDR entity seeking certification or the certified IDR entity will have 10 business days to provide a response. After the time period for providing the response has passed, the Departments will review the response (if any) and determine whether a denial or a revocation of certification is warranted. The decision will be subject to the appeal requirements of 26 CFR 54.9816–8T(e)(6)(v), 29 CFR 2590.716–8(e)(6)(v), and 45 CFR 149.510(e)(6)(v). If the Departments, after reviewing a certified IDR entity's response, find that the petition shows a failure to comply with the requirements of Code section 9816(c), ERISA section 716(c), or PHS Act section 2799A–1(c) but have not yet made a final decision pending appeal, a certified IDR entity may continue to work on previously assigned determinations. However, the certified IDR entity will not be permitted to accept new requests for IDR payment determinations unless and until the Departments issue a notice of the decision to the certified IDR entity finding that a revocation of certification is not warranted. If the entity is seeking certification, and the Departments find that denying certification is warranted, then the Departments will deny certification.

The IDR entity certification requirements included in these final rules are developed to ensure the integrity of the Federal IDR process. Failure to meet these standards puts at risk the Departments' ability to ensure providers, facilities, providers of air ambulance services, plans, and issuers can avail themselves of an equitable and efficient process. Therefore, the Departments may deny an IDR entity

[47] 18 U.S.C. 207 provides for certain restrictions on former officers, employees, and elected officials of the executive and legislative branches of the federal government.

certification if, during the process of certification, including as a result of a petition, the Departments determine the IDR entity fails to meet the applicable standards required for certification. Additionally, these interim final rules set forth other reasons that certification may be denied. For example, if the IDR entity has knowingly committed or participated in fraudulent or abusive activities such as by submitting to the Departments fraudulent data or information during the certification process or submitting data or information that the IDR entity knows to be false, certification may be denied. Another situation in which an IDR entity's application for certification might be denied for knowingly committing or participating in fraudulent or abusive activities would be when an IDR entity has engaged in fraudulent practices related to activities conducted outside the Federal IDR process. Additionally, if the IDR entity submits information as part of the certification process that demonstrates that the IDR entity cannot fulfill the responsibilities required of certified IDR entities, certification will be denied.

Also, to the extent the IDR entity has failed to comply with requests for information from the Departments as part of the certification process, certification may be denied. The Departments expect that as part of the certification process, the Departments may need to contact the IDR entities and request clarifying information.

Moreover, if in conducting payment determinations, including those conducted outside the Federal IDR process, the IDR entity has failed to meet the standards that applied to those determinations or reviews, including standards of independence and impartiality, certification may be denied. With respect to certified IDR entities applying for recertification, the Departments will also consider whether, in conducting payment determinations under the Federal IDR process, the certified IDR entity has met the standards applicable to those payment determinations. It is the Departments' view that, although certain conduct (for example, unethical conduct regarding payment determinations conducted outside the Federal IDR process) may not constitute a violation of the Federal IDR process, this conduct could indicate that the IDR entity may be unable to comply with the requirements of the Federal IDR process. Additionally, to the extent it is otherwise determined that the IDR entity is not fit or qualified to make determinations, certification may be denied.

If the Departments find, after review of the evidence, that a certified IDR entity is no longer qualified to make determinations due to an audit, a petition, or otherwise, the certification of the IDR entity may be revoked. A certified IDR entity's certification may be revoked prior to the end of the 5-year term for the following reasons.

First, a certified IDR entity's certification may be revoked prior to the end of the 5-year term if the Departments determine that the certified IDR entity has a pattern or practice of noncompliance with any of the requirements applicable to certified IDR entities under the Federal IDR process.

Second, if the certified IDR entity is operating in a manner that hinders the efficient and effective administration of the Federal IDR process, its certification may be revoked prior to the end of the 5-year term. For example, if a certified IDR entity consistently fails to meet the deadline for rendering its decisions as set forth in these interim final rules, its certification may be revoked. Also, if a certified IDR entity repeatedly fails to check for a conflict of interest between itself, its personnel, and third parties with which the certified IDR entity contracts, and the disputing parties, its certification may be revoked prior to the end of the 5-year term.

Third, if the certified IDR entity no longer meets the applicable certification standards set forth in these interim final rules under 26 CFR 54.9816–8T(e)(1), 29 CFR 2590.716–8(e)(1), and 45 CFR 149.510(e)(1), its certification may be revoked prior to the end of the 5-year term.

Fourth, if the certified IDR entity has committed or knowingly participated in fraudulent or abusive activities, including submission of false or fraudulent data to the Departments, its certification may be revoked prior to the end of the 5-year term. A situation in which an IDR entity's application for certification might be revoked for knowingly committing or participating in fraudulent or abusive activities would be where a certified IDR entity has engaged in fraudulent practices related to activities conducted outside the Federal IDR process.

Fifth, if the certified IDR entity no longer possesses the financial viability to provide dispute resolution under the Federal IDR process, its certification may be revoked prior to the end of the 5-year term. The Departments are of the view that a certified IDR entity must possess the requisite level of fiscal stability that demonstrates the entity is a viable entity able to continue to carry out the Federal IDR process in a timely and efficient manner as set forth in the No Surprises Act and these interim final rules.

Sixth, if the certified IDR entity has failed to comply with requests from the Departments made as part of an audit, including submission of records, its certification may be revoked prior to the end of the 5-year term. The audit process plays an important part in helping to ensure that certified IDR entities are abiding by the requirements set forth in these interim final rules. In order to ensure that the Federal IDR process is fair, equitable, and does not have an inflationary effect on health care costs due to certified IDR entities failing to properly apply the factors as set forth in these interim final rules, the Departments are of the view that it will be prudent to review certified IDR entities' processes and procedures. Therefore, failure to comply with such audits will be a basis for revocation of certification.

Seventh, if it is otherwise determined that the certified IDR entity is no longer fit or qualified to make payment determinations, its certification may be revoked prior to the end of the 5-year term. For example, the Departments may determine that an IDR entity is unfit to participate in the Federal IDR process if the IDR entity is engaged in actions that risk the integrity of the Federal IDR process.

If the Departments make a preliminary determination that an IDR entity's certification should be denied or that a certified IDR entity's certification should be revoked, the Departments will issue a notice of proposed denial to the IDR entity seeking certification or a notice of proposed revocation to the certified IDR entity within 10 business days of the preliminary determination. The notice will include the proposed effective date of denial or revocation, explain the reasons for denial or revocation, and provide an opportunity to request an appeal of the proposed denial or revocation. The Departments seek comment on whether final rules should include additional bases for revocation. The Departments also seek comment on whether certain facts and circumstances should result in immediate revocation of certification of the certified IDR entity and reassignment of any pending payment determinations prior to completion by that certified IDR entity.

In order for an IDR entity that has received a notice of proposed denial or certified IDR entity that has received a notice of proposed revocation to request an appeal of its proposed denial or revocation, as applicable, it must submit its request for an appeal to the Departments within 30 business days of

the date of the notice and in the manner prescribed by the notice. During the period when the IDR entity or certified IDR entity may appeal the denial or revocation, the Departments will not issue a notice of final denial or revocation. Furthermore, until a final decision on the appeal is rendered by the Departments, the certified IDR entity may complete any open IDR payment determinations assigned to it at the time of notification, but may not receive new assignments until a final decision regarding revocation has been made. Relevant information to support a request for appeal may include a statement of the facts, law, and arguments that negate or mitigate the evidence provided in support of the IDR entity's certification denial or the revocation of a certified IDR entity's certification, including a description of the actions the certified IDR entity or IDR entity has taken, is taking, or intends to take to cure the failures identified in the notice (if possible) and to prevent the failures from reoccurring.

In the event the IDR entity or certified IDR entity does not timely submit a request for appeal of the proposed denial or revocation, the Departments will issue a final notice of denial or revocation as described under 26 CFR 54.9816–8T(e)(6)(ii), 29 CFR 2590.716–8(e)(6)(iii), and 45 CFR 149.510(e)(6)(iii). Similarly, if the Departments reach a final determination upon appeal that the IDR entity's certification is denied or the certified IDR entity's certification is revoked, the Departments will issue a final notice of denial or revocation including an explanation of the reasons for final denial or revocation and consequences of such denial or revocation of certification to the IDR entity and the petitioner. Upon final notice of denial or revocation, the IDR entity shall not be considered a certified IDR entity and therefore shall not be eligible to accept payment determinations under the Federal IDR process. If, following a final decision denying or revoking a certification, the IDR entity comes into compliance with the requirements of 26 CFR 54.9816–8T(e), 29 CFR 2590.716–8(e), and 45 CFR 149.510(e), the IDR entity may again apply for certification beginning on the 181st calendar day after the date of the final notice of denial or revocation. The Departments are of the view that providing a 180-calendar-day cooling-off period provides adequate time for an IDR entity to correct and improve its processes to comply with the standards of these interim final rules, ensuring that IDR entities are afforded an opportunity to come into compliance and re-apply for certification. The Departments are using calendar days for this standard rather than business days for consistency with other, similar suspension periods, such as those in the guaranteed availability provisions under PHS Act section 2702(d)(2), as implemented at 45 CFR 147.104(c)(2).

The Departments will monitor the implementation of the Federal IDR process, as well as the petition process, to determine whether certified IDR entities are abiding by the applicable requirements. The Departments seek comment on any additional requirements regarding denial and revocation, and whether other steps may be required to prevent patterns and practices of noncompliance.

7. Reporting of Information Relating to the Federal IDR Process for Qualified IDR Items and Services That Are Not Air Ambulance Services

Code section 9816(c)(7), ERISA section 716(c)(7), and PHS Act section 2799A–1(c)(7) direct the Departments to make certain information related to the Federal IDR process available on a public website for each calendar quarter in 2022 and each calendar quarter in subsequent years. Code section 9816(c)(7)(C), ERISA section 716(c)(7)(C), and PHS Act section 2799A–1(c)(7)(C) specifically require the certified IDR entities to provide information to the Departments as determined necessary to carry out the requirements regarding publication of information related to the Federal IDR process. To ensure the Departments have the information needed to satisfy this requirement, these interim final rules provide that, within 30 business days of the close of each month, each certified IDR entity must report certain data and information in a form and manner specified by the Departments for qualified IDR items and services furnished on or after January 1, 2022 that were subject to payment determinations. Such reporting will be required as an ongoing condition of certification. The Departments anticipate that much of this information will be captured by the certified IDR entities during the normal course of the Federal IDR process. As discussed elsewhere in this preamble, the Departments expect that many of these reporting requirements will be captured as information submitted through the Federal IDR portal. To the extent the necessary information is captured directly through the portal, the Departments do not intend for certified IDR entities to report duplicative information. The Departments will provide additional guidance to certified IDR entities on their reporting obligations.

Under these interim final rules, the certified IDR entity must report the number of Notices of IDR Initiation submitted to the certified IDR entity during the immediately preceding month. In instances where the provider or facility submits the initial Notice of IDR Initiation, the certified IDR entity must submit to the Departments information on the size of the provider practice and the size of the facilities submitting Notices of IDR Initiation. Specifically, the certified IDR entity must specify whether the provider practice has fewer than 20 employees, 20 to 50 employees, 51 to 100 employees, 101–500 employees or more than 500 employees. For facilities, the certified IDR entity must specify whether the facility has 50 or fewer employees, 51 to 100 employees, 101–500 employees, or more than 500 employees. This information will allow the Departments to determine whether smaller providers and facilities have the resources necessary to make use of the Federal IDR process and will assist the Departments in determining whether larger organizations may have an unfair advantage in the process. It also will assist the Departments in determining the effect of the Federal IDR process on horizontal and vertical integration of providers and facilities, and in reporting on this effect to Congress, as required by statute in Code section 9816(c), ERISA section 716(c), PHS Act section 2799A–1(c), and section 109 of the No Surprises Act.

Additionally, with respect to Notices of IDR Initiation submitted during the immediately preceding month, certified IDR entities must report the number of Notices of IDR Initiation for which a final determination was made by the certified IDR entity under these interim final rules. The certified IDR entity also must report a description of the qualified IDR items and services for each Notice of IDR Initiation submitted during the immediately preceding month for which a payment determination was made. This information should include the relevant billing and service codes, such as the CPT, HCPCS, DRG codes, or National Drug Codes (if applicable). The certified IDR entity must also report the relevant geographic region for purposes of the QPA for the qualified IDR items and services with respect to which the Notice of IDR Initiation was provided.

These interim final rules also require that for each determination issued in relation to a Notice of IDR Initiation submitted during the immediately

preceding month, the certified IDR entity must report the offers submitted by each party expressed as both a dollar amount and the corresponding percentage of the QPA represented by that dollar amount, and whether the offer selected by the certified IDR entity was submitted by the plan or issuer, or the provider or facility. Where batched items and services have multiple QPAs, the certified IDR entities must report the offer as a percentage of each QPA that applied with respect to the batched items and services to which the offer applied. For example, if one batch of services included services to which two different QPAs applied, and the parties each submitted the same offer for all batched services, then the certified IDR entity must report each offer as a dollar amount and as a percentage of both QPAs. However, if instead each party submitted two offers—one that applied to the services for which one QPA applied and one that applied to the services for which the other QPA applied—then the certified IDR entity is required to report each offer separately and must express each offer as a dollar amount and as a percentage of the applicable QPA. As discussed earlier in this preamble, in making the determination, the certified IDR entity must provide a rationale for its decision, including the extent to which a decision relied on criteria other than the QPA. The certified IDR entity must also report the number of times the out-of-network rate determined exceeded the QPA. Where the QPA differs within a group of batched items and services, the certified IDR entity also must include whether the out-of-network rate (or various out-of-network rates, when more than one out-of-network rate is selected) exceeded the applicable QPA.

For each determination issued in relation to a Notice of IDR Initiation submitted during the immediately preceding month, the certified IDR entity must also report certain additional information on the parties involved. Specifically, the certified IDR entity must report the practice specialty or type of each provider or facility involved in furnishing the qualified IDR items or services at issue with respect to the determination. Additionally, the certified IDR entity must provide each party's name and address.

The certified IDR entity also must report the number of business days taken between the selection of the certified IDR entity and the selection of the payment amount by the certified IDR entity for each determination issued in relation to a Notice of IDR Initiation submitted during the immediately preceding month. Finally, the certified IDR entity must report the total amount of certified IDR entity fees paid to the certified IDR entity during the immediately preceding month. This total amount of certified IDR entity fees should not include amounts refunded by the certified IDR entity to the prevailing party or the administrative fees that are collected on behalf of the Departments.

8. Reporting of Information Relating to the Federal IDR Process for Qualified IDR Items or Services That Are Air Ambulance Services

Under Code section 9817, ERISA section 717, and PHS Act section 2799A–2, the Departments must publish on a public website for each calendar quarter in 2022 and each calendar quarter in a subsequent year certain information regarding disputes about air ambulance services that differs from the information required under Code section 9816, ERISA section 716, and PHS Act section 2799A–1 regarding disputes for other items and services to which the protections of the No Surprises Act apply. Therefore, 26 CFR 54.9817–2T(b)(3), 29 CFR 2590.717–2(b)(3) and 45 CFR 149.520(b)(3) specify that in applying the requirements of 26 CFR 54.9816–8T(f), 29 CFR 2590.716–8(f), and 45 CFR 149.510(f) to air ambulance services, the information that the certified IDR entity must report within 30 business days of the close of each month, for services furnished on or after January 1, 2022, in a form and manner specified by the Departments, is as follows.

The certified IDR entity must report the number of Notices of IDR Initiation submitted to the certified IDR entity that pertain to air ambulance services during the immediately preceding month. Additionally, with respect to Notices of IDR Initiation submitted during the immediately preceding month, the certified IDR entity must report the number of Notices of IDR Initiation for which there was a determination under 26 CFR 54.9816–8T(c)(4)(ii), 29 CFR 2590.716–8(c)(4)(ii), and 45 CFR 149.510(c)(4)(ii), as applied by 26 CFR 54.9817–2T(b)(1), 29 CFR 2590.717–2(b)(1), and 45 CFR 149.520(b)(1) for air ambulance services. The certified IDR entity must also report the number of times the out-of-network rate determined (or agreed to) exceeded the QPA for air ambulance services.

With respect to each Notice of IDR Initiation submitted during the immediately preceding month, the certified IDR entity must provide a description of each air ambulance service, including the relevant billing and service codes and point of pick-up (as defined in 42 CFR 414.605) for the services included in such Notice of IDR Initiation. For each Notice of IDR Initiation, the certified IDR entity must also provide the amount of the offer submitted by a plan or issuer (as applicable) and by the nonparticipating provider of air ambulance services, expressed as both a dollar amount and the corresponding percentage of the QPA represented by that dollar amount. Of these amounts, the certified IDR entity must also indicate whether the offer selected by the certified IDR entity was the offer submitted by the plan or issuer or by the provider of air ambulance services and the amount of the offer so selected, expressed as both a dollar amount and a percentage of the QPA. The certified IDR entity must also report the rationale for the certified IDR entity's decision, including the extent to which the decision relied on the criteria listed under 26 CFR 54.9817–2T(b)(2), 29 CFR 2590.717–2(b)(2), and 45 CFR 149.520(b)(2). Additionally, the certified IDR entity must identify the air ambulance vehicle type, including whether the vehicle is fixed wing or rotary wing (information which should be included in the relevant service code), and the clinical capability level of the vehicle (if the parties have provided such information). The certified IDR entity must also report the identity of each plan or issuer, and provider of air ambulance services, with respect to the Notice of IDR Initiation submitted during the immediately preceding month. Specifically, each certified IDR entity must provide each party's name and address, as applicable. The certified IDR entity must report the number of business days taken between the selection of the certified IDR entity and the certified IDR entity's selection of the payment amount. Finally, the certified IDR entity must also report the total amount of certified IDR entity fees paid to the certified IDR entity for the immediately preceding month. This total amount of certified IDR entity fees should not include amounts refunded by the certified IDR entity to prevailing parties or the administrative fees that are collected on behalf of the Departments.

9. Extension of Time Periods for Extenuating Circumstances

Under Code section 9816(c)(9), ERISA section 716(c)(9), PHS Act section 2799A–1(c)(9), and these interim final rules, the time periods specified in these interim final rules (other than the timing of the payments, including, if applicable, payments to the provider, facility or provider of air ambulance services) may be extended in the case of

extenuating circumstances at the Departments' discretion. The Departments may extend time periods on a case-by-case basis if the extension is necessary to address delays due to matters beyond the control of the parties or for good cause. Such extension may be necessary if, for example, a natural disaster impedes efforts by plans, issuers, providers, facilities, and providers of air ambulance services to comply with the terms of these interim final rules. Additionally, for the extension to be granted, the parties must attest that prompt action will be taken to ensure that the payment determination under this section is made as soon as administratively practicable. Parties may request an extension by submitting a Request for Extension due to Extenuating Circumstances through the Federal IDR portal, including an explanation about the extenuating circumstances that require an extension and why the extension is needed.

E. Applicability of the Rules Regarding the Federal IDR Process

The applicability of these interim final rules with respect to the items and services, plans and issuers, and providers, facilities, and providers of air ambulance services subject to these interim final rules, parallels that of the July 2021 interim final rules to ensure that the surprise billing protections of the No Surprises Act are implemented in a consistent manner. Finally, these interim final rules provide standards for certifying IDR entities, and standards for certified IDR entities. Accordingly, these interim final rules amend 26 CFR 54.9816–2T, 29 CFR 2590.716–2, and 45 CFR 149.20 to include references to 26 CFR 54.9816–8T and 54.9817–2T; 29 CFR 2590.716–8 and 2590.717–2; and 45 CFR 149.510 and 149.520 to ensure that the items and services, as well as entities subject to the balance billing protections under the July 2021 interim final rules, are eligible for the Federal IDR process under these interim final rules. The Departments solicit comment on whether any differences or departures from the approach taken in the July 2021 interim final rules are warranted.

These interim final rules implementing the Federal IDR process 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 and to certified IDR entities, health care providers and facilities, and providers of air ambulance services beginning on January 1, 2022. The interim final rules regarding IDR entity certification at 26 CFR 54.9816–8T(a), 26 CFR 54.9816–8T(e), 29 CFR 2590.718–8(a), 29 CFR 2590.718–8(e), 45 CFR 149.510(a) and 45 CFR 149.510(e), are applicable beginning on October 7, 2021 so that the Departments can begin certifying IDR entities before the Federal IDR process becomes applicable. 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, 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 PHS Act sections 2799A–1, 2799A–2, and 2799A–7 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) for plans years beginning on or after January 1, 2022. In addition, these interim final rules implementing the Federal IDR process 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 grandmothered or transitional plans). These interim final rules implementing the Federal IDR process do not apply to health reimbursement arrangements (HRAs), or other account-based group health 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 these plans makes concepts related to surprise billing, including the IDR process, inapplicable. Additionally, the Departments expect that account-based group health plans typically will be integrated with other coverage that will have protections against surprise billing (such as individual coverage HRAs) or will be otherwise exempt from these requirements (such as excepted benefit HRAs). Therefore, under these interim final rules, these requirements do not apply to individual coverage HRAs and other account-based plans, consistent with the existing applicability provisions in 26 CFR 54.9816–2T, 29 CFR 2590.716–2, and 45 CFR 149.20 with respect to other requirements in 26 CFR part 54, 29 CFR subpart D, and 45 CFR part 149. The Departments note that by statute certain plans and coverage are not subject to the interim final rules implementing the Federal IDR process. This includes a plan or coverage consisting solely of excepted benefits [48] as well as short-term, limited-duration insurance as defined under PHS Act section 2791(b)(5).[49] Excepted benefits are described in Code section 9832, ERISA section 733 and PHS Act section 2791. Under PHS Act section 2791(b)(5), short-term, limited-duration insurance is excluded from the definition of individual health insurance coverage and is therefore exempt from these interim final rules regarding the Federal IDR process and the statutory provisions these interim final rules implement. In addition, these interim final rules do not apply to retiree-only plans, because ERISA section 732(a) and Code section 9831(a) generally provide that part 7 of ERISA and chapter 100 of the Code respectively do not apply to plans with fewer than two participants who are current employees (including retiree-only plans, which cover fewer 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 approach with respect to health insurance coverage of retiree-only plans.[50] HHS intends to continue to follow this same approach, including with respect to the new market reforms established in the No Surprises Act.

[48] Code section 9831, ERISA section 732, and PHS Act section 2722; 26 CFR 54.9831–1(c), 29 CFR 2590.732(c), and 45 CFR 146.145(b).

[49] 26 CFR 54.9801–2, 29 CFR 2590.701–2, and 45 CFR 144.103.

[50] 75 FR 34537, 34540 (June 17, 2010).

IV. External Review and Section 110 of the No Surprises Act

Section 110 of the No Surprises Act states that ''[i]n applying the provisions of section 2719(b) of the [PHS Act] to group health plans and health insurance issuers offering group or individual health insurance coverage, the Secretary of HHS, Secretary of Labor, and Secretary of the Treasury, shall require, beginning not later than January 1, 2022, the external review process described in paragraph (1) of such section to apply with respect to any adverse determination by such a plan or issuer under Code section 9816 or 9817, ERISA section 716 or 717 or PHS Act section 2799A–1 or 2799A–2, including with respect to whether an item or service that is the subject to such a determination is an item or service to which such respective section applies.'' The statute defines the terms group health plan and health insurance issuer by reference to PHS Act section 2791, ERISA section 733, and Code section 9832, as applicable.

These interim final rules implement section 110 of the No Surprises Act in two ways. First, these interim final rules amend the scope of claims eligible for external review set forth in the regulations implementing PHS Act section 2719 to include adverse benefit determinations related to compliance with the surprise billing and cost-sharing protections under the No Surprises Act. Additionally, these interim final rules clarify the scope of external review in light of new surprise billing and cost-sharing protections under the No Surprises Act and provide examples of which types of adverse benefit determinations will be eligible for external review. Second, these interim final regulations extend the external review requirement to grandfathered health plans and health insurance issuers for adverse benefit determinations involving items and services covered by requirements of Code section 9816 or 9817, ERISA section 716 or 717, or PHS Act section 2799A–1 or 2799A–2, as added by the No Surprises Act. The Departments solicit comment on whether and to what extent additional guidance or changes to the existing regulations are needed to protect participants, beneficiaries, and enrollees from surprise medical bills, consistent with section 110 of the No Surprises Act.

A. Scope of Claims Eligible for External Review

Under PHS Act section 2719 and its implementing regulations, non-grandfathered group health plans and health insurance issuers offering non-grandfathered group or individual health insurance coverage must comply with any applicable state external review process, if that process includes, at a minimum, the consumer protections set forth in the NAIC Uniform External Review Model Act.[51] However, if the state external review process does not meet this standard, or if a plan or issuer is not subject to state insurance regulation, the plan or issuer must comply with the Federal external review process, as described in 26 CFR 54.9815–2719(d), 29 CFR 2590.715–2719(d), and 45 CFR 147.136(d).

State external review processes that meet the minimum standards must provide for the external review of adverse benefit determinations based on requirements for medical necessity, appropriateness, health care setting, level of care, or effectiveness of a covered benefit. The Federal external review process must be available for any adverse benefit determination by a plan or issuer that involves medical judgment, as well as a rescission of coverage. In the Departments' view, the scope of claims eligible for external review under state processes that meet the minimum standards for approval is substantially similar to the scope of claims eligible for external review under the Federal process.

In 2010, the Departments issued interim final rules that set forth the original scope of claims eligible for external review under the Federal external review process.[52] Specifically, any adverse benefit determination (including final internal adverse benefit determinations) could be reviewed unless it was related to a participant's or beneficiary's failure to meet the requirements for eligibility under the terms of a group health plan (for example, worker classification and similar issues were not within the scope of the Federal external review process). In response to stakeholder comments, the Departments issued an amendment in 2011 suspending the original rule and narrowing the scope to claims that involve: (1) Medical judgment (including, but not limited to, those based on the plan's or issuer's requirements for medical necessity, appropriateness, health care setting, level of care, or effectiveness of a covered benefit, or its determination that a treatment is experimental or investigational), as determined by the external reviewer; and (2) a rescission of coverage (whether or not the rescission has any effect on any particular benefit at the time).[53] The Departments finalized the narrowed scope in the 2015 final rules.[54]

Although the scope of Federal external review was narrowed in comparison to the scope as outlined in the 2010 interim final regulations, the Departments note that the scope of claims that are eligible for external review in general is broad, as many adverse benefit determinations involve medical judgment. The 2015 final regulations issued by the Departments include the following examples: (1) Whether treatment by a specialist is medically necessary or appropriate (pursuant to the plan's standard for medical necessity or appropriateness); (2) whether treatment involved ''emergency care'' or ''urgent care,'' affecting coverage or the level of coinsurance; (3) a determination that a medical condition is a preexisting condition; (4) whether a participant or beneficiary is entitled to a reasonable alternative standard for a reward under the plan's wellness program; and (5) whether a plan or issuer is complying with the nonquantitative treatment limitation provisions of the Mental Health Parity and Addiction Equity Act.[55]

The Departments have similarly provided a number of additional examples in preambles to rulemaking under PHS Act section 2719 to provide further clarification on the broad scope of the external review process. In the preamble to interim final rules issued in 2011, the Departments stated that examples of medical judgment would include the appropriate health care setting for providing medical care to an individual (such as outpatient versus inpatient care or home care versus rehabilitation facility); a plan's general exclusion of an item or service (such as speech therapy), if the plan covers the item or service in certain circumstances based on a medical condition (such as, to aid in the restoration of speech loss or impairment of speech resulting from a medical condition); and the frequency, method, treatment, or setting for a recommended preventive service, to the extent not specified in the recommendation or guideline of the U.S. Preventive Services Task Force, the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention, or the Health

[51] Available at *https://www.dol.gov/sites/dolgov/files/EBSA/laws-and-regulations/laws/affordable-care-act/for-employers-and-advisers/naic-uniform-review-model-act.pdf.*

[52] 75 FR 43329 (July 23, 2010).

[53] 76 FR 37207 (June 10, 2011).

[54] 80 FR 72191 (Nov. 18, 2015).

[55] 26 CFR 54.9815–2719(d)(1); 29 CFR 2590.715–2719(d)(1); 45 CFR 147.136(d)(1).

Resources and Services Administration.[56] In the preamble to final rules issued in 2015, the Departments also clarified that issues related to how a claim is coded may also involve medical judgment because ''[m]edical judgment is necessary to determine whether the correct code was used in the patient's case.'' [57]

Consistent with this principle, the Departments are of the view that many claims that result in an adverse benefit determination involving items and services subject to the surprise billing and cost-sharing protections under the No Surprises Act generally would be eligible for external review under the current scope as specified in the 2015 final regulations. However, as stated above, section 110 of the No Surprises Act directs the Departments to require the external review process under PHS Act section 2719 to apply with respect to any adverse determination by a plan or issuer under PHS Act section 2799A–1 or 2799A–2, ERISA section 716 or 717, or Code section 9816 or 9817, including with respect to whether an item or service that is subject to such a determination is an item or service to which the respective section applies. The Departments are of the view that it is important to ensure that consumers can avail themselves of external review in these situations and ensure that they are afforded full protection against surprise medical costs (including cost sharing), as intended by the No Surprises Act. Accordingly, these interim final rules amend the 2015 final rules to broaden the scope of external review requirements and explicitly require, to the extent not already covered, that any adverse determination that involves consideration of whether a plan or issuer is complying with PHS Act section 2799A–1 or 2799A–2, ERISA section 716 or 717, or Code section 9816 or 9817 is eligible for external review.

These interim final rules also amend the 2015 final regulations to add five new examples (examples number 3 through 7 in the regulation text) to clarify how the external review requirements apply to certain adverse benefit determinations involving items and services within the scope of the surprise billing and cost-sharing protections for out-of-network emergency services, nonemergency services performed by nonparticipating providers at participating facilities, and air ambulance services furnished by nonparticipating providers of air ambulance services under section Code section 9816 or 9817, ERISA section 716 or 717, or PHS Act section 2799A–1 or 2799A–2. The first new example illustrates that any determination of whether a claim is for treatment for emergency services that involves medical judgment or consideration of compliance with the cost-sharing and surprise billing protections is eligible for external review.

The second new example clarifies that whether a claim for items and services furnished by a nonparticipating provider at an in-network facility is subject to the protections under the No Surprises Act is eligible for external review because adjudication of the claim requires consideration of health care setting and level of care or compliance with cost-sharing and surprise billing protections.

The third new example clarifies that whether an individual was in a condition to receive a notice about the availability of the protections under the No Surprises Act and give informed consent to waive those protections is a claim eligible for external review because adjudication of the claim involves consideration of compliance with the cost-sharing and surprise billing protections and medical judgment.

The fourth new example illustrates that whether a claim for items and services is coded correctly, consistent with the treatment an individual actually received, is a claim eligible for external review because adjudication of the claim involves medical judgment.

The fifth new example illustrates that consideration of whether cost-sharing was appropriately calculated for claims for ancillary services provided by an out-of-network provider at an in-network facility involves consideration of compliance with the cost-sharing and surprise billing protections and is a claim eligible for external review.

The Departments solicit comment on these examples and whether any additional examples are needed. The Departments intend to ensure that this provision is implemented in a manner that affords consumers broad protection under section 110 of the No Surprises Act.

B. Application to Grandfathered Plans and Coverage

PHS Act section 2719 and its implementing regulations do not currently apply to coverage offered by health insurance issuers and group health plans that are grandfathered health plans because section 1251 of the Affordable Care Act provides that PHS Act section 2719 does not apply to grandfathered plans and coverage.

These interim final rules amend the regulations under PHS Act section 2719 to require grandfathered plans and coverage to provide for external review of claims covered by the protections of the No Surprises Act for plan years (or, in the individual market, policy years) beginning on or after January 1, 2022. This change is grounded in the text of section 110 of the No Surprises Act, in addition to the policy reasons stated earlier in this preamble regarding the Departments' intent to implement this provision broadly. Section 110 states that external review requirements shall ''apply with respect to any adverse determination by such a plan or issuer under section 2799A–1 or 2799A–2 of the PHS Act, section 716 or 717 of ERISA, or section 9816 or 9817 of the Code[.]'' These sections of the PHS Act, ERISA, and the Code, as well as all the other provisions of the No Surprises Act, as discussed in section I.A of this preamble, are all applicable to grandfathered plans and coverage. Thus, to ensure that adverse benefit determinations under grandfathered plans and coverage for claims subject to those provisions are eligible for external review, external review requirements must be applicable to grandfathered plans and coverage for those claims. The Departments solicit comment on this amendment, including whether any additional guidance is warranted to help grandfathered plans and issuers comply with these requirements.

The Departments recognize that the internal claims and appeals rules under 29 CFR 2560.503–1, as incorporated under regulations implementing PHS Act section 2719,[58] do not apply to issuers offering grandfathered coverage in the individual market, or grandfathered non-Federal Government plans. Those grandfathered plans and issuers offering that grandfathered coverage must make external review available for adverse benefit determinations under PHS Act section 2799A–1 or 2799A–2 when an enrollee has exhausted applicable appeal rights under state law or under the terms of the enrollee's coverage. In cases where these plans and issuers are not subject to a requirement to have an internal appeals process and have not otherwise instituted such a process, they must allow a claimant to request external review of an adverse benefit determination of claims covered by the protections under PHS Act sections 2799A–1 or 2799A–2 upon receipt of the adverse benefit determination.

[56] 76 FR 37207, 37216 (June 10, 2011).

[57] 80 FR 72191, 72209 (Nov. 18, 2015).

[58] 26 CFR 54.9815–2719; 29 CFR 2590.715–2719(c)(2)(i); 45 CFR 147.136.

V. Federal IDR Process for FEHB Carriers—Office of Personnel Management

OPM amends existing 5 CFR 890.114(a) to include references to the Departments' regulations to clarify that FEHB carriers are also subject to the Federal IDR process set forth in those regulations with respect to a qualified IDR item or service furnished by an FEHB carrier offering a health benefits plan in the same manner as those 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 FEHB carrier's contract. Through new paragraph 5 CFR 890.114(d), OPM adopts the Departments' rules as necessary to properly integrate the new standards with existing FEHB Program structure and sets forth the circumstances in which OPM will enforce these rules as applied to FEHB carriers, including by requiring carrier notice to the Director, in addition to the Departments, of an FEHB carrier's notice of initiation, or receipt of a provider's notice of initiation, the Federal IDR process. OPM will coordinate with the Departments in matters regarding FEHB carriers requiring resolution under the Federal IDR process and with respect to oversight of certified IDR entities' reports regarding FEHB carriers.

As discussed in the July 2021 interim final rules, all out-of-network rate determinations regarding qualified IDR items or services with respect to FEHB plans or carriers that are not resolved by open negotiation are subject to the Federal IDR process unless OPM contracts with FEHB carriers include terms that adopt state law as governing for this purpose.

VI. Overview of the Interim Final Rules Regarding Protections for the Uninsured—The Department of Health and Human Services

A. Good Faith Estimates for Uninsured (or Self-Pay) Individuals

1. Scope

The No Surprises Act adds PHS Act section 2799B–6(2), which requires health care providers and health care facilities, upon scheduling an item or service to be furnished to an individual or upon request of an individual, to inquire about such individual's health coverage status and to provide a notification (in clear and understandable language) of the good faith estimate of the expected charges for furnishing such item or service (including any item or service that is reasonably expected to be provided in conjunction with such scheduled or requested item or service and such item or service reasonably expected to be so provided by another provider or facility), with the expected billing and diagnostic codes for any such item or service.

In the case that the individual requesting a good faith estimate for an item or service or seeking to schedule an item or service to be furnished, is not enrolled in a certain type of plan or coverage or is not seeking to file a claim with such type of plan or coverage, PHS Act section 2799B–6(2)(B), and these interim final rules at 45 CFR 149.610, require providers and facilities to furnish the good faith estimate to the individual. These requirements under 45 CFR 149.610 apply only to good faith estimate notifications for uninsured (or self-pay) individuals as described in 45 CFR 149.610(a)(2)(xii) of these interim final rules. As discussed in section I.C of this preamble, these interim final rules do not include requirements implementing PHS Act section 2799B–6(2)(A), which requires providers and facilities to furnish good faith estimates to individuals' plans or issuers.

2. Definitions

For purposes of 45 CFR 149.610, HHS is defining certain terms at 45 CFR 149.610(a). Specifically, ''authorized representative'' means an individual authorized under state law to provide consent on behalf of the uninsured (or self-pay) individual, provided that the individual is not a provider affiliated with the facility or an employee of the facility represented in the good faith estimate, unless such provider or employee is a family member of the uninsured (or self-pay) individual. HHS considered defining authorized representative using the same definition as in 45 CFR 149.410 and 149.420; however, the definition in these interim final rules contain amendments to account for concepts that are not relevant to uninsured (or self-pay) individuals such as removing references to nonparticipating providers, participants, beneficiaries, and enrollees.

These interim final rules define, ''convening health care provider or convening health care facility (convening provider or convening facility)'' as the provider or facility who receives the initial request for a good faith estimate from an uninsured (or self-pay) individual and who is or, in the case of a request, would be responsible for scheduling the primary item or service as defined in these interim final rules. As discussed elsewhere in this preamble, the convening provider is responsible for providing the good faith estimate to an uninsured (or self-pay) individual.

HHS considered putting the responsibility for providing the good faith estimate on the ''treating health care provider,'' as defined in 45 CFR 149.30, but for many scheduled items or services, multiple providers and facilities could participate in delivering an individual's care, or be considered, a ''treating health care provider''. Because it is likely that an individual would only schedule an item or service or request a good faith estimate from one of the treating providers or facilities, the convening provider or facility would likely need to request additional scheduling from other providers or facilities to participate in delivering care. Therefore, such a provider or facility would need to alert the other providers or facilities who are providing items or services in conjunction with the scheduled item or service, when items or services are scheduled or a good faith estimate is requested. Furthermore, HHS understands that multiple providers and facilities may bill an individual for the respective items or services provided during a period of care. Therefore, it is important to define who is responsible for furnishing the good faith estimate to the individual that is inclusive of all the items or services to be provided by co-providers and co-facilities involved in the scheduled items or services or the items or services for which a good faith estimate is requested.

In these interim final rules, ''co-health care provider or co-health care facility (co-provider or co-facility)'' means a provider or facility other than a convening provider or a convening facility that furnishes items or services that are customarily provided in conjunction with a primary item or service (as defined for purposes of this section). Because PHS Act section 2799B–6(2) requires that the good faith estimate include any item or service that is reasonably expected to be provided in conjunction with such scheduled item or service (or such item or service for which a good faith estimate is requested) and such an item or service reasonably expected to be so provided by another health care provider or health care facility, HHS is distinguishing co-providers and co-facilities from the convening provider or convening facility who will furnish the good faith estimate inclusive of estimates from co-providers and co-facilities.

''Diagnosis code'' means the code that describes an individual's disease,

disorder, injury, or other related health conditions using the International Classification of Diseases (ICD) code set. In establishing requirements for implementation of HIPAA's Administrative Simplification provisions, HHS adopted specific code sets for diagnoses and procedures for use in standard health care transactions. The definition of diagnosis code used in this section aligns with the definition contained in the HIPAA Administrative Simplification standards at 45 CFR part 162.[59]

For purposes of 45 CFR 149.610, ''expected charge'' means, for an item or service, the cash pay rate or rate established by a provider or facility for an uninsured (or self-pay) individual, reflecting any discounts for such individuals, where the good faith estimate is being provided to an uninsured (or self-pay) individual; or the amount the provider or facility would expect to charge if the provider or facility intended to bill a plan or issuer directly for such item or service when the good faith estimate is being furnished to a plan or issuer.

HHS understands that providers and facilities establish gross charges or chargemaster rates that are considered their standard charge for an item or services and then often discounts are applied depending on the payer (with the exception of state laws that specify payment rates). For instance, in providing a good faith estimate to a plan or issuer, the provider or facility may include as the expected charge the undiscounted gross charge or chargemaster rate, which would then be used by the plan or issuer to determine the out-of-pocket payment amount of an insured individual. HHS understands that providers and facilities often make adjustments to their gross charges or chargemaster rates to establish a self-pay rate for uninsured (or self-pay) individuals. HHS is of the view that if an individual is not enrolled in a plan or coverage or is enrolled but is not seeking to have a claim for such item or service submitted to their plan or coverage, the expected charges included in the good faith estimate should reflect what the provider or facility expects to bill or charge the payer (in this case the uninsured or self-pay individual), and therefore for the purpose of these interim final rules, HHS has defined expected charges specific to what the uninsured (or self-pay) individual would be expected to pay.

HHS is of the view that the estimate of expected charges must reflect the anticipated billed charges, including any expected discounts or other relevant adjustments that the provider or facility expects to apply to an uninsured (or self-pay) individual's billed charges because of the role of the good faith estimate in the patient-provider dispute resolution process under PHS Act section 2799B–7 and as specified in 45 CFR 149.620. Under PHS Act section 2799B–7, an uninsured (or self-pay) individual can seek a determination from an SDR entity if the total billed charge from a provider or facility is substantially in excess of the expected charges listed in the good faith estimate for the provider or facility. Therefore, as discussed in detail below, these interim final rules require that for each item or service listed in the good faith estimate, a provider or facility must include the expected charge for each item or service, reflecting any available discounts or other relevant adjustments that the provider or facility expects to apply to an uninsured (or self-pay) individual's billed charges. For instance, certain hospital organizations that meet the general requirements for tax exemption under Code section 501(c)(3), are also required to meet the Financial Assistance Policy (FAP) requirements under Code sections 501(r)(4) through (6).[60] In this example, any adjustments expected to be applied under the FAP would be factored in and reflected in the amount reported in the good faith estimate for items or services. To promote more transparency, HHS considered requiring both undiscounted list prices and discounted prices to be included when discounted prices apply. HHS seeks comment on whether providers and facilities should be required to include both the list price and discounted price for an item or service when discounts apply.

Consistent with PHS Act section 2799B–6(2), these interim final rules define the term ''good faith estimate'' to mean a notification of expected charges for a scheduled or requested item or service,[61] including items or services that are reasonably expected to be provided in conjunction with such scheduled or requested item or service, provided by a convening provider, convening facility, co-provider, or co-facility.

''Health care facility (facility)'' is defined more broadly than the definition in 45 CFR 149.30, which applies in the context of balance billing protections for non-emergency services. For purposes of 45 CFR 149.610, ''health care facility (facility)'' means an institution (such as a hospital or hospital outpatient department, critical access hospital, ambulatory surgical center, rural health center, federally qualified health center, laboratory, or imaging center) in any state in which state or applicable local law provides for the licensing of such an institution, that is licensed as such an institution pursuant to such law or is approved by the agency of such state or locality responsible for licensing such institution as meeting the standards established for such licensing. While HHS considered applying the definition of health care facility from 45 CFR 149.30, doing so would limit the scope of providers and facilities for which 45 CFR 149.610 applies to only those providers relevant to the balance billing protections related to nonemergency items or services furnished by participating providers in nonparticipating facilities. The provisions in PHS Act section 2799B–6 do not specify such limitations.

For purposes of 45 CFR 149.610, ''health care provider (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, including a provider of air ambulance services. As the Departments noted in the July 2021 interim final rules, the No Surprises Act does not define ''provider.'' Some provisions use the word in a manner that includes providers of air ambulance services, while other provisions that use the word are inapplicable to providers of air ambulance services by the terms of the provisions. In this case, HHS is of the view that interpreting the term to include providers of air ambulance services in this context is critical to ensuring individuals obtain the benefits of a good faith estimate for a service that can be extremely costly. HHS recognizes that individuals will likely not be able to obtain a good faith estimate for emergency air ambulance services, as these are not generally scheduled in advance. However, making these requirements applicable to providers of air ambulance services helps to ensure that individuals can obtain a good faith estimate upon request or at the time of scheduling non-emergency air ambulance services, for which coverage often is not provided by a plan or issuer and thus even individuals with coverage often must self-pay.

[59] *https://www.cms.gov/regulations-and-guidance/administrative-simplification/code-sets.*

[60] Financial Assistance Policy and Emergency Medical Care Policy. *https://www.irs.gov/charities-non-profits/financial-assistance-policy-and-emergency-medical-care-policy-section-501r4.*

[61] For purposes of simplicity of language, these interim final rules in some instances refer to a requested good faith estimate for an item or service, as a requested item or service.

''Items or services'' has the same meaning given the term in 45 CFR 147.210(a)(2), which includes all encounters, procedures, medical tests, supplies, prescription drugs, durable medical equipment, and fees (including facility fees), provided or assessed in connection with the provision of health care. The definition of items or services in 45 CFR 147.210(a)(2) encompasses and accurately defines the types of items or services that are expected to be reported in the good faith estimate including items or services such as those related to dental health, vision, substance use disorders and mental health. HHS also clarifies that some items or services may not be included in a good faith estimate because they are not typically scheduled in advance and are not typically the subject of a requested good faith estimate, such as urgent, emergent trauma, or emergency items or services; however, HHS clarifies that to the extent an urgent care appointment is scheduled at least 3 days in advance, these interim final rules require a provider or facility to provide a good faith estimate.[62]

These interim final rules also define the term ''period of care'' to mean the day or multiple days during which the good faith estimate for scheduled or requested item or service (or set of scheduled or requested items or services) are furnished or are anticipated to be furnished, regardless of whether the convening provider, convening facility, co-providers, or co-facilities are furnishing such items or services, and also includes the period of time during which any facility equipment and devices, telemedicine services, imaging services, laboratory services, and preoperative and postoperative services that would not be scheduled separately by the individual, are furnished. HHS considered using the term episode of care but understands that the term episode of care is used within many different contexts regarding the provision of health care items or services.[63] In the context of this section, HHS is of the view that it is important to use the term period of care in order to clarify which items or services are expected to be provided in a good faith estimate.

''Primary item or service'' means the item or service to be furnished by the convening provider or convening facility that is the initial reason for the visit. HHS is of the view that additional distinctions beyond the definition of ''items or services'' must be made in order for providers and facilities to furnish clear and understandable good faith estimates. HHS considered using the term ''scheduled item or service'' which would more directly align with the statutory language. However, such distinction would have excluded the statutory provision whereby a good faith estimate must be issued upon the request of an uninsured (or self-pay) individual when items or services have not been scheduled. HHS is of the view that using the term ''primary item or service'' provides clarity for providers and facilities to establish and identify a main item or service for which a good faith estimate is being issued. Based on the primary item or service, the provider or facility could subsequently identify and include all items or services that would be furnished in conjunction with the primary item or service, and such items or services reasonably expected to be provided by a co-provider or co-facility.

''Service code'' means the code that identifies and describes an item or service using the CPT, HCPCS, DRG or National Drug Code (NDC) code sets. As noted earlier, in establishing requirements for implementation of HIPAA's Administrative Simplification provisions, HHS adopted specific code sets for diagnoses and procedures for use in standard health care transactions. The definition of service code used in this section aligns with the definition contained in the HIPAA Administrative Simplification standards at 45 CFR part 162.[64]

These interim final rules define the term ''uninsured (or self-pay) individual'' to mean an individual who does not have benefits for an item or service under a group health plan, group or individual health insurance coverage offered by a health insurance issuer, Federal health care program (as defined in section 1128B(f) of the Social Security Act), or a health benefits plan under chapter 89 of title 5, United States Code; or an individual who has benefits for such item or service under a group health plan or individual or group health insurance coverage offered by a health insurance issuer, or a health benefits plan under chapter 89 of title 5, United States Code but who does not seek to have a claim for such item or service submitted to such plan or coverage. These individuals are often referred to as self-pay individuals, therefore these interim final rules include the term self-pay when discussing uninsured individuals. As discussed elsewhere in this preamble, for the purposes of the interim final rules at 45 CFR 149.610 that implement PHS Act sections 2799B–6(1) and 2799B–6(2)(B), HHS is adopting the definition of uninsured (or self-pay) individuals from PHS Act sections 2799B–7 in order to align these two related sections.

HHS understands, and is of the view that it is appropriate, that consumers may request a good faith estimate without actually scheduling items or services to compare costs and make a decision about from which provider or facility they will seek care, or whether they will submit a claim to insurance or self-pay. These individuals would be considered self-pay for purposes of the requirement on the provider or facility to provide a good faith estimate. HHS clarifies that if an individual requests a good faith estimate as a self-pay individual and then ultimately decides to submit a claim to the individual's plan or issuer for the billed charges, the individual is no longer considered a self-pay individual as defined in these interim final rules and would not be eligible to use the patient-provider dispute resolution process as defined in 45 CFR 149.620. HHS also clarifies that for purposes of 45 CFR 149.610 and 149.620, the definition of uninsured (or self-pay) individuals includes individuals enrolled in short-term, limited-duration insurance, as defined in regulations at 26 CFR 54.9801–2, 29 CFR 2590.701–2, and 45 CFR 144.103, and not also enrolled in a group health plan, group or individual health insurance coverage offered by a health insurance issuer, Federal health care program (as defined in section 1128B(f) of the Social Security Act), or a health benefits plan under chapter 89 of title 5, United States Code.

HHS seeks comment on the terms defined in these interim final rules for purposes of this section. HHS is particularly interested in receiving information related to the appropriateness and usability of these definitions and whether additional terms should be included or defined.

3. Requirements for Providers and Facilities

For purposes of PHS Act sections 2799B–6, 2799B–6(1), and 2799B–6(2)(B) that are being implemented in these interim final rules, providers and facilities must meet certain requirements related to uninsured (or self-pay) individuals. Section 2799B–6 places the requirement to provide a good faith estimate, within the statutorily defined timeframes, upon

[62] Certain urgent, emergent trauma, or emergency care services may be subject to other protections discussed in the July 2021 interim final rules (86 FR 36872).

[63] *https://www.healthaffairs.org/do/10.1377/hblog20190326.202031/full/.*

[64] *https://www.cms.gov/regulations-and-guidance/administrative-simplification/code-sets.*

providers and facilities with whom an individual schedules an item or service, or from whom an individual requests a good faith estimate for an item or service, defined in these interim final rules as the convening provider or facility. However, HHS notes that section 2799B–6(2) requires that a good faith estimate of expected charges include any item or service that is reasonably expected to be provided in conjunction with such scheduled item or service and such items or services reasonably expected to be so provided by another provider or facility, defined in these interim final rules as a co-provider or co-facility.

In order for good faith estimates to provide individuals with the most accurate information available, HHS is of the view that it is not feasible to fully implement the statutory provisions under PHS Act section 2799B–6(2) without establishing certain requirements for convening providers and facilities and co-providers and co-facilities. In implementing these provisions, HHS is of the view that to the extent possible, an uninsured (or self-pay) individual is entitled to receive a clear and understandable document that informs the uninsured (or self-pay) individual of the expected costs associated with the care that they are considering or are scheduled to receive, and in order to do so, the expected charges that inform the good faith estimate should be provided by all providers and facilities who are reasonably expected to furnish the items or services that would be billed to the uninsured (or self-pay) individual. HHS seeks comment on publicly available resources, methods, and potential standardized formatting or design that could facilitate communication of good faith estimate information in a clear and understandable manner.

To this end, HHS is of the view that issuance of separate good faith estimate documents from each provider and facility involved in furnishing care for a primary item or service would place undue administrative burden upon uninsured (or self-pay) individuals to then aggregate various good faith estimates received in order to obtain a clear and understandable representation of all expected charges for an item or service. However, HHS also acknowledges that in some instances, it would not be practical nor feasible to expect a convening provider or facility to have sufficient knowledge of the expected charges for each item or service provided by a co-provider or co-facility. HHS is also of the view that convening providers and facilities should not be held responsible for the accuracy of expected charges for items or services for which the convening provider or facility does not bill the uninsured (or self-pay) individual (for instance, under the patient-provider dispute resolution process as described in 45 CFR 149.620).

HHS notes that the accuracy of the good faith estimate is relevant because if the actual billed charges substantially exceed the amounts reported in the good faith estimate, an uninsured (or self-pay) individual could seek a determination under the patient-provider dispute resolution process under 45 CFR 149.620. HHS is also of the view that it would not be appropriate to solely require that a convening provider or facility be accountable through the patient-provider dispute resolution process for items or services for which the convening provider or facility did not bill the uninsured (or self-pay) individual.

Therefore, HHS is using its general rulemaking authority to establish requirements under 45 CFR 149.610, discussed in detail below, for convening providers and facilities as well as co-providers and co-facilities for issuance of good faith estimates for uninsured (or self-pay) individuals. HHS is of the view that use of its general rulemaking authority to establish such requirements is necessary in order to implement the provisions of PHS Act section 2799B–6 in a manner that balances the statutory intent of providing uninsured (or self-pay) individuals with clear and understandable information regarding the expected costs of items or services, the responsibilities of various providers and facilities, and the inherent accountability established in the statute through the interaction between the issuance of good faith estimates under PHS Act section 2799B–6 and the patient-provider dispute resolution process under PHS Act section 2799B–7.

i. Requirements for Convening Providers and Facilities

These interim final rules establish in 45 CFR 149.610(b)(1) certain requirements for the convening provider or facility to verify whether an individual meets the definition of an uninsured (or self-pay) individual, to provide oral and written communication regarding the requirement to provide good faith estimates to uninsured (or self-pay) individuals upon scheduling an item or service or upon request, and to provide timely good faith estimates to uninsured (or self-pay) individuals. To determine whether a good faith estimate must be provided to an individual under 45 CFR 149.610(b)(1), the convening provider or facility must inquire and determine if the individual meets the definition of an uninsured (or self-pay) individual as established in 45 CFR 149.610(a)(2).

HHS is of the view that conveying information about the availability of good faith estimates prior to or upon scheduling an item or service aligns with and is most relevant when uninsured (or self-pay) individuals are considering whether to proceed with medical care while interacting with their providers or facilities. Requiring that providers and facilities notify uninsured (or self-pay) individuals of the availability of good faith estimates will help ensure that all uninsured (or self-pay) individuals understand that they can request a good faith estimate and will also receive a good faith estimate upon scheduling an item or service and upon request.

Therefore, HHS is using its general rulemaking authority to establish in 45 CFR 149.610(b)(1)(iii) that the convening provider or facility must inform uninsured (or self-pay) individuals that good faith estimates of expected charges are available to uninsured (or self-pay) individuals upon scheduling an item or service or upon request. Information regarding the availability of good faith estimates for uninsured (or self-pay) individuals must be provided in writing and orally. The convening provider or facility must provide written notice in a clear and understandable manner prominently displayed (and easily searchable from a public search engine) on the convening provider's or convening facility's website, in the office, and on-site where scheduling or questions about the cost of items or services occur. In addition, the convening provider or facility must orally inform uninsured (or self-pay) individuals of the availability of a good faith estimate when questions about the cost of items or services occur. Information regarding the availability of a good faith estimate must be made available in accessible formats and languages spoken by individuals considering or scheduling items or services with such convening provider or convening facility.

HHS anticipates providing a model notice for notifying uninsured (or self-pay) individuals of the availability of good faith estimates. However, HHS is not requiring the use of such model notice in order to allow providers or facilities flexibility to develop notices that would be most effective for their patient populations. HHS also recognizes the potential value in having a standardized notice that uninsured (or

self-pay) individuals can anticipate across providers and facilities. Therefore, HHS seeks comment on the potential for standardizing notices for use by all convening providers and convening facilities and other alternative or concurrent options for informing uninsured (or self-pay) individuals of the availability of good faith estimates that would meet the requirements under this section.

HHS notes that uninsured (or self-pay) individuals may use different terminology other than ''good faith estimate'' when requesting a good faith estimate. Therefore, these interim final rules at 45 CFR 149.610(b)(1)(iv) specify that convening providers and convening facilities shall consider any discussion or inquiry regarding the potential cost of items or services under consideration as a request for a good faith estimate.

PHS Act section 2799B–6(2) requires that the good faith estimate include any item or service that is reasonably expected to be provided in conjunction with a scheduled or requested item or service by another provider or facility. Therefore, these interim final rules at 45 CFR 149.610(b)(1)(v) require that the convening provider or facility contact all applicable co-providers and co-facilities no later than 1 business day after the request for the good faith estimate is received or after the primary item or service is scheduled, and request submission of expected charges for items or services that meet the requirements for co-providers and co-facilities under 45 CFR 149.610(b)(2) and (c)(2). The convening provider or convening facility must indicate in their request the date that the good faith estimate information must be received from the co-provider or co-facility. The co-provider or co-facility is responsible for providing timely information to the convening provider or convening facility as discussed later in this preamble. HHS is of the view that the convening provider or convening facility would not have accurate estimates to include in the good faith estimate without information being provided in a timely manner by the co-provider or co-facility. HHS seeks comments on methods and standardized processes, including use of HIPAA standard transactions, that could facilitate accurate and efficient transmission of good faith estimate information from co-providers or co-facilities to convening providers or convening facilities.

PHS Act section 2799B–6 requires that providers and facilities furnish the good faith estimate of the expected charges within certain defined timeframes. Specifically, PHS Act section 2799B–6 states that in the case of an individual who schedules an item or service to be furnished to such individual by such provider or facility at least 3 business days before the date such item or service is to be so furnished, that the notification of the good faith estimate of expected charges shall be provided no later than 1 business day after the date of such scheduling; in the case of such an item or service scheduled at least 10 business days before the date such item or service is to be so furnished (or if requested by the individual), that the notification of the good faith estimate of expected charges shall be provided no later than 3 business days after the date of such scheduling or such request. These interim final rules at 45 CFR 149.610(b)(1)(vi) codify these timeframes for good faith estimates.

HHS recognizes that circumstances may arise where the scope of information included in a good faith estimate changes (such as, a provider or facility represented in the good faith estimate is no longer able to furnish the items or services reported in the good faith estimate). In such circumstances, these interim final rules establish at 45 CFR 149.610(b)(1)(vii) and (viii) that the convening provider or convening facility must issue an uninsured (or self-pay) individual with a new good faith estimate no later than 1 business day before the item or service is scheduled to be furnished. If any changes in expected providers or facilities represented in a good faith estimate occur less than 1 business day before that the item or service is scheduled to be furnished, the replacement provider or replacement facility must accept the good faith estimate as their expected charges for the items or services being furnished that were provided by the original provider or facility and represented in the good faith estimate. These interim final rules also establish at 45 CFR 149.610(b)(2)(ii) and (iii) similar requirements for co-providers and co-facilities. HHS acknowledges the challenges these requirements impose on providers and facilities, and the potential disincentive that such a requirement could have on a provider's or facility's willingness to provide an item or service under such circumstances due to the fact that the patient-provider dispute resolution process, at 45 CFR 149.620, uses the good faith estimate to determine the eligibility of an item or service for dispute resolution. However, HHS is of the view that such requirements are necessary for consumer protections against facing surprise medical bills and without such a requirement an uninsured (or self-pay) individual would be unable to avail themselves of the patient-provider dispute resolution process in these circumstances.

HHS expects that any replacement provider or facility considering whether to furnish items or services will review the applicable good faith estimate and use that information to determine whether to furnish the applicable items or services. HHS is of the view that requiring the replacement providers or facilities to accept as their good faith estimate the expected charges reported in the existing good faith estimate mitigates the risk of providers or facilities circumventing the requirements of PHS Act 2799B–6 through the substitution of providers or facilities. Such requirements also provide important consumer protections intended by PHS Act 2799B–6 that are aimed to protect uninsured (or self-pay) individuals from unexpected medical bills. However, HHS seeks comment on whether this approach could have unintended consequences, such as delays in care if providers were to refuse to serve as replacements, and ways in which to alleviate any such effects.

In instances where a good faith estimate is provided upon the request of an uninsured (or self-pay) individual, upon the subsequent scheduling of the item or service to be furnished, these interim final rules at 45 CFR 149.610(b)(1)(ix) establish that a new good faith estimate must be provided to the uninsured (or self-pay) individual for the now scheduled item or service, and within the timeframes specified for good faith estimates for scheduled items or services under 45 CFR 149(b)(1)(vi)(A) and (B). HHS recognizes that uninsured (or self-pay) individuals might choose to request a good faith estimate in order to better understand anticipated costs, for instance in situations where an individual may wish to compare costs across providers or facilities. If an uninsured (or self-pay) individual had not previously scheduled the primary item or service, the individual may not have been evaluated for underlying conditions that could impact the accuracy of the good faith estimate. HHS encourages convening providers or facilities to review any previously issued good faith estimate related to the primary item or service and make all applicable changes when providing the new good faith estimate. HHS also encourages convening providers or convening facilities to communicate these changes upon delivery of the new good faith estimate to help patients understand what has changed between the initial

good faith estimate and the new good faith estimate.

HHS acknowledges that there are circumstances where recurring items or services are expected to be furnished to an uninsured (or self-pay) individual (for example, an uninsured (or self-pay) individual may need multiple physical therapy visits that would occur outside of the period of care for a surgical procedure). These interim final rules establish at 45 CFR 149.610(b)(1)(x) that the convening provider or facility may issue a single good faith estimate for recurring primary items or services if certain requirements are met. The good faith estimate for recurring items or services must include in a clear and understandable manner the expected scope of the recurring items or services (such as: timeframes, frequency, and total number of recurring items or services) in the good faith estimate. The scope of such a good faith estimate must not exceed 12 months. If additional recurrences of furnishing such items or services are expected beyond 12 months, a convening provider or convening facility must provide an uninsured (or self-pay) individual a new good faith estimate. Providers must also communicate such changes (such as timeframes, frequency, and total number of recurring items or services) upon delivery of the new good faith estimate to help patients understand what has changed between the initial good faith estimate and the new good faith estimate.

ii. Requirements for Co-Providers and Co-Facilities

Under these interim final rules at 45 CFR 149.610(b)(2)(i), a co-provider or co-facility must submit, upon the request of the convening provider or convening facility, good faith estimate information for items or services that are reasonably expected to be furnished by the co-provider or co-facility in conjunction with the primary item or service (as specified under the content requirements discussed later in this section of the preamble). Good faith estimate information submitted by co-providers or co-facilities must be received by the convening provider or facility no later than 1 business day after the co-provider or co-facility receives the request. In addition, co-providers and co-facilities must notify and provide new good faith estimate information to a convening provider or convening facility if the co-provider or co-facility anticipates any changes to the scope of good faith estimate information previously submitted to a convening provider or convening facility (such as anticipated changes to the expected charges, items, services, frequency, recurrences, duration, providers, or facilities). If any changes in the expected co-providers or co-facilities represented in a good faith estimate occur less than 1 business day before that the item or service is scheduled to be furnished, the replacement co-provider or co-facility must accept as its good faith estimate of expected charges the good faith estimate for the relevant items or services included in the good faith estimate for the item or service being furnished that was provided by the replaced provider or facility.

These interim final rules at 45 CFR 149.610(b)(2)(iv) also establish that in the event that an uninsured (or self-pay) individual separately schedules or requests a good faith estimate from a provider or facility that would otherwise be a co-provider or co-facility, that provider or facility is considered a convening provider or convening facility for such item or service and must meet all requirements in paragraphs (b)(1) and (c)(1) for issuing a good faith estimate to an uninsured (or self-pay) individual.

4. Content of a Good Faith Estimate for an Uninsured (or Self-Pay) Individual

In 45 CFR 149.610(c), these interim final rules establish requirements for the content that must be included in a good faith estimate that is issued to an uninsured (or self-pay) individual. As discussed later in this section of the preamble, these interim final rules at 45 CFR 149.610(c)(1) establish the elements that must be included in the good faith estimate issued by the convening provider or convening facility and 45 CFR 149.610(c)(2) establishes the content requirements for good faith estimate information that must be submitted by co-providers or co-facilities to the requesting convening provider or convening facility.

Specifically, the good faith estimate issued by the convening provider or convening facility to the uninsured (or self-pay) individual must include:

- Patient name and date of birth;
- Description of the primary item or service in clear and understandable language (and if applicable, the date the primary item or service is scheduled);
- Itemized list of items or services, grouped by each provider or facility, reasonably expected to be provided for the primary item or service, and items or services reasonably expected to be furnished in conjunction with the primary item or service, for that period of care including: (1) Those items or services reasonably expected to be furnished by the convening provider or convening facility, and (2) those items or services expected to be furnished by co-providers or co-facilities;
- Applicable diagnosis codes, expected service codes, and expected charges associated with each listed item or service;
- Name, NPI, and TIN of each provider or facility represented in the good faith estimate, and the state(s) and office or facility location(s) where the items or services are expected to be furnished by such provider or facility;
- List of items or services that the convening provider or convening facility anticipates will require separate scheduling and that are expected to occur before or following the expected period of care for the primary item or service. The good faith estimate must include a disclaimer directly above this list that states that separate good faith estimates will be issued to an uninsured (or self-pay) individual upon scheduling or upon request of the listed items or services and that for items or services included in this list, information such as diagnosis codes, service codes, expected charges and provider or facility identifiers do not need to be included as that information will be provided in separate good faith estimates upon scheduling or upon request of such items or services; and include instructions for how an uninsured (or self-pay) individual can obtain good faith estimates for such items or services;
- A disclaimer that informs the uninsured (or self-pay) individual that there may be additional items or services the convening provider or convening facility recommends as part of the course of care that must be scheduled or requested separately and are not reflected in the good faith estimate;
- A disclaimer that informs the uninsured (or self-pay) individual that the information provided in the good faith estimate is only an estimate of items or services reasonably expected to be furnished at the time the good faith estimate is issued to the uninsured (or self-pay) individual and that actual items, services, or charges may differ from the good faith estimate;
- A disclaimer that informs the uninsured (or self-pay) individual of their right to initiate the patient-provider dispute resolution process if the actual billed charges are substantially in excess of the expected charges included in the good faith estimate, as specified in 45 CFR 149.620; this disclaimer must include instructions for where an uninsured (or self-pay) individual can find information about how to initiate the patient-provider dispute resolution

process and state that the initiation of the patient-provider dispute resolution process will not adversely affect the quality of health care services furnished to an uninsured (or self-pay) individual by a provider or facility; and

- A disclaimer that the good faith estimate is not a contract and does not require the uninsured (or self-pay) individual to obtain the items or services from any of the providers or facilities identified in the good faith estimate.

Given that good faith estimate information submitted by co-providers or co-facilities must be included as part of the good faith estimate issued to the uninsured (or self-pay) individual, these interim final rules establish under 45 CFR 149.610(d)(2) that good faith estimate information submitted by co-providers or co-facilities to convening providers or convening facilities must include:

- Patient name and date of birth;
- An itemized list of items or services expected to be provided by the co-provider or co-facility that are reasonably expected to be furnished in conjunction with the primary item or service as part of the period of care;
- Applicable diagnosis codes, expected service codes, and expected charges associated with each listed item or service;
- Name, NPI, and TIN of the co-provider or co-facility, and the state(s) and office or facility location(s) where the items or services are expected to be furnished by the co-provider or co-facility; and
- A disclaimer that the good faith estimate is not a contract and does not require the uninsured (or self-pay) individual to obtain the items or services from any of the providers or facilities identified in the good faith estimate.

HHS expects that these requirements, along with the required methods and format for providing good faith estimates (see 45 CFR 149.610(e)) will result in good faith estimates that inform uninsured (or self-pay) individuals about the expected charges for the primary item or service, including the items or services reasonably expected to be furnished in conjunction with the primary item or service during a period of care.

The itemized list of items or services contained in a good faith estimate to an uninsured (or self-pay) individual must reflect the expected charges from the convening provider or facility and co-providers or co-facilities during a period of care. As discussed earlier, these interim final rules define a ''period of care'' as the day or multiple days during which the good faith estimate for scheduled or requested items or services (or a set of items or services) are furnished or are anticipated to be furnished, regardless of whether the convening provider or convening facility or co-providers or co-facilities are furnishing such items or services, and also includes the period of time during which any facility equipment and devices, telemedicine services, imaging services, laboratory services, and preoperative and postoperative services that would not be scheduled separately by the individual, are furnished. It is the intent of this definition of ''period of care'' to clarify that the good faith estimate should include all of the items or services that are typically scheduled as part of a primary item or service for which an individual does not need to engage in additional scheduling.

These interim final rules also establish at 45 CFR 149.610(c)(1)(vi) that in instances where a convening provider or convening facility anticipates that certain items or services will need to be separately scheduled (such as those items or services typical of the standard of care), the convening provider or facility must include a separate list of items or services that the convening provider or facility anticipates will require separate scheduling and that are expected to occur either prior to or following the expected period of care for the primary item or service. Additionally, the good faith estimate must include a disclaimer directly above this list that notifies the uninsured (or self-pay) individual that: (1) Separate good faith estimates will be issued to an uninsured (or self-pay) individual upon scheduling of the listed items or services or upon request; and (2) for items or services included in this list, information such as diagnosis codes, service codes, expected charges, and provider or facility identifiers may not be included as that information will be provided in separate good faith estimates upon scheduling of such items or services or upon request; and (3) include instructions for how an uninsured (or self-pay) individual can obtain good faith estimates for such items or services.

HHS also considered requiring that the good faith estimate include contact information for a provider's or facility's financial assistance office. HHS seeks comment on whether or not such information should be required on the good faith estimate.

HHS understands the value in having one good faith estimate that includes all items or services furnished prior to, as part of, and following the primary item or service, regardless of whether the items or services must be separately scheduled. HHS also understands that including all this information in one good faith estimate could potentially be helpful in allowing an uninsured (or self-pay) individual to fully understand their anticipated costs. However, HHS also appreciates the complexity in obtaining such information by a convening provider or convening facility, as the convening provider or convening facility may not be privy to or be able to reasonably predict which additional providers or facilities an uninsured (or self-pay) individual may choose to engage with outside of the period of care for the primary item or service. HHS seeks comment on whether the good faith estimate content should be expanded to include additional information and expected charges for items or services that are anticipated to be furnished prior to or following the period of care for the primary item or service but require separate scheduling by the uninsured (or self-pay) individual. HHS is particularly interested in the benefits, challenges, and resources that could facilitate provision of good faith estimates that include items or services beyond the period of care for the scheduled or requested primary items or services.

HHS provides the following example for illustrative purposes only and notes that this example should not be considered or construed to be comprehensive or applicable to any specific individual or set of circumstances. In the instance of a knee surgery, a good faith estimate could include an itemized list of items or services in conjunction with and including the actual knee surgery (such as physician professional fees, assistant surgeon professional fees, anesthesiologist professional fees, facility fees, prescription drugs, and durable medical equipment fees) that occur during the period of care. An individual would not typically schedule days in the hospital post-procedure separately from scheduling the primary service of a knee surgery. HHS would therefore expect that all the items or services that are reasonably expected to be provided from admission through discharge as part of that scheduled knee surgery, from all physicians, facilities, or providers be included in the good faith estimate.

Additionally, in this illustrative example, a provider or facility would furnish separate good faith estimates upon scheduling or upon request for any items or services that are necessary prior to or following provision of the

primary item or service beyond the period of care. Examples could include certain pre-operative or post-operative items or services that are not typically scheduled during the period of care for the knee surgery, such as certain laboratory tests or post-discharge physical therapy as discussed earlier.

HHS acknowledges that unforeseen factors could occur during the course of treatment, which could involve additional services, resulting in higher actual billed charges after receipt of care than was anticipated at the time the good faith estimate was provided to the uninsured (or self-pay) individual. These interim final rules do not require the good faith estimate to include charges for unanticipated items or services that are not reasonably expected and that could occur due to unforeseen events.

HHS expects that providers and facilities will use the coding that best describes the item or service for each item or service listed in the good faith estimate. When a single service code is available that captures reporting and billing for the component parts of an item or service, the single service code and expected charge for that single service code would be reported in the good faith estimate to capture the most comprehensive coding level; the component parts would not be included in the good faith estimate as they would not be separately reported or billed. For example, CPT code 85027 (*complete (CBC), automated (Hgb, Hct, RBC, WBC and platelet count)*) represents a laboratory test that measures a patient's hematocrit, hemoglobin, red blood cell count, leukocyte (white blood cell) counts, and platelet count. There are also individual CPT codes for each of the component parts of the service represented by CPT code 85027 (CPT codes: 85014 (*hematocrit (Hct)*), 85018 (*hemoglobin (Hgb)*), 85041 (*red blood cell (RBC), automated*), 85048 (*leukocyte (WBC), automated*), and 85049 (*platelet, automated)*). However, HHS expects that the good faith estimate would include expected charges for CPT code 85027, not expected charges for each component part since there is a single CPT code available that better captures reporting for all of the component parts of the laboratory service.[65]

Items or services included in the good faith estimate must be itemized (by each applicable service code), and clearly grouped and displayed as corresponding to the respective provider or facility that is expected to furnish those items or services. For each provider or facility represented in the good faith estimate, the total amount of expected charges must be included and displayed. HHS is of the view that certain identifying information (such as the provider's or facility's NPI and TIN) must be included in the good faith estimate to ensure that each provider or facility is accurately identified, particularly in instances where more than one provider or facility have the same name, but are separate and distinct entities for purposes of billing for items or services.

Chart 1 provides a visual example of how itemized lists of expected items or services could be displayed in the good faith estimate as suggested in the HHS model notice. HHS notes that this example is included for demonstration purposes only, is not required, and is not a mandatory or standardized format. HHS seeks comment on options for displaying and methods for standardizing the formatting for the itemized lists of items or services, and the required disclaimers. HHS also seeks comment regarding the potential benefits and challenges of using a standardized form that could serve as a base for good faith estimates issued to uninsured (or self-pay) individuals. As uninsured (or self-pay) individuals may be unfamiliar with reading and understanding itemized lists of items or services typically charged for by providers or facilities, HHS seeks comment regarding whether the notice should be required to include additional information to explain concepts such as itemized lists of items or services, content within the required disclaimers, or other information included within the good faith estimate. HHS is also interested in information regarding publicly available methods for displaying required information in good faith estimates in a clear and understandable manner.

CHART 1—EXAMPLE OF HOW ITEMIZED LISTS OF EXPECTED ITEMS OR SERVICES COULD BE DISPLAYED IN A GOOD FAITH ESTIMATE FOR UNINSURED (OR SELF-PAY) INDIVIDUALS

DETAILS OF SERVICES AND ITEMS FOR [PROVIDER/FACILITY 1]

Service/item	Address where service/ item will be provided	Diagnosis code	Service code	Quantity	Expected cost
	[Street, City, State, ZIP]	[ICD code]	[Service Code Type: Service Code Number].	.....	.....
Total Expected Charges from [Provider/Facility 1]				.....	$

Additional Health Care Provider/Facility Notes

DETAILS OF SERVICES AND ITEMS FOR [PROVIDER/FACILITY 2]

Service/item	Address where service/ item will be provided	Diagnosis code	Service code	Quantity	Expected cost
	[Street, City, State, ZIP]	[ICD code]	[Service Code Type: Service Code Number].	.....	.....

[65] CPT codes and descriptions are copyright 2020 American Medical Association. All Rights Reserved. CPT is a registered trademark of the American Medical Association (AMA).

DETAILS OF SERVICES AND ITEMS FOR [PROVIDER/FACILITY 2]—Continued

Service/item	Address where service/ item will be provided	Diagnosis code	Service code	Quantity	Expected cost
Total Expected Charges from [Provider/Facility 1]				.....	$

Additional Health Care Provider/Facility Notes

5. Required Methods for Providing Good Faith Estimates for Uninsured (or Self-Pay) Individuals

In 45 CFR 149.610(e), these interim final rules establish required methods for providing good faith estimates to uninsured (or self-pay) individuals. Consistent with statutory requirements, these interim final rules establish at 45 CFR 149.610(e)(1) that the good faith estimate must be provided in written form either on paper or electronically (for example, electronic transmission of the good faith estimate through the convening provider's patient portal or electronic mail), pursuant to the uninsured (or self-pay) individual's requested method of delivery, and within the timeframes specified under 45 CFR 149.610(b). For good faith estimates provided electronically, the good faith estimate must be provided in a manner that the uninsured (or self-pay) individual can both save and print, and must be provided and written using clear and understandable language and in a manner calculated to be understood by the average uninsured (or self-pay) individual.[66]

HHS notes that the good faith estimate is necessary for initiating the patient-provider dispute resolution process under 45 CFR 149.620, and thus must be issued in written form. Additionally, 45 CFR 149.610(e)(2) of these interim final rules establishes that to the extent that an uninsured (or self-pay) individual requests a good faith estimate be provided other than by paper or electronically (for example, by phone or orally in person), the convening provider or facility may orally discuss the information included in the good faith estimate. However, in order to meet the requirements of this section, the convening provider or convening facility must issue the good faith estimate in written form. The good faith estimate may be provided to an uninsured (or self-pay) individual's authorized representative instead of the individual, to the extent not prohibited under state law. HHS notes that authorized representatives from state Consumer Assistance Programs (CAPs) or legal aid organizations may also be resources for assisting individuals with good faith estimates. HHS recognizes and notes that similar discussions related to authorized representatives (and communication needs of underserved populations discussed elsewhere in this preamble) were also discussed in the July interim final rules. These interim final rules adopt similar standards for authorized representatives as the July 2021 interim final rules, with amendments to account for concepts that are not relevant to uninsured (or self-pay) individuals such as removing references to nonparticipating providers, participants, beneficiaries and enrollees.

In interpreting the statutory requirements regarding the use of clear and understandable language, HHS recognizes that communication, language, and literacy barriers are associated with decreased quality of care, poorer health outcomes, and increased utilization.[67] The use of appropriate language services and 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.[68] HHS is of the view that it is imperative that providers and facilities make these efforts to provide good faith estimate information in a manner understandable to the uninsured (or self-pay) individual to help achieve the goal of the statute and ensure that uninsured (or self-pay) individuals are aware of the good faith estimate information and the options available to them. HHS is of the view that when providing a good faith estimate, providers or facilities should also take into account any vision, hearing, or language limitations; communication needs of underserved populations; individuals with limited English proficiency; and persons with health literacy needs. These factors meaningfully contribute to whether the uninsured (or self-pay) individual can understand and ask any questions about the total expected costs for items or services.

Providers and facilities are also required to comply with other state and Federal laws regarding language access, to the extent applicable. HHS reminds providers and facilities that are recipients of Federal financial assistance that they must comply with Federal civil rights laws that prohibit discrimination. These laws include Section 1557 of the Patient Protection and Affordable Care Act,[69] Title VI of the Civil Rights Act of 1964,[70] and Section 504 of the Rehabilitation Act of 1973.[71] 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 providing qualified interpreters, written or sight translation of written good faith estimates in paper or electronic form into languages other than English. When language assistance services are provided, they must be provided free of charge and be accurate and timely. 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 in a timely manner and free of charge to the individual. Auxiliary aids and services may include sign language 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.

HHS seeks comment from persons in and representatives of racial/ethnic

[66] For additional resources, see Federal Plain Language Guidelines at *https://www.plainlanguage.gov/guidelines/*.

[67] Flores G. Language barriers to health care in the United States. N Engl J Med 2006; 355:229–231.

[68] *Id.*

[69] 42 U.S.C. 18116.

[70] 42 U.S.C. 2000d *et seq.*

[71] 29 U.S.C. 794.

minority and underserved communities, including those with limited English proficiency and those with disabilities who require information in alternate and accessible formats, lesbian, gay, bisexual, transgender, and queer (LGBTQ+) persons, 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 good faith estimates. HHS also seeks comment on how to best provide additional help and resources for these individuals, including state CAPs, legal services or other aid that may help patients with good faith estimates. HHS also seeks comment on additional or alternate policies HHS may consider to help address and remove such barriers. In furtherance of the goal of reducing disparities in health care and coverage, HHS intends to analyze data related to individuals' use of the patient-provider dispute resolution process described under 45 CFR 149.620, as added by PHS Act section 2799B–7, and the appeals process described under 45 CFR 147.136, as added by PHS Act section 2719, to understand where barriers to coverage or accessible information persist. HHS is seeking comment on how to use data related to these two processes to understand, analyze, and address continued disparities.

HHS is seeking comment on how the required methods for providing a good faith estimate to uninsured (or self-pay) individuals established under 45 CFR 149.610 may affect small or rural providers or facilities. HHS is particularly interested in whether there are alternatives to these interim policies that HHS could consider for potential future rulemaking that could meet the statutory requirements for provision of good faith estimates to uninsured (or self-pay) individuals.

6. Additional Compliance Provisions

HHS is of the view that compliance provisions (established at 45 CFR 149.610(f) of these interim final rules) are necessary to ensure that providers and facilities have taken reasonable steps to ensure the accuracy of the information included in a good faith estimate. These interim final rules further clarify in 45 CFR 149.610(e)(1) that a good faith estimate issued to an uninsured (or self-pay) individual is considered part of the patient's medical record and must be maintained in the same manner as a patient's medical record, and that convening providers and facilities must provide a copy of any previously issued good faith estimate furnished within the last 6 years to an uninsured (or self-pay) individual upon the request of the uninsured (or self-pay) individual.

While HHS acknowledges that some states have existing state laws related to the furnishing of good faith estimates, HHS is of the view that uninsured (or self-pay) individuals should still have access to a good faith estimate that meets the minimum requirements established in these interim final rules. Therefore at 45 CFR 149.610(f)(2) these interim final rules establish that providers or facilities that issue good faith estimates under state processes that do not meet the minimum requirements under this section fail to comply with the requirements of 45 CFR 149.610.

In circumstances in which a provider or facility, acting in good faith, makes an error or omission in a good faith estimate, HHS is establishing at 45 CFR 149.610(f)(3) that a provider or facility will not fail to comply with this section solely because, despite acting in good faith and with reasonable due diligence, the provider or facility makes an error or omission in a good faith estimate required under this section, provided that the provider or facility corrects the information as soon as practicable. However, if the services are furnished before the error in the good faith estimate is addressed, the provider or facility may be subject to patient-provider dispute resolution if the billed charges are substantially in excess of the good faith estimate (as described in 45 CFR 149.620).

Additionally, to the extent compliance with this section requires a provider or facility to obtain information from any other entity or individual, these interim final rules specify at 45 CFR 149.610(f)(4) that the provider or facility will not fail to comply with this section because it relied in good faith on the information from the other entity, unless the provider or facility knows, or reasonably should have known, that the information is incomplete or inaccurate. HHS notes that providers and facilities (including convening providers, convening facilities, co-providers or co-facilities) who experience other providers' or facilities' failures to comply with the requirements in these interim final rules may file a complaint for enforcement investigation under 45 CFR 149.450. If the provider or facility learns that the information is incomplete or inaccurate, the provider or facility must provide corrected information to the uninsured (or self-pay) individual as soon as practicable, and as noted above, may be subject to patient-provider dispute resolution if items or services furnished before a corrected good faith estimate could be issued to an uninsured (or self-pay) individual.

7. Applicability of the Good Faith Estimate Requirements

These interim final rules establish under 45 CFR 149.610(g)(1) that the requirements of this section are applicable for good faith estimates requested on or after January 1, 2022 by uninsured (or self-pay) individuals or for good faith estimates required to be provided to uninsured (or self-pay) individuals in connection with items or services scheduled on or after January 1, 2022. HHS recognizes that some providers or facilities may need to establish efficient and secure communication channels for transmission of good faith estimate information between convening providers or facilities and co-providers and co-facilities. While HHS notes that there are longstanding established standards for data exchange between providers established under HIPAA,[72] HHS is seeking comment on any existing challenges related to secure transmission of good faith estimate information between providers and facilities. HHS is also interested in whether publicly available standardized processes exist or could be developed that would facilitate and support efficient and timely transmission of good faith estimate information. HHS also seeks comments on how the Hospital Price Transparency requirements for hospitals to display standard charges in a consumer-friendly manner (45 CFR 180.60), and, specifically, the voluntary use of online price estimator tools (45 CFR 180.60(a)(2)), may be leveraged to provide a good faith estimate under these final rules. HHS also seeks comments on whether there are other opportunities for the convening provider to use the Hospital Price Transparency machine-readable file requirements (45 CFR 180.50) to inform good faith estimates with expected charges of co-providers or co-facilities from the comprehensive machine-readable files, whether or not the comprehensive machine-readable files can assist uninsured (or self-pay) individuals in determining if the good faith estimate charges are reasonable and/or accurate, and what limitations exist in using the comprehensive machine-readable files for purposes of

[72] *https://www.cms.gov/regulations-and-guidance/administrative-simplification/hipaa-aca.*

meeting the requirements of this section for provision of the good faith estimates to uninsured (or self-pay) individuals. General information regarding relevant interoperability or data exchange standards would also be of interest.

These interim final rules at 45 CFR 149.610(g)(2) establish that nothing in 45 CFR 149.610 alters or otherwise affects a provider's or facility's duty to comply with requirements under other applicable state or Federal laws, including those governing the accessibility, privacy, or security of information required to be disclosed under this section, or those governing the ability of properly authorized representatives to access uninsured (or self-pay) individuals' information held by providers or facilities, except to the extent a state law prevents the application of this section.

HHS understands that it may take time for providers and facilities to develop systems and processes for receiving and providing the required information from co-providers and co-facilities. Therefore, for good faith estimates provided to uninsured (or self-pay) individuals from January 1, 2022 through December 31, 2022, HHS will exercise its enforcement discretion in situations where a good faith estimate provided to an uninsured (or self-pay) individual does not include expected charges from co-providers or co-facilities. HHS notes that nothing prohibits a co-provider or co-facility from furnishing the information before December 31, 2022, and nothing would prevent the uninsured (or self-pay) individual from separately requesting a good faith estimate directly from the co-provider or co-facility, in which case the co-provider and co-facility would be required to provide the good faith estimate for such items or services. Otherwise during this period, HHS encourages convening providers and convening facilities to include a range of expected charges for items or services reasonably expected to be provided and billed by co-providers and co-facilities. To the extent states are the primary enforcer of these requirements, HHS encourages states to take a similar approach, and will not consider a state to be failing to substantially enforce these requirements if it takes such an approach from January 1, 2022 through December 31, 2022.

8. Applicability of Requirements to Notices Provided Under 45 CFR 149.420

The July 2021 interim final rules included provisions at 45 CFR 149.420(d) establishing the information that must be included in a written notice, if a non-participating provider or non-participating emergency facility seeks to obtain consent from a participant, beneficiary, or enrollee (or their authorized representative) to waive the balance bill protections. Specifically, the written notice must be provided in a form and manner specified by HHS in guidance, and must, among other things, 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). In the July 2021 interim final rules, HHS stated that in calculating the good faith estimated amount required to be included in the notice under 45 CFR 149.420(d)(2), the provider or facility is expected to apply the same process and considerations used to calculate the good faith estimate that is required under PHS Act section 2799B–6(2).

HHS recognizes that providers and facilities have some discretion in the assumptions that they make regarding which items or services to include in a good faith estimate, and that some natural variation may occur across providers and facilities in terms of which items or services they would include in an estimate. However, HHS is of the view that it is critical for providers and facilities to apply the same process and considerations in developing the good faith estimate required under PHS Act section 2799B–6(2) (as partially implemented in these interim final rules at 45 CFR 149.610) as in 45 CFR 149.420(d)(2) to avoid consumers receiving two different estimates describing care from the same provider or facility for the same care.[73]

Under 45 CFR 149.610, the ''expected charge'' for an item or service may vary depending on whether the good faith estimate is being provided to an uninsured (or self-pay) individual, or to a plan or issuer. HHS clarifies that the good faith estimate in the notice described in 45 CFR 149.420(c) must be developed using the definition of the expected charge that would apply when the good faith estimate is provided to a plan or issuer (that is, the amount the provider or facility would expect to charge if the provider or facility intended to bill a plan or issuer directly for such item or service). Because the notice in 45 CFR 149.420(c) would only be provided with respect to individuals enrolled in a group health plan or health insurance coverage, HHS is of the view that requiring the good faith estimate to align with the good faith estimate that would be provided under PHS Act section 2799B–6(2)(A) to a plan or issuer will help to avoid situations in which participants, beneficiaries, or enrollees subsequently receive an advanced explanation of benefits from their plan or issuer that is generated from a different estimate than the one provided in the notice, or in which participants, beneficiaries, or enrollees receive differing estimates regarding notice and consent under 45 CFR 149.420(d)(2) and regarding self-pay liability under 45 CFR 149.610. In instances where an individual receives a notice with a good faith estimate reflecting the amount that would be billed to a plan or issuer but intends to self-pay and the item or service is scheduled in advance, the individual would separately receive a good faith estimate reflecting the amount they would be charged as a self-pay individual under the requirements in 45 CFR 149.610. HHS acknowledges that the Departments are not codifying requirements regarding PHS Act section 2799B–6(2)(A), which requires providers and facilities to furnish good faith estimates to plans or issuers, and that HHS will defer enforcement of this requirement until rulemaking is effective to fully implement this requirement. That non-enforcement position does not extend to the requirement to provide a good faith estimate as part of the notice under 45 CFR 149.420(c). However, HHS seeks comment on whether providers and facilities should be allowed to calculate the good faith estimate under 45 CFR 149.420(d)(2) using the expected charge applicable to an uninsured (or self-pay) individual until such rulemaking occurs. HHS also seeks comment on whether it would be feasible for providers and facilities to provide an estimate or range of estimated costs for insured consumers upon request during this period of non-enforcement.

HHS recognizes that the good faith estimates required under 45 CFR 149.420(d)(2) and 45 CFR 149.610 may also differ if items or services from different provider(s) or facilities are included in the estimate. For example,

[73] For individuals who are seeking to submit a claim to their plan or coverage, the second estimate would be sent to the plan or issuer and used to develop the advanced explanation of benefits required to be provided under Code section 9816(f), ERISA section 716(f), and PHS Act section 2799A–1(f). As discussed previously, the Departments will defer enforcement of these requirements until the Departments have issued rulemaking regarding the requirements. The Departments recognize that participants, beneficiaries, and enrollees would not receive a second estimate (in the advanced explanation of benefits) from their plan or issuer until this rulemaking goes into effect.

an estimate required in the notice under 45 CFR 149.420(d)(2) would only include items or services provided by a nonparticipating provider that seeks to obtain consent to balance bill. In contrast, the good faith estimate required under these interim final rules would not be limited to items or services furnished by such providers. However, HHS expects that the estimates regarding items or services provided by a specific provider or facility in the notice provided under 45 CFR 149.420(c) would include the same items or services for that specific provider or facility as the good faith estimate provided under 45 CFR 149.610. Although the grand total of a good faith estimate under each of the two rules might differ depending on the number of providers furnishing estimates as part of one good faith estimate, HHS is of the view that the requirements in each of the two rules generally take into account the same process and considerations for calculating the good faith estimate.

B. Patient-Provider Dispute Resolution

1. Scope

PHS Act section 2799B–7 directs the Secretary of HHS to establish a process called a patient-provider dispute resolution process. Under this process an uninsured (or self-pay) individual who received a good faith estimate of the expected charges for an item or service, pursuant to PHS Act section 2799B–6, implemented at 45 CFR 149.610, may seek a determination from an SDR entity for the amount to be paid by the uninsured (or self-pay) individual to the provider or facility for such item or service. Uninsured (or self-pay) individuals are eligible for the patient-provider dispute resolution process after being furnished an item or service for which they received a good faith estimate if the individual is billed, by the provider or facility, charges that are substantially in excess of the good faith estimate.

HHS is adding new 45 CFR 149.620 to implement this patient-provider dispute resolution process. These interim final rules include specific definitions related to the patient-provider dispute resolution process; specify the items and services eligible for the process; establish requirements for what uninsured (or self-pay) individuals must provide to initiate the process; and specify the information providers and facilities must provide to an SDR entity to inform payment determinations. These interim final rules also establish requirements for SDR entities contracted to resolve the patient-provider dispute, including how SDR entities determine the payment amount, and certification standards that HHS will consider when contracting with SDR entities. These interim final rules also specify the administrative fee associated with the patient-provider dispute resolution process, and the minimum requirements for state patient-provider dispute resolution processes to operate in place of the Federal patient-provider dispute resolution process.

2. Definitions

For purposes of these interim final rules, the definitions under 45 CFR 149.610 apply. Definitions related to confidentiality set forth in § 149.510(a)(2), including the definitions for *breach, individually identifiable health information (IIHI),* and *unsecured IIHI* also apply to this section. These interim final rules also define three additional terms: ''billed charge,'' ''substantially in excess,'' and ''total billed charges'' under new 45 CFR 149.620(a)(2).

These interim final rules define ''billed charge'' to mean the amount billed by a provider or facility for an item or service. These interim final rules define ''total billed charges'' to mean the total of billed charges, by a provider or facility, for all primary items or services and all other items or services furnished in conjunction with the primary items or services to an uninsured (or self-pay) individual, regardless of whether such items or services were included in the good faith estimate.

These interim final rules define the term ''substantially in excess'' to mean with respect to the total billed charges by a provider or facility, an amount that is at least $400 more than the total amount of expected charges for the provider or facility listed on the good faith estimate. In defining ''substantially in excess,'' HHS notes that PHS Act section 2799B–7 does not include a definition for ''substantially in excess.'' HHS reviewed other uses of the term in existing Federal law. For example, section 1128(b)(6) of the Social Security Act provides that the Secretary of HHS may exclude any individual or entity from participation in any Federal health care program if the Secretary determines that the individual or entity submitted bills or requests for payment (where such bills or requests are based on charges or cost) under title XVIII of the Social Security Act or a state health care program containing charges (or, in applicable cases, requests for payment of costs) for items or services furnished substantially in excess of such individual's or entity's usual charges (or, in applicable cases, substantially in excess of such individual's or entity's costs) unless the Secretary finds there is good cause for such bills or requests containing such charges or costs. However, HHS notes that section 1128(b)(6) of the Social Security Act similarly does not include a definition for ''substantially in excess.'' Regardless, HHS is of the view that the term ''substantially in excess'' as used in PHS Act section 2799B–7 should be distinguished from the language of section 1128(b)(6) of the Social Security Act, as the provisions operate differently. Specifically, PHS Act section 2799B–7 specifies that an uninsured (self-pay) individual is eligible to seek a payment determination regarding the amount to be paid when the total billed charges substantially exceed the total expected charges in the good faith estimate. HHS is of the view that such a process should provide clear criteria that would make it easy for uninsured (or self-pay) individuals, providers, facilities, SDR entities, and HHS to determine eligibility for dispute resolution. HHS is also of the view that such eligibility criteria should be based on objective factors that are known in advance and are simple for providers, facilities, and uninsured (or self-pay) individuals to understand, which will reduce uncertainty over which items or services are subject to dispute resolution and which are not.

HHS considered establishing a definition for ''substantially in excess'' to mean that the total billed charges are greater than the total expected charges in the good faith estimate by a percentage of the total expected charges in the good faith estimate (for example, 20 percent of the total expected charges). However, HHS is mindful of the limitations in relying on percentages for determining the threshold of eligibility for dispute resolution. In particular, when using percentages, the dollar thresholds would vary significantly based on the magnitude of the expected charges in the good faith estimate. For example, if for an item or service, the expected charge in the good faith estimate is $300, 20 percent would equal $60, meaning the billed charges would need to equal or exceed $360 to be eligible for dispute resolution. However, if for an item or service, the expected charge in the good faith estimate is $25,000, the difference between the billed charge and the expected charge in the good faith estimate would need to be $5,000 or greater to be eligible for dispute resolution. In other words, basing the definition of ''substantially in excess'' on a percentage of the total expected

charges in the good faith estimate would make dispute resolution easier to access in cases where the associated dollar amounts are small. Conversely, in cases where the associated dollar amounts are very large, the threshold would be significantly larger in terms of dollars and more difficult for the claims to meet, which could result in many uninsured (or self-pay) individuals being unable to access dispute resolution despite receiving bills for items or services in amounts far greater, in absolute value, than the expected charges in the good faith estimate.

To address these limitations, HHS considered alternative approaches that included defining ''substantially in excess'' to mean that the total billed charges are greater than the total expected charges in the good faith estimate by the lesser of a percentage of the total expected charges in the good faith estimate or a flat maximum dollar amount. While this approach would mitigate concerns over higher cost items and services meeting the ''substantially in excess'' threshold, it would not address concerns over the uninsured (or self-pay) individual being easily able to bring dispute resolution claims for lower cost items or services. HHS is concerned that under such an approach, dispute resolution for lower cost items or services could be overused, thus potentially increasing costs for providers and facilities which could be passed on to individual consumers in the form of higher prices.

Similarly, HHS considered defining ''substantially in excess'' to mean an amount that is the greater of either a percentage of the total expected charges in the good faith estimate or a flat minimum dollar amount. By specifying a flat minimum dollar threshold amount, such an approach would address concerns over overuse of the patient-provider dispute resolution process for items or services at the lower end of costs. However, HHS remains concerned that such an approach could effectively put dispute resolution out of reach for uninsured (or self-pay) individuals in situations where the total expected charges for items or services are high, particularly for those who need to undergo more complex procedures. As an example, under this approach, when the total billed charges must be either equal to or greater than a flat minimum amount or predefined percentage above the expected charges, if the applicable flat amount is $400 and the applicable percentage of the expected charges in the good faith estimate were equal to 10 percent, total expected charges of $25,000 would mean the total billed charges must exceed the total expected charges in the good faith estimate by $2,500 or more in order to access dispute resolution. If, in this example, the total billed charges are less than $27,500, the uninsured (or self-pay) individual would be unable to resolve the unexpected bill using the patient-provider dispute resolution process. Even for individuals with sufficient savings or income, such a threshold would likely pose a major financial burden, and such a situation would be exacerbated for lower income individuals and those who lack sufficient savings. HHS is of the view that whether an individual needs to receive a high cost item or service is independent from an individual's income or assets or coverage status, and basing the definition of ''substantially in excess'' for the purposes of eligibility for the patient-provider dispute resolution process on the expected charges of an item or service without any consideration for the financial means of the uninsured (or self-pay) individual would create a massive gap in the consumer protections intended under PHS Act section 2799B–7. To provide another example, suppose an uninsured (or self-pay) individual has total expected charges in the good faith estimate equal to $2,100 and the ''substantially in excess'' standard is the greater of 10% of the total expected charges in the good faith estimate or $400. Under such a definition, the substantially in excess threshold would be $400, and if the total billed charges are $2,500 or greater, then the items or services are eligible for dispute resolution. Now, consider another uninsured (or self-pay) individual with total expected charges of $21,000; in this uninsured (or self-pay) individual's case, the total billed charges would need to exceed the total expected charges in the good faith estimate by $2,100 or more in order to be eligible for dispute resolution. The uninsured (or self-pay) individual with expected charges of $21,000 is in no less need of protection from surprise medical bills than the uninsured (or self-pay) individual with expected charges of $2,100, but in practice such individual would more likely be unable to access these important protections intended by the patient-provider dispute resolution due to the higher threshold.

HHS also considered a tiered percentage approach in which lower-cost services must exceed a higher percentage value, with a lower percentage value applicable for higher-cost items or services. However, HHS is of the view that such an approach would add undue complexity to the patient-provider dispute resolution process in determining whether items or services meet the ''substantially in excess'' threshold and would present the same concerns previously described. HHS also considered basing the definition of ''substantially in excess'' on billed charges that exceed a certain percentile for the same or similar services using an independent database. However, such a mechanism appears inconsistent with the statute, which contemplates costs for items or services to be determined ''substantially in excess'' based on the good faith estimate provided, rather than based on a specific benchmark, such as an independent database.

HHS is of the view that basing the definition of ''substantially in excess'' on a flat dollar amount, such as $400, allows for a straightforward way to calculate the eligibility of an item or service for patient-provider dispute resolution, and reduces the concerns described earlier regarding lower-cost items or services too easily meeting the eligibility threshold for dispute resolution and making it more difficult for higher-cost items and services to meet the eligibility threshold. HHS acknowledges that such an approach may result in situations in which the difference between the total billed charges and the total expected charges in the good faith estimate is small in relative terms but the item or service is eligible for dispute resolution. As an example, if the expected charge for an item or service in the good faith estimate is $100,000, basing ''substantially in excess'' on a flat $400 threshold, a billed charge of $100,400 (0.4% difference) or more would make the item or service eligible for dispute resolution, which could be argued by some as not ''substantially in excess.'' However, as discussed earlier in this section of the preamble, HHS is of the view that while the definition of ''substantially in excess'' should encompass the difference between the total billed charges and the total expected charges in the good faith estimate, focusing solely on the expected costs of items or services risks shutting out many uninsured (or self-pay) individuals from the patient-provider dispute resolution process and undermines the intended protections in PHS Act section 2799B–7. Additionally, even when the total expected charges are high, a relatively small additional charge may still create significant financial difficulties for the uninsured (or self-pay) individual. HHS did consider whether to have different flat dollar thresholds based on the

uninsured (or self-pay) individual's income, however, HHS is of the view that such a policy would be confusing to uninsured (or self-pay) individuals who would need to provide documentation to verify their income, which increases the burdens placed on such individuals and could pose a deterrent to participation. Based on consideration of the different approaches discussed earlier in this section of the preamble, HHS determined that the best approach for defining ''substantially in excess'' would be to base it on a flat dollar difference between the total billed charges and the total expected charges in the good faith estimate.

Because HHS views the patient-provider dispute resolution process established under PHS Act section 2799B–7 to be intended to protect uninsured (or self-pay) individuals from unexpected higher health care costs, it is appropriate to determine whether an amount is substantially in excess based on the perspective of individuals who are likely to be uninsured or underinsured, and not only the perspective of the average individual or the provider or facility. To that end, HHS looked to existing research to assess what amount Americans may struggle to cover in unexpected expenses. HHS is of the view that looking to Americans' ability to cover unexpected expenses is an important consideration when establishing protections for unexpected medical expenses, which remain a common unexpected expense for many. In a 2016 survey, the Federal Reserve reported that 22 percent of respondents experienced what they described as a major unexpected medical expense that they had to pay out-of-pocket in the previous 12 months.[74] Further, concerns over the potential costs of medical care may result in many Americans choosing to forego needed care.[75] Another recent study found that in 2020, 17.8 percent of individuals had medical debt reported to a credit bureau, the study also found that individuals collectively had greater medical debt in collections than all forms of nonmedical debt combined (the authors defined nonmedical debt as other sources of debt in collections, including credit cards, personal loans, utilities, and phone bills).[76]

In 2019, the Federal Reserve found that nearly 4 in 10 adults would have difficulty covering an emergency expense costing $400, with 12 percent of adults unable to pay their current month's bills if they also had an unexpected $400 expense.[77] The ability to cover an unexpected expense also varies significantly by social risk and demographic factors, for example, income, race, perceived health, and depression.[78] A 2016 survey by the Federal Reserve found that among respondents with a family income under $40,000, only 34 percent reported they would be able to pay an unexpected $400 expense using cash or its functional equivalent (including money currently in their checking/savings accounts, or available on a credit card that they would pay in full at their next statement). In addition, the Federal Reserve found that while 61 percent of non-Hispanic white respondents said that they would pay for an unexpected $400 expense using cash or its functional equivalent, for Hispanic and non-Hispanic black respondents, only 38 percent and 36 percent respectively reported that they would be able to pay for an unexpected $400 expense using cash or its functional equivalent.[79]

Other surveys have found results that were consistent with the Federal Reserve's findings. One such survey found that only 39 percent of Americans would cover an unexpected $1,000 expense using their savings.[80] The same survey also found that this number varied significantly with age and income, finding that only 33 percent of those in the millennial generation and only 21 percent of those making less than $30,000 per year would cover a hypothetical $1,000 expense using savings.[81] A survey by the Robert Wood Johnson Foundation found that 67 percent of those making less than $35,000 per year reported they would have difficulty paying off a hypothetical $1,000 expense.[82] Research by the Pew Charitable Trust also found that 55 percent of Americans to be ''savings-limited, meaning they can replace less than one month of their income through liquid savings.'' [83] For Americans at the bottom quintile of income, this amount is even less, with the typical family having less than 2 weeks of income in savings.[84]

While research shows that some Americans are financially prepared to cover unexpected costs, many Americans are unable to weather such unexpected expenses.[85] The Pew Charitable Trust found that more than half of families that experienced a financial shock (such as an unplanned expense or loss of income) reported having trouble making ends meet, and this number increased for younger, minority, and low-income households. The Pew Charitable Trust also found that households that experienced such events typically had lower savings and higher credit card debts than those that did not.[86]

While health care costs are not the only unexpected expenses people face, they constitute a large source of surprise expenses. The Robert Wood Johnson Foundation found that 38 percent of lower-income Americans and 31 percent of middle-income Americans reported experiencing significant problems with paying medical bills.[87] Many Americans, particularly those who are uninsured, report that they went without needed care, or delayed care, due to costs. For example, the Federal Reserve found that 38 percent of those with incomes below $40,000 went without some form of medical care in 2019.[88] Among uninsured individuals,

[74] Board of Governors of the Federal Reserve System, Report on the Economic Well-Being of U.S. Households in 2015 (May 2016), available at: *https://www.federalreserve.gov/2015-report-economic-well-being-us-households-201605.pdf.*

[75] For example, 24 percent of adults went without some form of medical care due to an inability to pay, down from 27 percent in 2017 and well below the 32 percent reported in 2013. Dental care was the most frequently skipped treatment (17 percent), followed by visiting a doctor (12 percent) and taking prescription medicines (10 percent). Board of Governors of the Federal Reserve System, Report on the Economic Well-Being of U.S. Households in 2018 (May 2019), available at: *https://www.federalreserve.gov/publications/2019-economic-well-being-of-us-households-in-2018-dealing-with-unexpected-expenses.htm.*

[76] Kluender R., Mahoney N., Wong F., Yin W. Medical Debt in the U.S., 2009–2020. JAMA. 2021;326(3):250–256. doi:10.1001/jama.2021.8694.

[77] Board of Governors of the Federal Reserve System, Report on the Economic Well-Being of U.S. Households in 2018 (May 2019), available at: *https://www.federalreserve.gov/publications/2019-economic-well-being-of-us-households-in-2018-dealing-with-unexpected-expenses.htm.*

[78] Board of Governors of the Federal Reserve System, Report on the Economic Well-Being of U.S. Households in 2015 (May 2016), available at: *https://www.federalreserve.gov/2015-report-economic-well-being-us-households-201605.pdf.*

[79] Board of Governors of the Federal Reserve System, Report on the Economic Well-Being of U.S. Households in 2015 (May 2016), available at: *https://www.federalreserve.gov/2015-report-economic-well-being-us-households-201605.pdf.*

[80] *https://www.bankrate.com/banking/savings/financial-security-january-2021/.*

[81] *https://www.bankrate.com/banking/savings/financial-security-january-2021/.*

[82] *https://www.rwjf.org/en/library/research/2019/12/life-experiences-and-income-inequality-in-the-united-states.html.*

[83] *https://www.pewtrusts.org/~/media/Assets/2015/01/FSM_Balance_Sheet_Report.pdf.*

[84] *https://www.pewtrusts.org/~/media/Assets/2015/01/FSM_Balance_Sheet_Report.pdf.*

[85] *https://www.pewtrusts.org/~/media/assets/2015/10/emergency-savings-report-1_artfinal.pdf.*

[86] *https://www.pewtrusts.org/~/media/assets/2015/10/emergency-savings-report-1_artfinal.pdf.*

[87] *https://www.rwjf.org/en/library/research/2019/12/life-experiences-and-income-inequality-in-the-united-states.html.*

[88] *https://www.federalreserve.gov/publications/2019-economic-well-being-of-us-households-in-2018-dealing-with-unexpected-expenses.htm.*

47 percent went without some form of medical care due to concerns over costs.[89] Research reinforces the findings of the Federal Reserve and indicates that additional risk factors such as perceived health and depression increase an individual's likelihood of reporting that health care is unaffordable.[90] [91] For these groups facing high health care related financial burdens, which include those most likely to be uninsured and underinsured,[92] unexpected expenses of $400 or more would reasonably constitute a substantial amount.

HHS also considered setting the flat dollar lower than $400. However, as discussed in greater detail in section VI.B.8 of this preamble, HHS expects to contract with SDR entities directly and will pay the SDR entity costs. Based on conversations with stakeholders and research of similar state processes, HHS found that the amount that dispute resolution entities charge for similar dispute resolution processes is around $400 per case. A study by the Commonwealth Fund similarly found costs for dispute resolution ranging between $300 and $600.[93] HHS found that other state dispute resolution processes could potentially charge the uninsured (or self-pay) individual high fees to initiate a dispute. For example, in New York, the cost to the uninsured (or self-pay) individual for dispute resolution could be as much as $395, and in Maine as much as $450.[94] However, as is further discussed in section VI.B.8 of this preamble, HHS will only charge a small administrative fee, meaning that uninsured (or self-pay) individuals will be mostly insulated from the costs of dispute resolution. HHS acknowledges that the costs to the government for conducting dispute resolution would not be a consideration for the uninsured (or self-pay) individual in determining whether to initiate a dispute, as they would not be required to pay those costs. However, HHS is of the view that it would not make sense to conduct dispute resolution cases where the amount in dispute is less than the cost for the dispute resolution entity. As a result, HHS is of the view that setting the substantially-in-excess floor equal to $400 is a reasonable and appropriate approach and would ensure that the minimum amount in dispute for the patient-provider dispute resolution process is comparable to the expected costs for dispute resolution.

In addition, HHS considered whether to set the substantially-in-excess threshold floor at a higher amount than $400. However, HHS remains concerned that setting the flat dollar floor for the substantially-in-excess threshold greater than $400 could ultimately result in many uninsured (or self-pay) individuals, particularly those who received lower cost items or services, being unable to access the patient-provider dispute resolution process. As a result, HHS is of the view that limiting patient-provider dispute resolution to items or services where the total billed charges exceed the total expected charges in the good faith estimate by $400 or greater strikes the appropriate balance that helps ensure that amounts in dispute are sufficiently large to justify the costs of maintaining and operating the dispute resolution process; that burdens on providers, facilities, and the Federal Government are minimized; and that all uninsured (or self-pay) individuals are able to access the dispute resolution process to resolve unexpected billed amounts.

As HHS obtains additional experience with the patient-provider dispute resolution process, HHS intends to review data on the use of the process, such as the volume of dispute resolution cases, differences between the total expected charges in the good faith estimate and the total billed charges in cases that go to dispute resolution, data on payment determination amounts by SDR entities, the success rate for uninsured (or self-pay) individuals who initiate dispute resolution, and characteristics of initiation requests that are determined ineligible, and in future years may propose adjustments to the definition of ''substantially in excess.''

HHS seeks comment on the definition for ''substantially in excess,'' including whether the $400 amount should be set higher or lower, whether there is any other specific dollar value that would be more appropriate, or whether a different method for determining ''substantially in excess'' should be considered. HHS also seeks 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. HHS also seeks comment on how these definitions may impact market incentives, including the accuracy of good faith estimates.

3. Eligibility for Patient-Provider Dispute Resolution

The patient-provider dispute resolution process in PHS Act section 2799B–7 applies to uninsured (or-self-pay) individuals who received, pursuant to PHS Act section 2799B–6, a good faith estimate of the expected charges for scheduled or requested items or services from a provider or facility, and who after being furnished such item or service is billed by such provider or facility charges substantially in excess of such estimate. To clarify what items and services are eligible for the patient-provider dispute resolution process, HHS is adding 45 CFR 149.620(b) which specifies that items or services provided by a convening provider, convening facility, co-provider, or co-facility are eligible for the patient-provider dispute resolution process if the total billed charges (by the particular convening provider, convening facility, or co-provider or co-facility listed in the good faith estimate), are substantially in excess of the total expected charges for that specific provider or facility listed on the good faith estimate, as required under 45 CFR 149.610, regardless of whether the items or services included in the total billed charges were listed in the good faith estimate, or whether the co-provider or co-facility was listed on the good faith estimate.

Good faith estimates for scheduled items or services, or when requested, as specified in 45 CFR 149.610, are intended to provide a comprehensive estimate of expected charges for items or services furnished during the period of care. PHS Act section 2799B–6 and 45 CFR 149.610 require providers or facilities to include any item or service that is reasonably expected to be provided in conjunction with an item or service, including an item or service reasonably expected to be so provided by another provider or facility.

HHS is of the view that an uninsured (or self-pay) individual should be able

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[89] *https://www.federalreserve.gov/publications/2019-economic-well-being-of-us-households-in-2018-dealing-with-unexpected-expenses.htm.*

[90] Kielb E.S., Rhyan C.N., Lee J.A. Comparing Health Care Financial Burden With an Alternative Measure of Unaffordability. *Inquiry.* 2017;54:46958017732960. doi:10.1177/0046958017732960.

[91] Amin K., Claxton G., Ramirez G., Cox C. How Does Cost Affect Access to Care? *Peterson-KFF Health System Tracker.* January 2021. Available at *https://www.healthsystemtracker.org/chart-collection/cost-affect-access-care/#item-start.*

[92] Kielb E.S., Rhyan C.N., Lee J.A. Comparing Health Care Financial Burden With an Alternative Measure of Unaffordability. *Inquiry.* 2017;54:46958017732960. doi:10.1177/0046958017732960. Also see, Amin K., Claxton G., Ramirez G., Cox C. How Does Cost Affect Access to Care. *Peterson-KFF Health System Tracker.* January 2021. Available at *https://www.healthsystemtracker.org/chart-collection/cost-affect-access-care/#item-start.* Also see, Tolbert J., Orgera K., Key Facts About the Uninsured Population. *Kaiser Family Foundation.* November 2020. Available at *https://www.kff.org/uninsured/issue-brief/key-facts-about-the-uninsured-population/.*

[93] *https://www.commonwealthfund.org/blog/2020/how-states-are-using-independent-dispute-resolution-resolve-out-network-payments-surprise.*

[94] *https://www.dfs.ny.gov/system/files/documents/2020/10/idr_patient_application.pdf* and *https://dispute.maximus.com/me/indexME.*

to initiate the patient-provider dispute resolution process when the total billed charge for an item or service from a particular provider or facility represented in the good faith estimate exceeds the substantially in excess threshold defined at 45 CFR 149.620(a)(2). Therefore, these interim final rules specify that an item or service provided by a convening provider, convening facility, co-provider or co-facility are eligible for the patient-provider dispute resolution process if the total billed charges (by the particular convening provider or facility, or co-provider or co-facility listed in the good faith estimate), are substantially in excess of the of total expected charges for that specific provider or facility listed on the good faith estimate, as required under 45 CFR 149.610.

As an example, an uninsured (or self-pay) individual receives a good faith estimate that lists expected charges for 3 services, A, B, and C. Services A and B are provided by provider Y and service C is provided by co-provider Z. The total billed charges for services A and B must exceed the total expected charges for services A and B by at least $400 more than the amount listed in the good faith estimate in order for the uninsured (or self-pay) individual to be eligible to initiate patient-provider dispute resolution against provider Y. Similarly, the billed charge for service C must exceed the expected charges for service C by at least $400 more than the amount listed in the good faith estimate in order for the uninsured (or self-pay) individual to be eligible for the patient-provider dispute resolution against co-provider Z.

An item or service is eligible for patient-provider dispute resolution based on the total billed charges from the provider or facility, regardless of whether such items or services are included in a good faith estimate. HHS recognizes that unforeseen factors during the course of treatment may occur, which could involve additional items or services from providers and facilities, and may result in higher billed charges after receipt of care than was anticipated at the time the good faith estimate was provided to the uninsured (or self-pay) individual. However, HHS is of the view that if an item or service is eligible for patient-provider dispute resolution only if it is explicitly listed in the good faith estimate, providers and facilities may be incentivized to omit items and services from the good faith estimate in order to avoid the patient-provider dispute resolution process. It is HHS's view that Congress intended to create a process which allows uninsured (or self-pay) individuals to dispute the final billed charges, if such charges are substantially in excess of the expected charges in the good faith estimate; and therefore any item or service that was not included in the good faith estimate, yet resulted in total billed charges substantially in excess of the total expected charges in the good faith estimate, should be eligible for patient-provider dispute resolution.

Therefore, if the total billed charges, which includes charges for new items or services, exceeds the total expected charges by at least $400 more than the amount in the good faith estimate, the items or services are eligible for patient-provider dispute resolution, despite the new items or services not being itemized in the good faith estimate. For example, co-provider Z bills an uninsured (or self-pay) individual for services C, D, and E, even though services D and E were not included in the good faith estimate. If the differences between the total billed charges for services C, D, and E are substantially in excess of the total expected charges in the good faith estimate for service C, then the uninsured (or self-pay) individual is eligible to initiate patient-provider dispute resolution against co-provider Z for services C, D, and E.

Although convening providers and convening facilities are required to include expected charges from co-providers and co-facilities in the good faith estimate, HHS understands that there may be instances when an uninsured (or self-pay) individual may receive a bill that includes providers or facilities that were not included in the good faith estimate: Specifically, if a co-provider or co-facility that is reflected on the good faith estimate is substituted at the last moment to a different co-provider or co-facility. While PHS Act section 2799B–7 requires that an item or service where the total billed charges are substantially in excess of the total expected charges in the good faith estimate will be eligible for patient-provider dispute resolution, expected charges for the replacement co-provider or co-facility may not be available. Regardless, HHS is of the view that the consumer protections of PHS Act section 2799B–7 should still apply in these circumstances as they are aimed to protect uninsured (or self-pay) individuals from unexpected medical bills, and allowing a co-provider or co-facility to circumvent these protections simply due to not being directly represented on the good faith estimate would undermine these protections. Therefore, HHS is adding 45 CFR 149.620(b)(2) that specifies that an item or service billed by a co-provider or co-facility that replaced the original co-provider or co-facility covered under a good faith estimate is eligible for dispute resolution if the total billed charge is substantially in excess of the expected charges included on the good faith estimate for the original co-provider or co-facility. However, if the replacement co-provider or co-facility provides the uninsured (or self-pay) individual with a new good faith estimate of expected charges in accordance with 45 CFR 149.610(b)(2) then the determination of whether an item or service billed by the replacement co-provider or co-facility is eligible for dispute resolution is based on whether the total billed charges for the replacement co-provider or co-facility are substantially in excess of the total expected charges included in the good faith estimate provided by the replacement co-provider or co-facility.

HHS is of the view that had the convening provider known that the items or services from these particular co-providers or co-facilities would be needed, they would have been included on the good faith estimate. Therefore, HHS is of the view that such an approach for an item or service billed by a replacement co-provider or co-facility is necessary and appropriate to ensure such item or service is eligible for dispute resolution if the total billed charges are substantially in excess of the total expected charges in the good faith estimate even if the billing provider or facility did not provide the original estimate of expected charges in the good faith estimate. HHS acknowledges the challenges these requirements impose on providers and facilities, and the potential disincentive that such a requirement could have on a provider's or facility's willingness to provide an item or service under such circumstances given the patient-provider dispute resolution process, at 45 CFR 149.620, uses the expected charges contained in the good faith estimate to determine the eligibility of an item or service for patient-provider dispute resolution. However, HHS is of the view that such requirements are necessary for the intended consumer protections regarding surprise medical bills, and that, without such a requirement, an uninsured (or self-pay) individual may be unable to avail themselves of the patient-provider dispute resolution process in these circumstances. HHS also recognizes that these particular situations may be more complex for an uninsured (or self-pay) individual to determine eligibility for dispute resolution. HHS seeks comment

on the approach for eligibility in cases where the co-provider or co-facility has been replaced with a different co-provider or co-facility, comments on whether there are other complex situations where clarification would be helpful, and the feasibility of such an approach to eligibility, as well as comments on alternative approaches.

HHS considered whether to base eligibility for patient-provider dispute resolution on whether an individual item or service listed on a good faith estimate is billed an amount substantially in excess of the expected charge for the item or service. However, HHS is of the view that basing the eligibility for patient-provider dispute resolution on each individual item or service would add complexity as each item or service listed on the good faith estimate would need to be assessed separately for eligibility. Additionally, by basing the eligibility for patient-provider dispute resolution on an individual item or service, providers and facilities could potentially avoid dispute resolution by ensuring that no single billed charge exceeds the estimate provided on the good faith estimate by more than the substantially in excess threshold, even though the total of all billed charges for a provider or facility might substantially exceed the total expected charges in the good faith estimate. As a result, to fully protect the uninsured (or self-pay) individual, the individual items and services would need to be totaled by provider or facility, with the total billed charges by provider or facility subject to the substantially in excess standard. HHS is of the view that, because the uninsured (or self-pay) individual understood the items or services to most likely cost the amount listed in the good faith estimate with respect to each provider or facility, focusing on the total billed charges by each provider or facility ensures that patient-provider dispute resolution is available when the total billed charges for each provider or facility substantially exceeds the amount that the individual expects to pay.

HHS also considered basing the eligibility on the total billed charges for all items or services and all providers or facilities listed on the good faith estimate. However such an approach would be significantly more complex given that the good faith estimate could consist of estimates from multiple providers and facilities who would bill the uninsured (or self-pay) individual separately. It could also potentially increase the burden on the uninsured (or-self pay) individual who would likely need to submit multiple bills from multiple providers or facilities. Additionally, such an approach could require a provider or facility to respond to a notice requesting additional documentation from an SDR entity due to the billing of other providers, even when the provider or facility did not bill an uninsured (or self-pay) individual an amount substantially in excess of the good faith estimate.

As discussed in section VI.A.2 of this preamble, these interim final rules define expected charges, for an item or service, as, the cash pay rate or rate established by a provider or facility for an uninsured (or self-pay) individual, reflecting any discounts for such individuals, where the good faith estimate is being provided to an uninsured (or self-pay) individual; or the amount the provider or facility would expect to charge if the provider or facility intended to bill a plan or issuer directly for such item or service when the good faith estimate is being furnished to a plan or issuer. Therefore, HHS would anticipate that the expected charges in the good faith estimate include applicable discounts and rates the provider or facility would ultimately charge an uninsured (or self-pay) individual rather than a standard list price or chargemaster rate. However, HHS remains concerned about the potential incentives for providers and facilities to inflate good faith estimates, for example, by overestimating the costs for items or services, providing a higher list price (or chargemaster rate) rather than the price the uninsured (or self-pay) individual would be expected to pay when accounting for any discounts, upcoding to a more expensive service, or adding additional unnecessary services which could lead to higher good faith estimates overall and could discourage uninsured (or self-pay) individuals from obtaining needed care. Furthermore, HHS is also concerned that providers or facilities may interpret an individual's decision to seek care after receiving the good faith estimate as their ability to pay the expected charges and therefore be disincentivized to offer the uninsured (or self-pay) individuals with charity care or discounted rates. HHS acknowledges that the availability of the patient-provider dispute resolution process may lead providers or facilities to estimate prices higher than they otherwise would have. However, HHS is very concerned that a provider or facility may increase the good faith estimate amount specifically to circumvent the ability of the uninsured (or self-pay) individual to access the patient-provider dispute resolution process, resulting in uninsured (or self-pay) individuals being charged higher prices and as a result the uninsured (or self-pay) individual foregoing needed care due to concerns over the potential costs. Additionally, this behavior could potentially lead to a situation where an uninsured (or self-pay) individual ultimately receives an inflated good faith estimate, but after receiving treatment is billed an amount higher than the good faith estimate yet less than the substantially in excess threshold, and is therefore unable to access dispute resolution due to the expected charges in the good faith estimate being overestimated. HHS acknowledges that an uninsured (or self-pay) individual may not necessarily know if a good faith estimate is inflated. However, as discussed in section VI.A.4 of this preamble, the good faith estimate will provide an itemized list of the expected items or services in advance, including the applicable diagnosis codes, expected service codes, and expected charges associated with each listed item or service. HHS is of the view that this will provide needed transparency for uninsured (or self-pay) individuals about the items or services they expect to be provided and the estimated costs with which they can compare with good faith estimates from other providers or through price transparency information such as the Hospital Price Transparency requirements described in 45 CFR part 180. HHS seeks comment on what other resources are available to assist individuals in determining the reasonableness of the good faith estimates they receive, particularly those who are uninsured (or self-pay) and with low health literacy. HHS also seeks comments on ways to raise awareness of these resources and on other resources that could be utilized by uninsured (or self-pay) individuals.

HHS notes that a provider or facility intentionally providing expected charges they know to be incomplete or inaccurate in the good faith estimate could violate the requirements in PHS Act section 2799B–6, which requires that the estimates being provided be good faith estimates, and thus could be subject to enforcement actions under PHS Act section 2799B–4. HHS is of the view that it is important for an uninsured (or self-pay) individuals to be able to file complaints regarding a provider or facility who they believe is not complying with the good faith estimate requirements and patient-provider dispute resolution process requirements, such as in cases where an individual believes a provider or facility is inflating the good faith estimate.

Therefore, HHS is amending the regulations at 45 CFR 149.450 to expand the scope to include subpart G of part 149, which includes 45 CFR 149.610 and 45 CFR 149.620, among the provisions for which HHS can receive and resolve complaints concerning a provider's or facility's failure to meet the specified requirements. HHS seeks comment on this approach.

HHS also considered whether there should be an additional backstop that would allow an uninsured (or self-pay) individual to access patient-process dispute resolution based on allegations that the provider or facility willfully overestimated the expected charges in the good faith estimate in order to avoid dispute resolution. Under such an approach, the good faith estimate would be reviewed to ensure that the good faith estimate reasonably reflect only the expected charges for the item or service, and that the good faith estimate did not include items or services extraneous to those that were reasonably expected to be provided in conjunction with such scheduled item or service. If HHS were to determine that such requirements had not been met, the uninsured (or self-pay) individual would be deemed eligible to initiate the patient-provider dispute resolution process for such items or services. However, these interim final rules do not include such an approach as HHS was concerned this approach would add significantly more complexity to the patient-provider dispute resolution process. HHS seeks comment on this potential approach of allowing uninsured (or self-pay) individuals to initiate dispute resolution for good faith estimates they believe to have been overinflated in order for providers and facilities to avoid dispute resolution.

As noted elsewhere in this preamble, with regards to an item or service furnished by co-providers and co-facilities, providers and facilities subject to these interim final rules may need additional implementation time to develop appropriate communication channels that may not yet exist among various co-providers or co-facilities. As stated in section VI.A.7 of this preamble, with respect to good faith estimates provided to uninsured (or self-pay) individuals on or after January 1, 2022 through December 31, 2022, HHS will exercise its enforcement discretion in situations where the good faith estimate does not include expected charges for items and services from a co-provider or co-facility. During this period, HHS encourages convening providers and facilities to include a range of expected charges for such items and services during the period of care. HHS understands that it may take time for providers and facilities to develop systems and processes for receiving and providing the required information regarding items and services provided by co-providers and co-facilities. HHS is of the view that without having such processes in place, co-providers and co-facilities who provide items or services may be subjected to patient-provider dispute resolution in situations where the co-providers or co-facilities were unable to provide complete and accurate pricing information to the convening provider or facility, and as a result would not provide sufficient detail to provide accurate good faith estimates. As a result, during the period of enforcement discretion, further discussed in section VI.A.7 of this preamble, items or services to be provided by a co-provider or co-facility that appear on the good faith estimate that do not include an estimate of expected charges or that appear as a range of expected charges would not be eligible for the patient-provider dispute resolution process. However, HHS emphasizes that this particular application for patient-provider dispute resolution eligibility would apply only in 2022 to allow additional time for the convening provider and convening facility to build the necessary systems and processes to receive accurate estimates from co-providers and co-facilities. HHS notes, that nothing prevents a co-provider or co-facility from furnishing the information as required in 45 CFR 149.610 before December 31, 2022, and under such circumstances, a co-provider or co-facility must comply with the patient-provider dispute resolution requirements in 45 CFR 149.620. Additionally, nothing would prevent the uninsured (or self-pay) individual from separately requesting a good faith estimate directly from the co-provider or co-facility in which case the patient-provider dispute resolution requirements in 45 CFR 149.620 would apply. HHS seeks comment on the approach for eligibility for the patient-provider dispute resolution process, including the feasibility of such approach, including the approach for eligibility for co-providers and co-facilities in 2022, as well as comment on alternative approaches to increase consumer protections against unexpected medical bills from co-providers and co-facilities during 2022.

HHS also recognizes that uninsured (or self-pay) individuals in underserved and racial/ethnic minority communities, including individuals with vision, hearing, or language limitations, individuals with limited English proficiency, lesbian, gay, bisexual, transgender, and queer (LGBTQ+) individuals, and persons with health literacy needs, may face additional barriers to paying for high unexpected health care costs, understanding their rights related to good faith estimates, patient-provider dispute resolution, and how and when to initiate the dispute resolution process. HHS seeks comment from underserved and racial/ethnic minority communities on additional barriers individuals from these communities may face in understanding and exercising their rights related to these topics, and how to address them. HHS also seeks feedback on outreach and education activities, efforts, and resources available for underserved and racial/ethnic minority communities, including individuals with vision, hearing, or language limitations, individuals with limited English proficiency, lesbian, gay, bisexual, transgender, and queer (LGBTQ+) individuals, and persons with health literacy needs, to help ensure that these rights and tools are available, accessible, and understood such that they can be used equitably by all uninsured (or self-pay) individuals in appropriate circumstances. HHS also recognizes that groups such as CAPs and legal aid organizations play an important role in helping consumers, particularly those in underserved and racial/ethnic minority communities, including individuals with vision, hearing, or language limitations; individuals with limited English proficiency; and persons with health literacy needs, with complex heath care issues, which may also include assistance with the patient-provider dispute resolution process. HHS seeks comment on how to best to support the efforts of these organizations in assisting uninsured (or self-pay) individuals throughout the patient-provider dispute resolution process.

4. Initiation of Patient-Provider Dispute Resolution

PHS Act section 2799B–7 requires patient-provider dispute resolution be available when an uninsured (or self-pay) individual is billed by a provider or facility for items or services in an amount that is ''substantially in excess'' of the expected charges in the good faith estimate for the provider or facility.

HHS is specifying under 45 CFR 149.620(c) that when an uninsured (or self-pay) individual is billed for items or services where the total billed charges for a provider or facility is substantially in excess of the total expected charges in the good faith estimate for the

provider or facility, the uninsured (or self-pay) individual or their authorized representative (excluding any providers or facilities directly represented in the good faith estimate, providers associated with such providers or facilities, or non-clinical staff associated with such providers or facilities), may submit a notification (initiation notice) to the Secretary of HHS to initiate the patient-provider dispute resolution process. HHS is of the view that a provider should generally not be permitted to represent the uninsured (or self-pay) individual in dispute resolution for items or services where the provider was represented on the good faith estimate, even if the provider would not be a party to the dispute. HHS is of the view that there is a 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. However, HHS acknowledges that many providers would generally not be inclined to assist the uninsured (or self-pay) individuals with initiating a dispute resolution even without this restriction. HHS further clarifies that providers may serve as authorized representatives for uninsured (or self-pay) individuals, provided they do not meet the previously described exclusion criteria. HHS also clarifies that CAPs and legal aid organizations can also serve as authorized representatives for the purpose of the patient-provider dispute resolution process as such organizations may have experience assisting consumers with billing issues. Additionally, all materials created for the patient-provider dispute resolution process, including the Federal IDR portal, will be compliant with the language access requirements of section 508 of the Rehabilitation Act of 1973 to meet accessibility needs.[95] HHS seeks comment on what additional supports are necessary for community organizations, such as CAPs and legal aid organizations, to assist uninsured (or self-pay) individuals with the dispute resolution process. Providers and facilities are also required to comply with other state and Federal laws regarding language access, to the extent applicable. HHS reminds providers and facilities that are recipients of Federal financial assistance that they must comply with Federal civil rights laws that prohibit discrimination. These laws may include Section 1557 of the Patient Protection and Affordable Care Act, Title VI of the Civil Rights Act of 1964, and Section 504 of the Rehabilitation Act of 1973, as applicable. Section 1557 of the Patient Protection and Affordable Care Act and Title VI of the Civil Rights Act of 1964 require covered entities to take reasonable steps to ensure meaningful access for individuals with limited English proficiency, which may include provision of language assistance services, such as providing qualified interpreters or written translation of written good faith estimates in paper or electronic form into languages other than English. When language assistance services are provided, they must be provided free of charge and be accurate and timely. Section 1557 of the Affordable Care Act and Section 504 of the Rehabilitation Act of 1973 require covered entities to take appropriate steps to ensure effective communication with individuals with disabilities, including provision of appropriate auxiliary aids and services in a timely manner and free of charge 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. HHS also seeks comment on what additional supports are necessary for persons in and representatives of minority and underserved communities, including those with limited English proficiency, those with disabilities who require information in alternate and accessible formats, and stakeholders who serve such communities.

The initiation notice must be submitted to the Secretary of HHS, and postmarked within 120 calendar days of receiving the initial bill containing charges for the item or service that is substantially in excess of the expected charges in the good faith estimate, for the provider or facility. HHS is specifying calendar days instead of business days in this instance, because it is HHS' experience in administering other consumer-facing programs such as the Federally Facilitated Marketplace, that consumers have an easier time calculating and responding to deadlines that are measured by calendar days rather than business days. HHS considered whether to specify a timeframe shorter than 120 calendar days. However, HHS is concerned that requiring the initiation notice to be submitted in less than 120 calendar days would not provide sufficient time for an uninsured (or self-pay) individual to collect and submit the required information. HHS also considered a timeframe greater than 120 calendar days, or no time limit; but HHS is of the view that due to the requirement, as discussed later in this section, that once the patient-provider dispute resolution process has been initiated, a provider or facility must not move the bill for the disputed item or service into collection or threaten to do so, or if the bill has already moved into collection, the provider or facility should cease collection efforts, as well as the requirement that the provider or facility suspend the accrual of any late fees on unpaid bill amounts until after the dispute resolution process has concluded, providing for a longer timeframe could increase uncertainty for a provider or facility over whether an uninsured (or self-pay) individual will file a dispute resolution request. As a result, HHS is of the view that having a clear timeframe with which an uninsured (or self-pay) individual can initiate a dispute resolution request is both necessary and appropriate. HHS seeks comment on the appropriateness of allowing individuals 120 calendar days to initiate the dispute resolution process, and whether more or less time should be allowed for an uninsured (or self-pay) individual to initiate dispute resolution, or whether there should not be a time limit at all.

The initiation notice may be submitted through the Federal IDR portal, electronically, or on paper, in a form and manner specified by the Secretary of HHS. The initiation notice must include: (1) Information sufficient to identify the items or services under dispute, including the date of service or date the item was provided and a description of the item or service; (2) a copy of the bill for the items and services under dispute (the copy can be a photocopy or an electronic image so long as the document is readable); (3) a copy of the good faith estimate for the items and services under dispute (the copy can be a photocopy or an electronic image so long as the document is readable); (4) the contact information of the parties involved, including name, email address, phone number and mailing address; (5) the state where the items or services in dispute were furnished; and (6) the uninsured (or self-pay) individual's

[95] For 508 standards, see the US Access Board's final rule at: *https://www.federalregister.gov/documents/2017/01/18/2017-00395/information-and-communication-technology-ict-standards-and-guidelines; see also Information and Communication Technology Revised 508 Standards and 255 Guidelines,* U.S. Access Board, *https://www.access-board.gov/ict/* (last visited Sept. 10, 2021).

communication preference, through the Federal IDR Portal, or electronic or paper mail.

In addition to the required information, the uninsured (or self-pay) individual must submit with the initiation notice an administrative fee to the SDR entity as described in 45 CFR 149.620(g) and section VI.B.8 of this preamble. The amount of the administrative fee, as well as the manner in which it must be submitted, will be clarified in guidance by HHS. PHS Act section 2799B–7(c) contemplates that the uninsured (or self-pay) individual pay an administrative fee, and that such fee should be set in a manner not to create a barrier to access the process. While HHS acknowledges that requiring an uninsured (or self-pay) individual to pay an administrative fee upfront may discourage some individuals from initiating the patient-provider dispute resolution process, HHS is of the view that requiring a nominal upfront administrative fee will help prevent the submission of unnecessary claims to the patient-provider dispute resolution process and ensure that dispute resolution resources are available in necessary cases. HHS also notes that as further discussed in section VI.B.8 of this preamble, if the uninsured (or self-pay) individual prevails in the dispute resolution process, the SDR entity will adjust the final payment determination amount to include a reduction in the final payment determination amount that accounts for the uninsured (or self-pay) individual's administrative fee payment, thus allowing the uninsured (or self-pay) individual to recoup the administrative fee paid.

The date of initiation of the patient-provider dispute resolution process will be the date of receipt of such initiation notice. HHS will provide additional information in guidance on how the uninsured (or self-pay) individual can submit the initiation notice, including necessary steps for the process and a standard notification form to ensure the uninsured (or self-pay) individual is able to include all the necessary information to initiate the dispute resolution process. In addition to the guidance, uninsured individuals will be informed of how to initiate the patient-provider dispute resolution process through information that providers and facilities must include on the good faith estimates, as discussed in section VI.A.4 of this preamble. HHS also intends to conduct outreach and education to consumer advocates, CAPs, legal aid organizations and other stakeholders to assist consumers through this process.

HHS expects to leverage the Federal IDR portal described in section III of this preamble to facilitate the operation of the patient-provider dispute resolution process. The Federal IDR portal will allow uninsured (or self-pay) individuals or their authorized representatives to submit the initiation notices, upload documentation, receive notices from HHS and the SDR entity, upload additional supporting documentation, and view the SDR entity's payment determination. HHS expects that providers and facilities will also utilize the Federal IDR portal to receive notices from HHS and the SDR entity, upload documentation, upload additional supporting documentation, and view the SDR entity's determination. HHS intends for the SDR entity to utilize the Federal IDR portal in all cases, as HHS is of the view that utilizing the Federal IDR portal to facilitate the patient-provider dispute resolution process is preferable and will allow for more efficient operation of the process, faster and easier receipt of notices and submission of documentation, and would allow all the relevant information on a specific patient-provider dispute resolution case to be accessible in one place. HHS is aware that an individual or a provider or facility may not be able to utilize the Federal IDR portal depending on various factors and as a result the individual, provider, or facility may choose to communicate with HHS or the SDR entity using other methods, including electronic or paper mail. Additionally, HHS recognizes that minority and underserved communities, including those with limited English proficiency and those with disabilities may prefer information in alternate and accessible formats and may not be best served by using the Federal IDR portal. HHS intends to put in place processes to ensure accessibility of the system for these communities, and HHS seeks comments on this approach.

Once the initiation notice has been received, HHS will select an SDR entity according to the process further described in section VI.B.6 of this preamble. After the SDR entity has been selected, the SDR entity will provide notice to the uninsured (or self-pay) individual and the provider or facility through the Federal IDR portal, or electronic or paper mail, that a patient-provider dispute resolution initiation request has been received and is under review, the SDR entity will also include information identifying the item or service under dispute, and the date the initiation notice was received. The SDR entity will also notify the uninsured (or self-pay) individual, and the provider or facility, that while the dispute resolution process is pending, the provider or facility must not move bills for the disputed items or services into collection or threaten to do so, or if the bill has already moved into collection, the provider or facility should cease collection efforts until the dispute has been settled. The provider or facility must also suspend the accrual of any late fees on unpaid bill amounts until after the dispute resolution process has concluded. Additionally, the provider or facility must not take or threaten to take retributive action against an uninsured (or self-pay) individual for utilizing the patient-provider dispute resolution process. The notice will also provide information to the uninsured (or self-pay) individual about the availability of consumer assistance resources that can assist them with the dispute.

The SDR entity will review the initiation notice submitted by the uninsured (or self-pay) individual to ensure that the disputed items or services meet the eligibility criteria for the patient-provider dispute resolution process and that the initiation notice contains all the required information. The SDR entity will notify the uninsured (or self-pay) individual electronically or by mail, depending on the individual's preference, of the outcome of the review including in cases where the initiation notice is determined to be incomplete or the item or service is determined ineligible for dispute resolution, in which case the uninsured (or self-pay) individual would be provided 21 calendar days to submit any missing information or provide supplemental information to demonstrate the item or service is eligible for the dispute resolution process. To assist consumers with understanding the timeline to submit the supplemental information, such insufficiency notice will provide a date by which the additional information must be postmarked or submitted electronically. HHS is of the view that providing the uninsured (or self-pay) individual with 21 calendar days is appropriate as it provides consumers with an opportunity to resolve any deficiencies in the initiation notice and access the dispute resolution process if eligible. If the insufficiency notice is not made available to an individual in a format that is accessible to individuals with disabilities or with low-English proficiency within 14 calendar days of such a request from the individual, a 14-calendar day extension will be granted to allow sufficient time for document

submission, so that the individual, in this situation, will have a total of 35 calendar days to submit supplemental information. HHS also considered a timeframe greater than 21 calendar days, or no time limit, however, HHS is concerned that due to the requirement that a provider or facility must not move the bill for the disputed item or service into collection or threaten to do so, or if the bill has already moved into collection, the provider or facility should cease collection efforts, and the provider or facility suspend the accrual of any late fees on unpaid bill amounts until after the dispute resolution process has concluded, providing for a longer timeframe could increase burdens and uncertainty for a provider or facility. The 21-calendar-day timeframe is also consistent with external review processes in some states.[96] HHS seeks comments on whether 21 calendar days is a sufficient timeframe for uninsured (or self-pay) individuals to submit additional documentation through the mail or electronically, or whether a different timeframe should be considered.

Once the SDR entity has determined that an item or service is eligible for dispute resolution, the SDR entity must provide notification of the determination to both parties (the uninsured (or self-pay) individual and the provider or facility) through the Federal IDR portal, or electronic or paper mail, and must request that the provider or facility provide certain information within 10 business days as described in 45 CFR 149.620(d) and in section VI.B.7.ii of this preamble.

While the dispute resolution process is pending, the provider or facility must not move bills for the disputed items or services into collection or threaten to do so until after dispute resolution process has concluded, or if the bill has already moved into collection, the provider or facility should cease collection efforts until the dispute has been settled. The provider or facility must also suspend the accrual of any late fees on unpaid bill amounts until after the dispute resolution process has concluded. PHS Act section 2799B–7 established a process that would provide a mechanism for an uninsured (or self-pay) individual who is billed an amount for an item or service that is substantially in excess of the expected charges in the good faith estimate to seek a determination on the amount to be paid. If the provider or facility were to move the bill, if fully or partially unpaid, to collection or to accrue late fees prior to the SDR entity determining a payment amount, the consumer protections intended in PHS Act section 2799B–7 would be undermined. In order for an uninsured (or self-pay) individual to avoid moving the bill into collection or the accrual of late fees, the uninsured (or self-pay) individual would effectively be required to pay the bill in full prior to determination and seek a refund from the provider or facility if the individual prevails. HHS is of the view that through the patient-provider dispute resolution process, the uninsured (or self-pay) individual is actively working in good faith to resolve a payment dispute and should not be effectively punished for utilizing such process by the accrual of late fees or movement of the bill into collections. HHS is of the view that use of its general rulemaking authority to establish such requirements is necessary and appropriate in order to implement the provisions of PHS Act section 2799B–7 in a manner that furthers the statutory intent to protect consumers by ensuring that uninsured (or self-pay) individuals can use the patient-provider dispute resolution process without being penalized for utilizing such process or being required to pay the billed charges upfront to avoid late fees or collections activities. HHS seeks comment on this approach of disallowing the movement of a bill into collections and the suspension of the accrual of late fees.

In addition, HHS is using its general rulemaking authority to establish requirements under 45 CFR 149.620 to prohibit a provider or facility from taking or threatening to take any retributive action against an uninsured (or self-pay) individual for utilizing the patient-provider dispute resolution process to seek resolution for a disputed item or service. If a provider or facility were to take or threaten to take retributive action against an uninsured (or self-pay) individual, such action could create a chilling effect for the uninsured (or self-pay) individual to utilize the dispute resolution process, which would undermine the consumer protections intended in PHS Act section 2799B–7. As a result, HHS is of the view that it is necessary and appropriate to require a provider or facility to not take or threaten to take any retributive action against an uninsured (or self-pay) individual for utilizing the patient-provider dispute resolution process.

5. Certification of Selected Dispute Resolution Entities

PHS Act section 2799B–7 requires the Secretary of HHS to recognize or establish a process to contract with and certify entities to resolve payment disputes between uninsured (or self-pay) individuals. Additionally, PHS Act section 2799B–7 requires entities certified under this process to satisfy, at a minimum, the criteria in PHS Act section 2799A–1(c). HHS intends to contract with and certify only that number of entities it believes will be necessary to timely resolve the volume of patient-provider disputes, rather than pursue an open process under which all entities who meet IDR entity requirements will be certified to resolve patient-provider payment disputes. Moreover, HHS will compensate SDR entities directly for their services under a contract that complies with the Federal Acquisition Regulation (FAR) as further implemented or supplemented by the HHS Acquisition Regulation.[97] Through this contract process, HHS will assess the dispute resolution entity for compliance with all applicable SDR entity certification requirements. HHS is of the view that this approach will reduce the overall cost of the program, which is funded primarily through appropriations to HHS, reduce the administrative burden associated with collecting fees from a large number of certified entities who may have differing fee schedules, and will allow for HHS to control the cost of the program to ensure that low-income individuals are able to access the patient-provider dispute resolution process. For the first year of the patient-provider dispute resolution program under PHS Act section 2799B–7, HHS anticipates contracting with between 1 and 3 SDR entities. HHS is of the view that 1 to 3 SDR entities will be sufficient in the first year to conduct the dispute resolution process for the anticipated number of cases outlined in the Economic Impact and Paperwork Burden section of these interim final rules. It will also ensure through the contracting process that the volume estimates are tenable for the contracted SDR entities. Additionally, given the timeline required by statute to implement the patient-provider dispute resolution process and the timeline under which these rules will become effective, HHS is of the view that contracting with a limited number of entities may be necessary to ensure the timely launch of the program.[98] HHS is of the view that attempting to procure

[96] Some state processes have a 15-business day time frame which would generally translate to 21 calendar days. *See e.g., https://insurance.mo.gov/consumers/health/externalreviewprocess.php.*

[97] *See* 48 CFR, Chapter 3 (HHS-specific regulations governing federal acquisitions for services).

[98] *See* FAR 6.302–2 (allowing less than full and open competition where an agency's need for services is of an unusual and compelling urgency).

SDR entity services from more than 3 entities will increase the burden associated with certifying IDR entities for the Federal IDR process discussed in section III of this preamble and with contracting SDR entities for the patient-provider dispute resolution process, and will limit HHS' ability to effectively launch the programs in accordance with statutory deadlines. HHS also is of the view that contracting with more than 3 SDR entities in the first year will unsustainably increase the administrative burden associated with launching both programs, and may impose sufficient risk to cause delays in implementation.

For these reasons, HHS is of the view that contracting with a limited number of SDR entities is preferable to adopting an ''any willing provider'' model. Accordingly, through this contract process, HHS will assess an entity's compliance with the SDR entity certification requirements to ensure the entity satisfies the certification criteria discussed later in this section of the preamble.

SDR entities will be assessed on whether they meet the applicable certification requirements during the contracting process with HHS and such process will be separate and distinct from the certification process applicable to IDR entities that will provide IDR services for providers, providers of air ambulance services, facilities, plans and issuers as required under 26 CFR 54.9816–8T and 54.9817–2T, 29 CFR 2590.716–8 and 2590.717–2, and 45 CFR 149.510, and 45 CFR 149.520. Although an SDR entity may apply for certification as an IDR entity, SDR entities are not required to do so. However, consistent with the statutory requirement, SDR entities will be required to meet the same requirements as certified IDR entities, with a few exceptions outlined later in this section of this preamble. SDR entities will be required to report on those data elements from providers and facilities that HHS deems necessary to accurately describe and assess the administration of the patient-provider dispute resolution program. Therefore, the requirements laid out in section III.D.5 of this preamble will also apply to SDR entities as a condition of receiving a contract award from HHS for the patient-provider dispute resolution program.

For example, PHS Act section 2799A–1(c)(4)(A)(v) requires a certified IDR entity to maintain the confidentiality of individually identifiable health information (IIHI) obtained in the course of conducting determinations. Under these interim final rules, HHS outlines certain standards related to confidentiality, including security, privacy, and breach notification requirements that apply to an IDR entity seeking certification. See section III.D.5 of this preamble for further discussion on the applicable confidentiality requirements. Under 45 CFR 149.620(d)(1), HHS specifies that an SDR entity must satisfy the Federal IDR entity certification criteria specified in 45 CFR 149.510(e), with a few exceptions specified in 45 CFR 149.620(d)(2). As part of this requirement, an SDR entity must comply with all the confidentiality requirements that apply to certified IDR entities in 26 CFR 54.9816–8T(e)(2)(v), 29 CFR 2590.716–8(e)(2)(v) and 45 CFR 149.510(e)(2)(v). Similarly, the definitions related to confidentiality in 45 CFR 149.510(a)(2) also apply for 45 CFR 149.620. Therefore, the definitions for ''breach,'' ''individually identifiable health information (IIHI)'' and ''unsecured IIHI'' that apply for IDR entities also apply for SDR entities. HHS seeks comment on the confidentiality requirements for an SDR entity, including whether additional requirements should be considered.

In addition, like IDR entities, SDR entities are required to comply with other state and Federal laws regarding language access, to the extent applicable. HHS reminds SDR entities that they, along with providers and facilities that are recipients of Federal financial assistance, must comply with Federal civil rights laws that prohibit discrimination. These laws include Section 1557 of the Patient Protection and Affordable Care Act, Title VI of the Civil Rights Act of 1964, and Section 504 of the Rehabilitation Act of 1973. Section 1557 of the Patient Protection and Affordable Care Act and title VI of the Civil Rights Act of 1964 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 providing qualified interpreters or written translations in paper or electronic form into languages other than English. When language assistance services are provided, they must be provided free of charge and be accurate and timely. Section 1557 of the Patient Protection and Affordable Care Act and Section 504 of the Rehabilitation Act of 1973 require covered entities to take appropriate steps to ensure effective communication with individuals with disabilities, including provision of appropriate auxiliary aids and services in a timely manner and free of charge to the individual. Auxiliary aids and services may include sign language 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. HHS also seeks comment on what additional measures are necessary for persons in racial/ethnic minority and underserved communities, including those with limited English proficiency, those with disabilities who require information in alternate and accessible formats, lesbian, gay, bisexual, transgender, and queer (LGBTQ+) persons, and stakeholders who serve such communities.

Unlike the process for certifying IDR entities, HHS intends to contract only with SDR entities that will be able to conduct patient-provider dispute resolution in all applicable states where the patient-provider dispute resolution process will apply. As such, SDR entities will need to submit information on their ability to operate nationwide through the contract process. Additionally, IDR entity fees that certified IDR entities will charge as the cost for providing dispute resolution services will not apply in the case of SDR entities, which will be paid for their services through contracts with HHS. Therefore, SDR entities will not be required to submit a fee schedule for batched and non-batched claims. Additionally, SDR entities will not be required to submit policies and procedures regarding holding IDR entity fees in a trust or escrow account, though they will still be required to submit policies and procedures regarding holding administrative fees and remit them to HHS in a manner specified by HHS.

Additionally, an SDR entity must also submit a conflict-of-interest mitigation policy that will not apply to IDR entities. Given that HHS intends to contract with a limited number of SDR entities under this program, HHS is of the view that additional standards for conflict-of-interest mitigation should apply to SDR entities, as there will likely be fewer entities available to conduct dispute resolution. Therefore, in addition to the requirement for certified IDR entities to submit policies and procedures for the ongoing auditing, mitigation, and reporting of conflicts of interest within their

organizations, SDR entities will be expected to include a mitigation plan for situations when no one in the entire organization will be able to conduct dispute resolution on a case due to an entity-level conflict of interest, which could include utilizing a subcontractor without a conflict of interest that meets SDR entity requirements to conduct the patient-provider dispute resolution for that case. Since there is a possibility that a single SDR entity will be contracted for this process, or that all available SDR entities indicate a conflict of interest that cannot be mitigated, HHS is of the view that additional requirements must be applied through these regulations and the contracting process to ensure that in the event that an entity-level conflict of interest occurs, SDR entities will be able to initiate strategies to fairly and impartially resolve disputes in the absence of another available SDR entity. Through the acquisition process, HHS will ensure compliance with FAR subpart 9.5 regarding organizational and consultant conflicts of interest in order to mitigate the potential for entity-level conflicts of interest that may preclude all available SDR entities from fairly and impartially resolving disputes.

While details on expectations for documentation and review for certified IDR entities will come through guidance, similar details and documentation requests will be done through the acquisition process for SDR entities. As such, all requirements laid out in this section and the applicable requirements outlined in section III.D.5 of this preamble for certified IDR entities will be assessed through the Federal acquisition process to ensure SDR entities have sufficient expertise and capabilities to conduct dispute resolution cases for the patient-provider dispute resolution process.

In subsequent years, case volume and other factors as necessary will be used by HHS to determine and adjust the number of contracted SDR entities needed for the patient-provider dispute resolution process. HHS is of the view that this approach will reduce the overall cost and administrative oversight burdens of the program, which is funded primarily through appropriations to HHS. Since contracting will allow HHS to negotiate lower rates for conducting dispute resolution cases with a limited number of entities, rather than paying set fee schedules associated with each SDR entity as in the Federal IDR process, HHS will be able to reduce both costs to HHS and administrative burdens associated with collecting varying fees from a large number of entities. HHS also is of the view that this approach will allow HHS to control the fees assessed to uninsured (or self-pay) individuals entering the patient-provider dispute resolution process to ensure that low-income individuals can participate in the process.

HHS seeks comment on the SDR entity contracting process, including the applicable certification requirements, specifically as to whether these are the appropriate standards regarding the patient-provider dispute resolution process, if additional standards should be applied, and if so, what those standards should be.

6. Selection of an SDR Entity for Patient-Provider Dispute Resolution

PHS Act section 2799B–7 requires the Secretary of HHS to provide a method to select a patient-provider dispute resolution entity to conduct individual dispute resolutions between patients and providers. As described more fully in section VI.B.5 of this preamble, during the first year of the program, HHS expects to contract with between 1 to 3 SDR entities to conduct patient-provider dispute resolutions.

Similar to the IDR process and for the same reasons described in section III.B.1 of this preamble, the general conflict-of-interest standards laid out in section III.B.1 of this preamble will also apply to SDR entities contracted by HHS for the patient-provider dispute resolution process. These standards include the mandatory period which prohibits personnel who have been a party to the payment determination being disputed, or who were employees or agents of such a party within 1 year immediately preceding dispute resolution assignment, from being assigned to a case.

As discussed in section VI.B.5 of this preamble, SDR entities will also be required to have in place an approved mitigation plan for addressing conflicts of interest. For example, such a mitigation plan could include processes under which any specific dispute resolution personnel who presents a conflict of interest could be walled off from having any role in or knowledge of the relevant payment dispute. To address conflicts of interest that exist at the entity level, the SDR entity could design a plan under which it would subcontract payment disputes to a different entity that meets SDR entity requirements. As part of the contract process, and as discussed in section VI.B.5 of this preamble, the SDR entity must submit specific mitigation plans such as proof of a subcontractor who meets the SDR entity requirements for HHS to assess, and approve as part of the acquisition process, and in accordance with the conflict-of-interest requirements set forth in FAR subpart 9.5. HHS is of the view that this approach will sufficiently mitigate the potential that conflicts of interest that exist to the extent that a case may not able to be resolved fairly and impartially, because having a subcontractor provides an avenue for cases to be sent for dispute resolution when the SDR entity has a conflict of interest. HHS also is of the view that ensuring that processes are in place to identify and address potential conflicts of interest is important to ensure impartiality in payment determinations and the timely and efficient resolution of disputes.

Upon receiving a request to initiate patient-provider dispute resolution case from an uninsured (or self-pay) individual, HHS will select 1 of the contracted SDR entities to serve as the entity to conduct the dispute resolution process. Selection of an SDR entity that will resolve a particular dispute will occur in round robin fashion to ensure equal allocation of cases to SDR entities, unless conflicts of interest arise. In the event that the assigned SDR entity has a conflict of interest that cannot be sufficiently mitigated by applying the SDR entity's conflicts mitigation plan, the next SDR entity in line will be selected. HHS is of the view that this approach will help ensure the selection process runs smoothly, supports the timely resolution of disputes consistent with applicable regulations, and that SDR entity caseloads are allocated efficiently. Upon receiving an assignment from the Secretary of HHS to make a determination for an item or service, the SDR entity shall ensure that no conflict of interest exists, and in such case no conflict exists, the SDR entity shall notify the uninsured (or self-pay) individual and the provider or facility of the selection of the SDR entity as described in section VI.B.4 of this preamble.

In the event that an SDR entity attests that a conflict of interest exists in relation to an assigned payment dispute, the SDR entity must notify the Secretary of HHS no later than 3 business days following selection. Additionally, either party (the uninsured (or self-pay) individual, or the provider or facility) may attest that a conflict of interest exists in relation to the SDR entity assigned to a payment dispute, in which case the SDR entity must notify the Secretary of HHS no later than 3 business days following receipt of the attestation.

In the event a conflict of interest exists, HHS will then automatically

select a different SDR entity from the remaining pool of contracted entities using a round robin approach. If no other contracted SDR entity, and no subcontracted entity, is able to provide the patient-provider dispute resolution services due to conflicts of interest that cannot be sufficiently mitigated or any other reason, HHS may seek to contract with an additional SDR entity as needed, to conduct dispute resolution in this case. HHS recognizes that while the Department expects these particular situations to be very rare, contracting with an additional SDR entity could take time and would make meeting the required patient-provider dispute resolution timeframes challenging. HHS notes that, as discussed in section VI.B.10 of this preamble, the time periods specified in these interim final rules may be extended in the case of extenuating circumstances at HHS' discretion on a case-by-case basis if the extension is necessary to address delays due to matters beyond the control of the parties or for good cause. In these rare cases, HHS anticipates that it may be appropriate to exercise such discretion if needed. For example, in the event that HHS needs to contract with an additional SDR entity, the time periods specified in this section may be extended at HHS' discretion to allow for HHS to contract with that SDR entity. HHS seeks comment on this approach, including comment on the feasibility of such approach and comment on alternative approaches HHS should consider. HHS also seeks comment on whether it is feasible or appropriate to seek assistance from the pool of certified IDR entities to provide patient-provider dispute resolution services in these circumstances.

These interim final rules also define certain terms related to conflict-of-interest standards applicable to SDR entities certified and contracted to resolve patient-provider disputes. Such an approach to conflict of interest is similar to the approach taken by the Federal IDR process discussed in section III.D.5 of this preamble. HHS is of the view that maintaining consistent standards between the Federal IDR process and the patient-provider dispute resolution process is a straightforward approach and serves to minimize stakeholder confusion over what the applicable standard will be. In general, a ''conflict of interest'' means, with respect to a party to a payment determination, or SDR entity, a material relationship, status, or condition of the party, or SDR entity that impacts the ability of the SDR entity to make an unbiased and impartial payment determination. For purposes of the patient-provider dispute resolution process, a conflict of interest exists when an SDR entity is: A provider or a facility, an affiliate or a subsidiary of a provider or facility, or an affiliate or subsidiary of a professional or trade association representing a provider or facility. A conflict of interest also exists when an SDR entity, or any personnel assigned to a determination, has a material familial, financial, or professional relationship with a party to the payment determination being disputed, or with any officer, director, or management employee of the provider, the provider's group or practice association, or the facility that is a party to the dispute. HHS is of the view that these requirements are necessary to ensure that payment disputes between an uninsured (or self-pay) individual and a provider or facility are conducted by impartial third parties. HHS seeks comment on this approach, including the feasibility of such approach, and whether additional requirements related to conflict of interest should be considered.

7. Payment Determination for Patient-Provider Dispute Resolution

i. Determination of Payment Amount Through Settlement

While the SDR entity payment determination is pending, HHS recognizes that the two parties to the patient-provider dispute resolution process (the uninsured (or self-pay) individual and the provider or facility) may agree to resolve the dispute by settling on a payment amount. Therefore, new 45 CFR 149.620(f)(1) states that at any point after the dispute resolution process has been initiated but before the date on which a determination is made by the SDR entity, the parties can settle the payment amount through either an offer of financial assistance or an offer to accept a lower amount, or an agreement by the uninsured (or self-pay) individual to pay the billed charges in full.

In the event that the parties agree to settle on a payment amount, the provider or facility should notify the SDR entity through the Federal IDR Portal, electronically, or in paper form, as soon as possible, but no later than 3 business days after the date of the agreement. The settlement notification must contain at a minimum, the settlement amount, the date upon which settlement was reached, and documentation demonstrating that the provider or facility and uninsured (or self-pay) individual have agreed to the settlement. The settlement notice must also document that the provider or facility has applied a reduction to the uninsured (or self-pay) individual's settlement amount that is equal to at least half the amount of the administrative fee paid as discussed in section VI.B.8 of this preamble. Once the SDR entity receives the notification of the settlement, the SDR entity shall close the dispute resolution case as settled and the agreed upon payment amount will apply for the items or services.

HHS also clarifies that payment of the billed charges (or a portion of the billed charges) by the uninsured (or self-pay) individual (or by another party on behalf of the uninsured (or self-pay) individual) does not demonstrate agreement by the uninsured (or self-pay) individual to settle at that amount or any other amount. For example, if the uninsured (or self-pay) individual has already made payment or entered into a payment plan and then chooses to enter dispute resolution, the fact that they previously paid, or agreed to pay, all or part of the billed charges may not be used by the provider or facility to prove that a settlement has been reached to avoid the patient-provider dispute resolution process.

HHS is of the view that providing an opportunity for the uninsured (or self-pay) individual and the provider or facility to come to terms on a payment amount that is mutually agreeable for the parties involved is appropriate as it may help resolve payment disputes quickly without the need for a determination by an SDR entity. Such a process can also incentivize a provider or facility to offer to accept a lower amount or to provide financial assistance to the uninsured (or self-pay) individual. However, HHS clarifies that neither party (the uninsured (or self-pay) individual or the provider or facility) is required to negotiate a settlement for the billed charges, and the decision to enter into a settlement on the payment amount is optional. In cases where there is no settlement, the SDR entity will make a determination as discussed in section VI.B.7.iii of this preamble.

HHS recognizes that to the extent that a provider or facility believes that a settlement may be more beneficial for them than the SDR entity determination, the provider or facility may be incentivized to seek a settlement. While such an outcome may be desirable in that it can lead to a quick resolution and could lead to provider or facility offering to accept a lower payment amount or other financial assistance to the uninsured (or self-pay) individual, HHS is concerned that the uninsured (or

self-pay) individual, particularly those without representation, would be at a disadvantage when negotiating with the provider or facility. HHS seeks comment on these concerns, including whether additional consumer protections should be considered, and ways HHS can increase an uninsured (or self-pay) individual's access to effective representation, through legal aid organizations or other groups.

ii. Determination of Payment Amount Through Patient-Provider Dispute Resolution

As part of the SDR determination process, 45 CFR 149.620(f)(2) requires that the health care provider or health care facility must submit information to the SDR entity not later than 10 business days after the receipt of the notice from the SDR entity initiating the patient-provider dispute resolution process described in section VI.B.4. This information must include: (1) A copy of the good faith estimate provided to the uninsured (or self-pay) individual for the items or services under dispute (the copy can be a photocopy or an electronic image so long as the document is readable); (2) a copy of the billed charges provided to the uninsured (or self-pay) individual for items or services under dispute (the copy can be a photocopy or an electronic image so long as the document is readable); and (3) documentation demonstrating that the difference between the billed charges and the expected charges in the good faith estimate reflects the costs of a medically necessary item or service and is based on unforeseen circumstances that could not have reasonably been anticipated by the provider or facility when the good faith estimate was provided. While the statute does not specify what a provider or facility should provide to the SDR entity to inform the SDR entity's determination decision or how long a provider or facility should have to report such information, HHS is of the view that it is both necessary and appropriate to require the provider or facility to provide the copies of the bill and good faith estimate for the item or service in question as such information can be helpful for the SDR entity to verify the eligibility of the dispute in question. Although the uninsured (or self-pay) individual will provide a copy of the bill and good faith estimate, requiring the provider or facility to also provide the bill and good faith estimate will allow the SDR entity to verify the information in the bill and good faith estimate provided by the uninsured (or self-pay) individual and identify any potential discrepancies. HHS believes it is also necessary and appropriate to provide a means for a provider or facility to submit documentation or an explanation to support the billed charges, such as information related to the patient's relevant medical history that is necessary to demonstrate that the item or service is medically necessary and is based on unforeseen circumstances that could not have reasonably been anticipated by the provider or facility when the good faith estimate was provided. HHS is of the view that such documentation from the provider or facility would assist the SDR entity with making a fair assessment whether the billed charge is appropriate because otherwise the SDR entity would be unfamiliar with the facts that would allow the SDR entity to assess medical necessity, and whether the need for the items or services was foreseeable. The interim final rules require that this information be submitted within 10 business days, this time period is similar to the Federal IDR process requirements for submitting documentation to support a dispute resolution determination as outlined in PHS Act section 2799B–1. HHS is of the view that a 10-business-day time period is sufficient for a provider or facility to gather and submit the required information, as this information should be documented as part of the individual's patient record.

Not later than 30 business days after receipt of the information from the provider described in section 45 CFR 149.620(f)(2)(i), the SDR entity must make a determination on the amount to be paid by such uninsured (or self-pay) individual taking into account the requirements described in section VI.B.7.iii of this preamble. The 30-business day timeframe is also similar to the requirement in the Federal IDR process in PHS Act section 2799A–1(c)(5) where not later than 30 business days after the selection of the certified IDR entity, the certified IDR entity must select one of the offers submitted by the plan or issuer and the provider or facility to be the out-of-network rate for the item or service. HHS is of the view that 30 business days should provide sufficient time for an SDR entity to review the submitted information and issue a determination. The SDR entity is required to assess the information submitted by the provider or facility according to the requirements described in 45 CFR 149.620(f)(3) and discussed in section VI.B.7.iii of this preamble.

iii. Requirements for Determination

45 CFR 149.620(f)(3) sets forth the requirements for SDR entities in making payment determinations. As described in section VI.A.3 of this preamble, the itemized list of items or services in a good faith estimate must reflect the expected charges from the convening provider or facility and items and services reasonably expected to be provided by co-providers or co-facilities and must be built upon accurate information that was known at the time the good faith estimate was given to the uninsured (or self-pay) individual. As a result, the SDR entity should use the expected charges in the good faith estimate as the presumed appropriate amount and unless the provider or facility provides credible information justifying the difference between the total billed charges and the good faith estimate by demonstrating that the difference between the billed charges and the expected charges in the good faith estimate for the item or service reflects the costs of a medically necessary item or service and is based on unforeseen circumstances that could not have reasonably been anticipated by the provider or facility when the good faith estimate was provided. For this purpose, information is credible if upon critical analysis the information is worthy of belief and consists of trustworthy information. This is the same standard the Departments are adopting at 26 CFR 54.9816–8T, 29 CFR 2590.716–8, and 45 CFR 149.510 for the Federal IDR processes discussed in section III.D.4 of this preamble. HHS is of the view that maintaining a consistent standard of review among IDR entities and SDR entities, while still recognizing the inherent differences in the respective processes based on the applicable parties, minimizes program complexity and reduces the potential for confusion among providers and facilities over the applicable standards for review.

As stated previously, HHS acknowledges that unforeseen factors during the course of treatment could result in additional items or services furnished and could result in higher billed amounts after receipt of care than was anticipated at the time the good faith estimate was provided. HHS does not expect that the good faith estimate would include charges for unanticipated items or services that could occur due to unforeseen events. In cases where changes in the underlying circumstances occur during treatment and would reasonably result in higher than expected charges, the SDR entity may consider additional factors that support charges for medically necessary items or services. As information to demonstrate that the difference between

the billed charges and the expected charges for an item or service in the good faith estimate reflects the costs of a medically necessary item or service and is based on unforeseen circumstances that could not have reasonably been anticipated by the provider or facility when the good faith estimate was provided, providers or facilities should provide documentation, which can include a written explanation, detailing any change in circumstances, how that change resulted in a higher billed charge than the expected charge for the item or service in the good faith estimate, and why the billed charge reflects the cost of a medically necessary item or service. HHS considered requiring the provider or facility to provide only evidence that the difference between the billed charges and the expected charges for the item or service in the good faith estimate reflects the costs of a medically necessary item or service, and not require the provider or facility demonstrate the item or service is based on unforeseen circumstance that could not have reasonably been anticipated when the good faith estimate was provided. However, HHS is of the view that an item or service that is medically necessary and could reasonably have been anticipated should already be included on the good faith estimate and without such information the uninsured (or self-pay) individual would not have been provided with an accurate estimate of the expected charges. HHS is of the view that not requiring the provider or facility to demonstrate that the item or service could not have been anticipated could incentivize a provider or facility to not list all items or services on the good faith estimate which could lead to less-accurate estimates provided to uninsured (or self-pay) individuals.

Uninsured (or self-pay) individuals may also submit additional documentation through the Federal IDR portal, although they are not required to provide documentation beyond the information included in the initiation notice, such as the good faith estimate and the billed charges.

The SDR entity must review any documentation submitted by the uninsured (or self-pay) individual or their authorized representative, and a provider or facility, and must make a determination as to whether the provider or facility has provided credible information for each billed item or service to demonstrate that the difference between the billed charge and the expected charge in the good faith estimate reflects the costs of a medically necessary item or service and is based on unforeseen circumstances that could not have reasonably been anticipated by the provider or facility when the good faith estimate was provided. The SDR entity should make this determination separately for each unique billed item or service. HHS is of the view that this helps ensure that the SDR entity review is comprehensive and that the facts and circumstances for each billed charge are considered by the SDR entity. HHS is also of the view that this approach ensures that the uninsured (or self-pay) individual is only billed charges that reflect medically necessary items or services and are based on unforeseen circumstances that could not have reasonably been anticipated by the provider or facility when the good faith estimate was provided.

For any item or service where the billed charge is equal to or less than the expected charge in the good faith estimate, the SDR entity will determine the payment amount to be the billed charge. If the billed charge is higher than the expected charge for an item or service in the good faith estimate and the SDR entity determines the provider or facility has not provided credible information that the difference between the billed charge and the expected charge for the item or service in the good faith estimate reflects the costs of a medically necessary item or service and is based on unforeseen circumstances that could not have reasonably been anticipated by the provider or facility when the good faith estimate was provided, the SDR entity must determine the amount to be paid by the uninsured (or self-pay) individual for the item or service to be equal to the expected charge for the item or service listed in the good faith estimate. If the SDR entity determines that the provider or facility has provided credible information that the difference between the billed charge and the expected charge for the item or service in the good faith estimate reflects the costs of a medically necessary item or service and is based on unforeseen circumstances that could not have reasonably been anticipated by the provider or facility when the good faith estimate was provided, the SDR entity must select as the amount to be paid by the uninsured (or self-pay) individual to be the lesser of: (1) The billed charge; or (2) the median payment amount for the same or similar service in the geographic area, as defined in 45 CFR 149.140(a)(7), that is reflected in an independent database as defined in 45 CFR 149.140(a)(2), or if the amount reflected in the independent database is less than the expected charge in the good faith estimate, the good faith estimate amount.

In cases in which the SDR entity determines that the provider or facility has provided credible information that difference between the billed charge and the expected charge for the item or service in the good faith estimate reflects the costs of a medically necessary item or service that could not have reasonably been anticipated by the provider or facility when the good faith estimate was provided, HHS considered whether to always require the SDR entity to set the payment amount equal to the billed charge. However, HHS is concerned that such an approach may increase the incentive for providers and facilities to inflate their billed charges, particularly in cases where the provider or facility believes they can justify the additional billed charge. Requiring the SDR entity to select as a payment amount the median payment amount for the same or similar item or service in a geographic area, if lower than the billed charge but higher than the expected charge in the good faith estimate, ensures that the uninsured (or self-pay) individual is protected from billed charges that are above the market rate for items or services provided. HHS acknowledges that under this approach an SDR entity can determine a payment amount lower than the original billed charge in circumstances where a provider or facility submits credible information justifying the additional item or service as reflecting a medically necessary item or service and is based on unforeseen circumstances that could not have reasonably been anticipated by the provider or facility when the good faith estimate was provided. HHS also recognizes that such an approach could increase the incentive for the uninsured (or self-pay) individual to initiate patient-provider dispute resolution even in cases where the uninsured (or self-pay) individual believes the extra billed charges to be justified. However, HHS is of the view that PHS Act section 2799B–7 establishes important consumer protections from unexpected billed charges that are substantially in excess of the expected charges in the good faith estimate, even in cases where the difference between the billed charge and the expected charges in the good faith estimate may reflect the costs of a medically necessary item or service and is based on unforeseen circumstances that could not reasonably been anticipated when the good faith estimate was provided. These protections ensure that the uninsured (or self-pay) individual is protected from excessive billed charges even

when such billed charges reflect a medically necessary item or service and are based on unforeseen circumstances that could not reasonably been anticipated when the good faith estimate was provided. In addition, HHS is of the view that the median payment amount is a reasonable payment amount, as the methodology was established to calculate a fair market rate for an item or service, and although this methodology was developed for group health plans and health insurance issuers offering group or individual health insurance coverage, it can also be leveraged to determine whether the billed charge is less than a fair market price, instead of creating separate standards regarding median rates as applied to the QPA and payment amounts applied to the patient provider dispute resolution process.

For new items or services not originally listed on the good faith estimate, if the SDR entity determines the provider or facility did not provide credible information that demonstrates that the billed charge for the new item or service reflects the costs of a medically necessary item or service and is based on unforeseen circumstances that could not have reasonably been anticipated by the provider or facility when the good faith estimate was provided, the SDR entity will determine a payment amount equal to $0. HHS is of the view that PHS Act section 2799B–7 establishes consumer protections for uninsured (or self-pay) individuals in the event they receive surprise charges that are not reflected in the good faith estimate. HHS is of the view that requiring the uninsured (or self-pay) individual to pay for items or services they did not anticipate, absent a determination that such a billed charge is supported by credible information that the billed charge reflects a medically necessary item or service and is based on unforeseen circumstances that could not have reasonably been anticipated by the provider or facility when the good faith estimate was provided, would run counter to the protections intended in PHS Act section 2799B–7. If the SDR entity determines that a provider or facility has provided credible information that the billed charge for new items or services that did not appear on the good faith estimate reflects the costs of a medically necessary item or service that is based on unforeseen circumstances that could not have reasonably been anticipated by the provider or facility when the good faith estimate was provided, then the SDR entity must determine the charge to be paid by the uninsured (or self-pay) individual for the new item or service as the lesser of two payment amounts: (1) The billed charge; or (2) the median payment amount for the same or similar service in the geographic area, as defined in 45 CFR 149.140(a)(7), that is reflected in an independent database as defined in 45 CFR 149.140(a)(2).

After making a determination for all items or services subject to patient-provider dispute resolution, the SDR entity must add together the amounts to be paid for all items and services. As further discussed in section VI.B.8 of this preamble, in cases in which the final amount determined by the SDR entity is lower than the total billed charges, the SDR entity must reduce the final amount by an amount equal to the administrative fee amount paid by the individual (to account for the administrative fee charged to the provider or facility) to calculate the final payment determination amount to be paid by the uninsured (or self-pay) individual for the items or services subject to the SDR entity determination. HHS acknowledges that under this approach, particularly in cases where the provider or facility submits credible information to justify the additional billed charges, the SDR entity may still determine a lower payment amount than the billed charge and the provider or facility would end up paying an administrative fee in a large portion of patient-provider dispute resolution cases. However, HHS is of the view that the intent behind the consumer protections in PHS Act section 2799B–7 is to protect the uninsured (or self-pay) individual from unexpected billed charges that are substantially in excess of the expected charges in the good faith estimate, and as a result, the uninsured (or self-pay) individual should be held harmless in cases where the process results in a lower payment amount.

Once the final payment determination amount has been calculated, the SDR entity must inform the uninsured (or self-pay) individual and the provider or facility using the Federal IDR portal, and depending on the individual's or provider's or facility's preference, electronically or by paper mail, of such determination, along with the SDR entity's justification for making such a determination.

To provide an example of how the payment determination would operate in practice, consider a situation in which an uninsured (or self-pay) individual initiates the dispute resolution process against a provider for services A, B, C, and D. Services A and B were listed on the good faith estimate. The expected charge for service A was higher than the billed charge for service A, the expected charge for service B was lower than the billed charge for service B, and services C and D were not included on the good faith estimate and are thus new services. The difference between the total of the billed charges for services A, B, C, and D and the total expected charges for services A and B (services C and D were new services and not included in the good faith estimate) was determined to be at least $400 more than the amount listed in the good faith estimate, and thus these services were found to be eligible for patient-provider dispute resolution. When the SDR entity reviews the documentation submitted by the provider, because the billed charge for service A is less than the expected charge for service A, the SDR entity determines the amount to be paid to be equal the billed charge for service A. If the SDR entity determines the provider did not provide credible information that the difference between the higher billed charge and the expected charge for service B reflects the costs of a medically necessary item or service and is based on unforeseen circumstances that could not have reasonably been anticipated by the provider or facility when the good faith estimate was provided, then the SDR entity determines the amount to be paid for service B to be equal to the expected charge for service B on the good faith estimate. If the SDR entity determines the provider did provide credible information that billed charges for services C and D reflects the costs of medically necessary items or services and are based on unforeseen circumstances that could not have reasonably been anticipated by the provider or facility when the good faith estimate was provided, the SDR entity would determine the amounts to be paid for services C and D. Due to services C and D being new services, and as a result not having a corresponding expected charges in the good faith estimate, the SDR entity shall determine the payment amounts for services C and D to be the lesser of: (1) The billed charge; or (2) the median payment amount for the same or similar service in that geographic area, as defined in 45 CFR 149.140(a)(7), that is reflected in an independent database as defined in 45 CFR 149.140(a)(2) (had expected charges for services C or D been included in the good faith estimate, the median payment amount for the same or similar service in that geographic area, as defined in 45 CFR 149.140(a)(7), that is reflected in an independent database as defined in 45 CFR 149.140(a)(2) should not be considered if less than the expected charges for the services

contained in the good faith estimate). The SDR entity would then add together all the payment amounts determined for services A, B, C, and D. Due to the uninsured (or self-pay) individual's payment amount being determined to be lower than the initial billed charge, the SDR entity adjusts the final determination amount to reduce it by an amount equal to the uninsured (or self-pay) individual's administrative fee payment, to calculate the final determination amount. The SDR entity then notifies the uninsured (or self-pay) individual and the provider of the determination, the determination amount, and the reasons for the determination and closes the case.

In determining the median payment amount from an independent database, the requirements and methodology set forth in 45 CFR 149.140(c)(3) apply. HHS is of the view that utilizing the same methodology for the calculation of median rates for the QPA, when a plan or issuer does not have sufficient internal information to calculate the QPA, as the methodology for calculating the median payment amounts under the patient-provider dispute resolution process is reasonable and appropriate. This approach will allow an equivalent standard to be applied across multiple instances where the regulation refers to median rates, and will reduce confusion that may result from conflicting standards or definitions. HHS is of the view that creating a separate methodology specifically for the calculation of median payment amounts, using an independent database, as they pertain to the patient-provider dispute resolution process is unnecessary and therefore SDR entities must use this methodology when determining a median payment amount. HHS seeks comment on this methodology as a reasonable way to calculate median payment amounts for purposes of the patient-provider dispute resolution process.

HHS considered whether to allow the SDR entity to have discretion to determine a payment amount lower than the expected charges in the good faith estimate. However, HHS is of the view that such an approach would result in less transparency and predictability for the uninsured (or self-pay) individuals, providers, and facilities regarding the outcome of the patient-provider dispute resolution process. PHS Act sections 2799B–6 and 2799B–7 establishes a backstop for an uninsured (or self-pay) individual that protects them from unexpected bills that substantially exceed the expected charges in the good faith estimate. Given that the provider or facility is required to provide the uninsured (or self-pay) individual with a good faith estimate upon scheduling or upon request prior to furnishing the items or services to the individual. HHS is of the view that the good faith estimate represents charges the uninsured (or self-pay) individual would likely expect to pay for the items or services. Therefore, the good faith estimate represents an appropriate amount to be determined as the payment amount when the uninsured (or self-pay) individual prevails. Additionally, setting the payment amount equal to the good faith estimate protects the uninsured (or self-pay) individual from unexpected billed charges in cases where the extra charges do not reflect the costs of a medically necessary item or service that is based on unforeseen circumstances that could not have reasonably been anticipated by the provider or facility when the good faith estimate was provided while providing predictability to uninsured (or self-pay) individuals, providers and facilities on what to expect from the patient-provider dispute resolution process. However, HHS recognizes that such an approach may encourage providers or facilities to be overinclusive regarding the list of expected charges in the good faith estimate, thus leading to higher good faith estimates than they otherwise would have provided.

HHS seeks comment on the approach for the determination of payment amounts by the SDR entity, including the feasibility of the approach, as well as comment on alternative approaches. HHS also seeks comment on ways to reduce the incentives for providers and facilities to over include items or services on the good faith estimate, and the circumstances, if any, in which requiring the SDR entity to set a payment amount below the expected charges in the good faith estimate would be appropriate. HHS also seeks comment on the use of the median amount for the same or similar service in the geographic area, as defined in 45 CFR 149.140(a)(7), that is reflected in an independent database as defined in 45 CFR 149.140(a)(2), including comment on the feasibility of such an approach, and comment on whether a different methodology should also be considered.

iv. Effects of Determination

Under the Federal IDR process established in PHS Act sections 2799A–1(c)(5)(E) and 2799A–2(c)(5)(D), determinations made by a certified IDR entity are binding upon the parties involved, in the absence of a fraudulent claim or evidence of misrepresentation of facts presented to the IDR entity involved. PHS Act section 2799B–7 establishes a separate dispute resolution process to determine payment amounts made to a provider or facility by an uninsured (or self-pay) individual when the uninsured (or self-pay) individual is billed charges substantially in excess of the expected charges in the good faith estimate; however, the statute is silent regarding the effects of such determinations. HHS is of the view that it is both necessary and appropriate to similarly require that determinations made by SDR entities be binding upon all parties involved, in the absence of a fraudulent claim or evidence of misrepresentation of facts presented to the SDR entity involved regarding such claim. HHS is of the view that use of its general rulemaking authority to establish such requirements is necessary and appropriate in order to implement the provisions of PHS Act section 2799B–7 to ensure the consumer protections established under PHS Act section 2799B–7 operate as intended. Without making the determination binding, the consumer protections established in PHS Act section 2799B–7 would be significantly diminished and the cost for administering the program may outweigh the benefits. Therefore, under 45 CFR 149.620(f)(4), a determination made by an SDR entity will be binding upon the parties involved, in the absence of a fraudulent claim or evidence of misrepresentation of facts presented to the SDR entity regarding such claim, except that the provider or facility may provide financial assistance or agree to an offer for a lower payment amount than the SDR entity's determination, or the individual may agree to pay the billed charges in full, or the uninsured (or self-pay) individual and the provider or facility may agree to a different payment amount. HHS seeks comment on the approach regarding SDR entity determinations being binding, including the feasibility of such approach, as well comment on alternative approaches. HHS also seeks comment on subject of judicial review. PHS Act section 2799A–1(c)(5)(E) requires that determinations not be subject to judicial review, except in a case described in any paragraphs (1) through (4) of section 10(a) of title 9, United States Code. HHS seeks comment on the feasibility or desirability of adopting a similar application for the patient-provider dispute resolution process, as well as comment on alternative approaches.

8. Costs of Patient-Provider Dispute Resolution Process

PHS Act section 2799B–7, as added by the No Surprises Act, directs the

Secretary of HHS to establish an administrative fee ''to participate in the patient-provider dispute resolution process in such a manner as to not create a barrier to an uninsured (or self-pay) individual's access to such process.'' Aside from the administrative fee, discussed later in this section, the No Surprises Act does not specifically address requirements for how the costs for the SDR entity to conduct patient-provider dispute resolution determinations (dispute resolution costs) should be funded.

HHS considered various approaches with respect to how the dispute resolution costs should be treated for the patient-provider dispute resolution process. HHS recognizes that it is important for the SDR entity to be appropriately compensated for providing patient-provider dispute resolution services. HHS considered maintaining a similar fee structure as in the Federal IDR process where the non-prevailing party would be required to pay all the costs of the IDR entity. However, HHS is of the view that requiring an uninsured (or self-pay) individual to pay the entire dispute resolution costs in cases where the provider or facility prevails in the dispute resolution process could be prohibitive for individuals to access the dispute resolution process. HHS is also concerned that requiring a provider or facility to pay dispute resolution costs when they do not prevail could impose a burden on the provider or facility and potentially provide an incentive for the provider or facility to raise prices for uninsured (or self-pay) individuals to account for potential dispute resolution costs or avoid treating uninsured (or self-pay) individuals altogether.

HHS is also of the view that while the patient-provider dispute resolution process is similar to the Federal IDR process in several important ways, the patient-provider dispute resolution process does have unique distinctions. In particular, while in the Federal IDR process, both the providers (and providers of air ambulance services) and the payers can initiate the IDR process, and both parties have an incentive to resolve the dispute, in the patient-provider dispute resolution process only the uninsured (or self-pay) individual can initiate the dispute resolution process, and HHS is concerned that the provider or facility would not have the same incentive to participate in the dispute resolution process as the uninsured (or self-pay) individual. Similarly, there will likely be a significant imbalance in both power and knowledge between the provider or facility and the uninsured (or self-pay) individual initiating the dispute resolution process. As a result, HHS is of the view that a different approach to dispute resolution costs is needed for the patient-provider dispute resolution process. As a result, HHS determined that an approach where HHS would pay dispute resolution costs by directly contracting with SDR entities is the appropriate approach, as it would address the concerns discussed earlier in this section of the preamble. HHS is also of the view that such an approach will streamline the patient-provider dispute resolution process and minimize potential burdens on uninsured (or self-pay) individuals, and providers and facilities.

HHS is adopting an approach for the patient-provider dispute-resolution process in which HHS will pay dispute resolution costs through contracts with SDR entities. Such an approach ensures that the uninsured (or self-pay) individual would not be required to pay dispute resolution costs, and as a result, such costs would not pose a barrier to accessing the dispute resolution process. Adopting such an approach in which HHS pays the dispute resolution costs would minimize the burdens placed on uninsured (or self-pay) individuals and on providers or facilities, and reduce the incentives for providers and facilities to increase prices or restrict an uninsured (or self-pay) individual's access to needed care. Adopting an approach where the individual would not be required to bear the dispute resolution costs would help ensure that such costs would not be a barrier to the uninsured (or self-pay) individual's access to the dispute resolution process.

Aside from dispute resolution costs, PHS Act section 2799B–7 requires that the Secretary of HHS establish an administrative fee to participate in the patient-provider dispute resolution process in such a manner as to not create a barrier to an uninsured (or self-pay) individual to participate in such process. HHS is aware that not requiring the uninsured (or self-pay) individual to pay dispute resolution costs could lead to overutilization of the patient-provider dispute resolution process; however, this concern is mitigated by limiting the availability of the patient-provider dispute resolution only to cases where the total billed charge for items or services per provider or facility are billed in excess of the expected charges by at least $400 more than the amount listed in the good faith estimate, as discussed in section VI.B.2 of this preamble. In addition, HHS is of the view that requiring parties to the dispute resolution process to pay an administrative fee to offset some of the Federal costs for implementing the patient-provider dispute resolution program is appropriate. Such a requirement is also similar to the Federal IDR process, which requires all parties to pay an administrative fee to cover Federal costs; however, under that process, the fee is required to equal the estimated costs to the Federal Government, while in the patient-provider dispute resolution process the administrative fee is required to be established so that it would not create a burden for the uninsured (or self-pay) individual to participate in the dispute resolution process.

HHS intends to assess an administrative fee on the non-prevailing party (providers, facilities, and uninsured (or self-pay) individuals) to the patient-provider dispute resolution process. For purposes of the patient-provider dispute resolution process, the prevailing party means the provider or facility when the SDR entity determines the total amount to be paid to be equal to the total billed charges, whereas the prevailing party means the uninsured (or self-pay) individual when the SDR entity determines the total amount to be paid to be less than the total billed charges. Upon the SDR entity determination, if the uninsured (or self-pay) individual is the prevailing party, the SDR entity would apply a reduction, equal to the administrative fee amount paid by the individual, to the final determination amount to be paid by the individual for the items or services. HHS is of the view that requiring the non-prevailing party to pay the entire administrative fee (either in a payment made directly to the SDR entity in the case of the uninsured (or self-pay) individual, or in a reduction in the final payment determination amount as in the case of the provider or facility) ensures that both parties are treated the same with regards to the administrative fee assessed. Additionally, requiring only the non-prevailing party to pay the administrative fee will help ensure that the party that prevails in dispute resolution is not penalized for participating in the process. Under this approach, the uninsured (or self-pay) individual who is the initiating party in the patient-provider dispute resolution process will pay the administrative fee at the process initiation through the SDR entity. HHS is of the view that since the uninsured (or self-pay) individual is the initiating party, waiting for the provider or facility to submit the administrative fee prior to the SDR entity making a determination may result in undue delays to the

process. In cases in which the uninsured (or self-pay) individual prevails in dispute resolution, the SDR entity would apply a reduction equal to the administrative fee paid by the individual to the final determination amount to be paid by the individual for the items or services. HHS is of the view that requiring the provider or facility to pay the administrative fee to the uninsured (or self-pay) individual through a reduction in the final determination amount to be paid is the appropriate approach as it simplifies the number of transactions, rather than requiring the provider or facility to provide a payment directly to the SDR entity. This approach also ensures that in cases in which the uninsured (or self-pay) individual prevails, the SDR entity will reduce the amount the uninsured (or self-pay) individual ultimately is required to pay for an item or services by the amount of the administrative fee paid so that it is not left to the provider or facility to apply the reduction equal to the administrative fee paid to the final payment amount. In cases where the provider or facility prevails in dispute resolution, the SDR entity would not reduce the final payment amount by an amount equal to the amount of the administrative fee paid by the uninsured (or self-pay) individual.

In cases described in section VI.B.7.i of this preamble where the parties to dispute resolution agree to settle the payment amount prior to the SDR entity making a determination, both parties will be responsible for paying half the amount of the administrative fee. In this case, the provider or facility will document in the settlement notice described in section VI.B.7.i of this preamble that it has reduced the settlement amount by at least half of the administrative fee amount paid by the uninsured (or self-pay) individual.

HHS intends to establish an administrative fee in guidance in a manner that will not create a barrier to an uninsured (or self-pay) individual's access to the patient-provider dispute resolution process. In setting the fee HHS is considering expected costs to HHS for operating the patient-provider dispute resolution program, including contractor costs, and costs to HHS for utilizing the Federal IDR portal for patient provider dispute resolution cases. However, due to the requirements in PHS Act section 2799B–7 that such administrative fee must not pose a burden to participate for uninsured (or self-pay) individual to participate in the patient-provider dispute resolution process, HHS is of the view that it is necessary and appropriate to limit the size of the administrative fee. As a result, HHS expects the fee to be no more than $25, which HHS believes would allow HHS to offset some of the costs of operating the dispute resolution process while keeping the administrative fee low enough to ensure uninsured (or self-pay) individuals are able to access the dispute resolution process. HHS considered whether to base the administrative fee on annual household income but is concerned that such an approach would require an uninsured (or self-pay) individual to submit financial documentation to verify their income which could significantly increase complexity to initiate the dispute resolution process and could create additional burdens for an uninsured (or self-pay) individual to participate. HHS intends to evaluate patient-provider dispute resolution case volume, contract costs, and other Federal costs for the program and may adjust this fee in subsequent years through guidance to ensure that the fee continues to mitigate overutilization of the patient-provider dispute resolution process, offsets some of HHS's costs of operating the dispute resolution process, and also does not pose a burden for uninsured (or self-pay) individuals regarding participation in the process. HHS seeks comment on this approach, including comment on whether the administrative fee should be higher or lower, the feasibility of the approach to collecting the administrative fee, including comment on alternative approaches that HHS should consider. HHS also seeks comment on ways to ensure public awareness of the dispute resolution process, including the administrative fee and how payments are handled, as well as comment on potential unintended or disparate impacts of administrative costs on underserved and underrepresented populations.

9. Deferral to State Patient-Provider Dispute Resolution Processes

The No Surprises Act establishes strong consumer protections for uninsured (or self-pay) individuals to have access to the patient-provider dispute resolution process in cases in which billed charges substantially exceed expected charges in the good faith estimate. HHS is of the view that PHS Act section 2799B–7 operates in such a way that all uninsured (or self-pay) individuals, regardless of state, are required to have at least the minimum protections set forth in the statute. However, HHS has considered circumstances where states may wish to develop their own processes for resolving disputes between uninsured (or self-pay) individuals and providers or facilities. HHS is of the view that when a state law is in effect that provides a process for resolving disputes between an uninsured (or self-pay) individual and a provider or facility that meets or exceeds the consumer protections contained in PHS Act section 2799B–7, such a process should continue to apply. In addition, HHS believes that such an approach is consistent with other provisions of the No Surprises Act such as allowing allow the application of a state law established to determine the total amount payable under such a plan, coverage, or issuer for certain emergency services. HHS is adding new 45 CFR 149.620(h) to establish a process by which HHS will determine whether a state patient-provider dispute resolution process provides at least the same level of consumer protections as does the Federal process. HHS will communicate with the state and determine whether a state law provides for such a dispute resolution process, and ensure that such process meets or exceeds certain minimum Federal requirements. If HHS determines that the state has in effect a state law that meets or exceeds the minimum Federal requirements, then HHS will defer to the state process. In such case the patient-provider dispute resolution process operated by HHS will not be available in that state. As further discussed in section VI.B.5 of this preamble, as part of the contracting and certification process for an SDR entity, the entity must demonstrate the ability to operate nationwide, including the ability to operate in states where a state process is terminated so that uninsured (or self-pay) individuals continue to have access to a process that meets Federal standards. HHS will direct any patient-provider dispute resolution requests received by HHS from uninsured (or self-pay) individuals in that state to the state process to adjudicate the dispute resolution initiation request according to the state process. HHS will assess such state process for compliance with the minimum Federal standards to ensure any such state process includes the same or greater level of consumer protection as would apply under the Federal patient-provider dispute resolution process. If HHS determines that such state process meets or exceeds the minimum Federal standards, HHS will discuss such determination with the state as well as notify the state in writing of such determination.

HHS considered what minimum requirements a state law must include in order for HHS to determine that the state's law is at least as consumer

protective as the protections contained in the No Surprises Act. At a minimum, the state process should: (1) Be binding, unless the provider or facility offers for the uninsured (or self-pay) individual to pay lower amount than the determination amount; (2) take into consideration a good faith estimate, that meets the minimum standards established under 45 CFR 149.610, provided by the provider or facility to the uninsured (or self-pay) individual; (3) have a fee to participate in the patient-provider dispute resolution process that is equal to or lower than the Federal administrative fee; and (4) have in place conflict-of-interest standards that at a minimum meet the requirements set forth in 45 CFR 149.620(d) and (e)(3).

In order to ensure that a state process continues to meet or exceed the consumer protections contained in the No Surprises Act, HHS will review changes to the state process on an annual basis (or at other times if HHS receives information from the state that would indicate the state process no longer meets the minimum Federal requirements) to ensure the state process continues to meet or exceed the minimum Federal standards. HHS is of the view that having a process to reassess state dispute resolution processes is important for ensuring that uninsured (or self-pay) individuals receive at least the same level of protection as the Federal standard. In the event that the state process is terminated, or HHS determines that it no longer meets the minimum Federal requirements, HHS will make the Federal process available to ensure that ensures the state's residents have access to a dispute resolution process that meets the minimum Federal requirements.

Although the Federal process will be available for uninsured (or self-pay) individuals except in states where HHS has made a determination that the state has established a State process that includes the same or greater level of consumer protection as would apply under the Federal process, HHS recognizes that some states may have in place other programs that seek to resolve payment disputes between uninsured (or self-pay) individuals and providers or facilities that do not meet the minimum Federal standards and thus would not take the place of the Federal dispute resolution process. However, HHS notes that nothing would prevent the uninsured (or self-pay) individual from voluntarily choosing to use such state programs to resolve a payment dispute instead of utilizing the Federal dispute resolution process. HHS seeks comment on the approach to allow the HHS to defer to a state established patient-provider dispute resolution process that meets certain minimum Federal standards, including the feasibility and appropriateness of such approach, and whether additional minimum Federal standards should be considered.

10. Extension of Time Periods for Extenuating Circumstances

Similar to the provisions set forth in section III.D.8 in this preamble for the Federal IDR process under Code section 9816(c)(9), ERISA section 716(c)(9), PHS Act section 2799A–1(c)(9), and codified at 26 CFR 54.9816–8T(g), 29 CFR 2590.716–8(g), and 45 CFR 149.510(g), the time periods specified in these interim final rules (other than the time for payment of the administrative fees discussed in section VI.B.4 of this preamble) may be extended in the case of extenuating circumstances at HHS' discretion on a case-by-case basis if the extension is necessary to address delays due to matters beyond the control of the parties or for good cause. Such extension may be necessary if, for example, a natural disaster impedes efforts by individuals, providers, and facilities to comply with the terms of these interim final rules. Additionally, for the extension to be granted, the parties must attest that prompt action will be taken to ensure that the payment determination under this section is made as soon as administratively practicable. The parties may request an extension by submitting a request for an extension due to extenuating circumstances, such as a natural disaster or other circumstances impeding efforts to comply with the terms of these interim final rules, through the Federal IDR portal if the extension is necessary to address delays due to matters beyond the control of the parties or for good cause.

11. Applicability of the Patient-Provider Dispute Resolution Process

The provisions in PHS Act section 2799B–7 require the patient-provider dispute resolution process to be established by the Secretary of HHS no later than January 1, 2022. Consistent with this statutory provision, the requirements under 45 CFR 149.620 are applicable to uninsured (or self-pay) individuals; providers, facilities, and providers of air ambulance services; and SDR entities, beginning on or after January 1, 2022. The interim final rules regarding SDR entity certification at 45 CFR 149.620(a) and 45 CFR 149.620(d), are applicable beginning on October 7, 2021 so that HHS can begin certifying SDR entities before the patient-provider dispute resolution process becomes applicable.

VII. Waiver of Proposed Rulemaking

Code section 9833, ERISA section 734, and PHS Act section 2792 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.

Under the Administrative Procedure Act (APA) (5 U.S.C. 551 *et seq.*), a general notice of proposed rulemaking is not required when an agency for good cause finds 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. 5 U.S.C. 553(b)(B). In addition, section 553(d) ordinarily requires a 30-day delay in the effective date of a final rule from the date of its publication in the **Federal Register**. This 30-day delay in effective date can be waived, however, if an agency finds good cause to support an earlier effective date. Finally, Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996 (also known as the Congressional Review Act or CRA) requires a delay in the effective date for major rules unless an agency finds good cause that notice and public procedure are impracticable, unnecessary, or contrary to the public interest, in which case the rule shall take effect at such time as the agency determines. 5 U.S.C. 801(a)(3), 808(2).

The Secretaries and the 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 a full public notice and comment process has been completed and find that there is good cause to waive the delay in effective date for certain provisions of these interim final rules.

The No Surprises Act was enacted on December 27, 2020, as title I of Division BB of the Consolidated Appropriations Act, 2021. The IDR and internal claims appeals and external review provisions generally apply for plan years (in the individual market, policy years) beginning on or after January 1, 2022. The provisions related to protections for the uninsured generally apply beginning on 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. The provisions related to the certification of IDR and SDR entities, as described in the Applicability Dates section of this final rule, apply beginning October 7, 2021.

These interim final rules require plans, issuers, providers, facilities, and providers of air ambulance services to follow a certain process in determining out-of-network payment amounts for certain specified services. These regulations are intended to work in concert with the protections against surprise billing already instituted in the July 2021 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 premium or contribution rates and in making other changes to benefit designs. In some cases, issuers will need time to secure approval for required changes in advance of plan or policy years.

These interim final rules also set up certification requirements for IDR entities and requirements to which they must adhere in selecting payment offers. IDR entities will need time to acquire the necessary expertise and evidence of qualification to apply for certification in order to be prepared to conduct payment determinations for plan years beginning on or after January 1, 2022.

The Departments and OPM anticipate that 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, will allow plans and issuers to account for the regulations as they finalize rates and plan offerings and will allow IDR entities to seek certification and be available to take part in the Federal IDR process when these interim final rules go into effect.

Health plans and issuers, and providers, facilities and providers of air ambulance services, require these rules to be in place to determine the out-of-network rates for emergency services, services by out-of-network providers at in-network facilities in certain circumstances, and air ambulance services. Without these final rules, providers, facilities and providers of air ambulance services will not be able to resort to the Federal IDR process (and are no longer able to balance bill patients), leaving the possibility that they will be undercompensated for their services. Such undercompensation could threaten the viability of these providers, facilities and providers of air ambulance services. This in turn, could lead to participants, beneficiaries and enrollees not receiving needed medical care, undermining the goals of the No Surprises Act. Additionally, and for the same reasons, the failure to promulgate this rule in a timely fashion could lead to additional industry consolidation, potentially driving health costs higher.

The Departments considered whether they could exercise enforcement discretion while a rule was proposed and then finalized. However, the No Surprises Act requires that the government set up and administer a Federal IDR process to determine out-of-network rates. Therefore, the Department must establish set rules for this process, including for the certification of certified IDR entities, in order that certified IDR entities, rather than the Departments, may determine out-of-network rates as contemplated by the No Surprises Act.

These interim final rules place new requirements on providers, facilities and providers of air ambulance services regarding how they must initiate open negotiation and the Federal IDR process, as well as what information they must provide to certified IDR entities when engaging in the Federal IDR process. Providers, facilities, and providers of air ambulance services require time to implement these new requirements to ensure compliance by January 1, 2022.

In addition to the requirements for the Federal IDR process, these interim final rules require providers and facilities to furnish a good faith estimate of expected charges upon request or upon scheduling an item or service. Providers and facilities are required to inquire if an individual is enrolled in a group health plan, group or individual health insurance coverage, or a Federal health care program, and if enrolled in such plan or coverage, if the individual is seeking to have a claim for such item or service submitted to such plan or coverage. In the case that the individual is enrolled in such a plan or coverage (and is seeking to have a claim for such an item or services submitted to such plan or coverage), PHS Act section 2799B–6 requires that the provider or facility furnish the good faith estimate to the individual's plan or the issuer of the coverage to inform the advanced explanation of benefits that plans and issuers are required to provide a participant, beneficiary or enrollee under PHS section 2799A–1(f), Code section 9816(f), and ERISA section 716(f).[99] In the case that the individual requesting or scheduling a good faith estimate for an item or service is uninsured (or self-pay), these interim final rules at 45 CFR 149.610 require providers and facilities to furnish the good faith estimate to the individual. Providers and facilities will need time to implement requirements for furnishing good faith estimates to uninsured (or self-pay) individuals and time to develop processes for sharing and receiving information required for the good faith estimate with co-providers and co-facilities. Issuing these rules as interim final rules, rather than as a notice of proposed rulemaking, should allow providers and facilities to account for the regulations as they implement requirements to inquire about an individual's enrollment in

[99] As stated in the August 20, 2021 FAQs issued by the Departments, the Departments have received feedback from the public about the challenges of developing the technical infrastructure necessary for providers and facilities to transmit to plans and issuers starting January 1, 2022 the good faith estimates required under PHS Act section 2799B–6, which plans and issuers must then include in the advanced explanation of benefits. Accordingly, until rulemaking to fully implement this requirement to provide such a good faith estimate to an individual's plan or coverage is adopted and applicable, HHS will defer enforcement of the requirement that providers and facilities provide good faith estimate information for individuals enrolled in a health plan or coverage and seeking to submit a claim for scheduled items or services to their plan or coverage. Additionally, stakeholders have requested that the Departments delay the applicability date of Code section 9816(f), ERISA section 716(f), and PHS Act section 2799A–1(f) until the Departments have established standards for the data transfer between providers and facilities and plans and issuers and have given enough time for plans and issuers and providers and facilities to build the infrastructure necessary to support the transfers. The Departments agree that compliance with these sections is likely not possible by January 1, 2022, and therefore intend to undertake notice and comment rulemaking in the future to implement these provisions, including establishing appropriate data transfer standards. Until that time, the Departments will defer enforcement of the requirement that plans and issuers must provide an advanced explanation of benefits. HHS will investigate whether additional interim solutions for insured consumers are feasible. The Departments note that any rulemaking to fully implement Code section 9816(f), ERISA section 716(f), and PHS Act sections 2799A–1(f) and 2799B–6(2)(A) will include a prospective applicability date that provides plans, issuers, providers, facilities, and providers of air ambulance services with a reasonable amount of time to comply with new requirements. HHS encourages states that are primary enforcers of these requirements with regard to providers and issuers to take a similar enforcement approach, and will not determine that a state is failing to substantially enforce these requirements if it takes such an approach. See FAQs about Affordable Care Act and Consolidated Appropriations Act, 2021 Implementation Part 49 (August 20, 2021), available at *https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-49.pdf* and *https://www.hhs.gov/guidance/document/faqs-about-affordable-care-act-and-consolidated-appropriations-act-2021-implementation.*

health care coverage and to furnish a good faith estimate to an uninsured (or self-pay) individual when these interim final rules goes into effect.

These interim final rules provide further protections for uninsured (or self-pay) individuals by requiring the Secretary of HHS to establish a process (patient-provider dispute resolution) under which an uninsured (or self-pay) individual may seek a determination from a certified dispute resolution entity for billed charges in excess of the good faith estimate. These interim final rules also place new requirements on uninsured (or self-pay) individuals, and providers or facilities regarding how they must initiate patient-provider dispute resolution, what information they must provide to dispute resolution entities for the dispute resolution process, and costs associated with patient-provider dispute resolution. Similar to the Federal IDR process, these interim final rules also establish certification requirements for SDR entities and requirements to which they must adhere in determining payment amounts. SDR entities will need time to acquire the necessary expertise, and enter into a contract with HHS to provide patient-provider dispute resolution. Issuing these rules as interim final rules, rather than as a notice of proposed rulemaking and waiving the delay in effective date for the provisions related to SDR certification will allow SDR entities to account for the regulations as they seek to contract with HHS and be available for patient-provider dispute resolution determinations when the related provisions in these interim final rules go into effect. Further, uninsured (or self-pay) individuals, providers, and facilities will need to understand what is required of them to engage in the patient-provider dispute resolution process when the interim final rules go into effect.

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 these interim final rules become effective, and that it is in the public interest to promulgate interim final rules. Further, for the same reasons as authorized by section 808(2) of the CRA, the Departments find it is impracticable and contrary to the public interest not to waive the delay in effective date for certain provisions of this IFC under section 801 of the CRA. Therefore, the Departments find there is good cause to waive the CRA's delay in effective date pursuant to section 808(2) of the CRA and establish certain policies in this IFC applicable as of the date of display at the Office of the Federal Register.

VIII. Economic Impact and Paperwork Burden

A. Summary

The Departments and OPM 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 Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health, and safety effects; distributive impacts; and equity). Executive Order 13563 emphasizes the importance of quantifying costs and benefits, reducing costs, harmonizing rules, and promoting flexibility.

Under Executive Order 12866, ''significant'' regulatory actions are subject to review by OMB. Section 3(f) of the Executive Order 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, 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. Based on the Departments' estimates, OMB's Office of Information and Regulatory Affairs has determined this rulemaking is ''economically significant'' as measured by the $100 million threshold, and hence also a major rule under Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996 (also known as the Congressional Review Act). Accordingly, the Departments have prepared a Regulatory Impact Analysis that, to the best of our ability, presents the costs and benefits of this rulemaking.

1.1. Need for Regulation

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 or facility that, generally unbeknownst to the participant, beneficiary, or enrollee, is a nonparticipating provider or facility with respect to the individual's coverage. In the context of this discussion, medical services include air ambulance services. Surprise bills usually occur in situations where a patient is unable to choose a health care provider, emergency facility, or provider of air ambulance services. When they are unable to choose, they are unable to ensure they only receive care from providers or emergency facilities participating in their plan's or coverage's network.

Surprise bills can cause significant financial hardship and cause individuals to forgo care. 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.[100] A project carried out by Vox, a news and opinion website, which collected emergency department medical bills reported instances of accident victims who received care at out-of-network hospitals and received bills of over $20,000.[101] 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

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

[101] 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.

populations.[102] Communities experiencing poverty and other social risk factors are particularly impacted as surprise medical bills can negatively affect consumers' abilities to eliminate debt and create wealth, and ultimately can impact a family for generations.[103] 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.[104]

It has become common practice in the health care system for plans, issuers, and FEHB carriers to negotiate with health care providers. Plans, issuers, and FEHB carriers offer preference to these providers by listing them as ''in-network providers,'' and in return, providers charge discounted rates to the plans, issuers, and FEHB carriers.[105] Joining a plan's, issuer's, or FEHB carrier's network assures providers of patient volume in exchange for lower reimbursements. However, for specialties for which consumers typically do not shop, such as services rendered by emergency departments, patient volume does not depend on whether specific providers are in-network.[106] There is less of an incentive for these providers to engage in negotiations with plans, issuers, and FEHB carriers.[107] One study looked at claims data from a large commercial issuer for the period 2010–2016 and found that over 39 percent of emergency department visits to in-network hospitals resulted in an out-of-network bill, and 37 percent of inpatient admissions to in-network hospitals resulted in at least one out-of-network bill.[108]

Since the passage of the Emergency Medical Treatment and Labor Act (EMTALA) in 1986, Medicare-participating hospitals are required to provide emergency services, regardless of patients' abilities to pay.[109] Because of emergency physicians' legal obligation under EMTALA, and the inability of patients to make treatment decisions, including by selecting providers, in emergency settings, there are fewer incentives for emergency providers to contract with issuers.[110] A large portion of emergency providers' costs are distributed to patients with health benefits, providing justification for plans, issuers, and FEHB carriers to offer smaller networks. Consequently, in recent years, plans, issuers, and FEHB carriers have been offering narrower networks alongside larger discounts, resulting in lower premiums but with fewer in-network options for consumers.[111]

An additional factor contributing to the current environment is the increasing participation of private equity groups in the health care market through the acquisition of physician groups.[112] Anesthesiology, emergency medicine, family practice, and dermatology were the most common medical specialties in acquired physician groups.[113] The private equity business model often centers on risky investments with short-term horizons. These firms often take on large amounts of debt to acquire an asset, then introduce structural and operational changes to extract value or increase revenue growth potential in the aim of selling the asset for a higher valuation.[114] These firms often take on legally complex governance structures designed to protect the private equity firms from regulatory liability.[115] By 2013, two private equity firms accounted for 30 percent of the physician staffing market.[116] One study found that in 2017, hospitals acquired by private equity groups accounted for 7.5 percent of all nongovernmental hospitals and 11 percent of all discharges from nongovernmental hospitals.[117] Private equity groups are also involved in air ambulance transport services. In 2018, two of the three

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[102] 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.*

[103] 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/.*

[104] 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 health care for underserved populations. MedCity News (February 22, 2021). *https://medcitynews.com/2021/02/confronting-disparities-in-access-to-healthcare-for-underserved-populations-in-2021/.*

[105] Greaney, Thomas. ''Surprise Billing: a Window into the U.S. Health Care System.'' American Bar Association. (September 2020). *https://www.americanbar.org/groups/crsj/publications/human_rights_magazine_home/health-matters-in-elections/surprise-billing/#:~:text=The%20%E2%80%9Csurprise%E2%80%9D%20typically%20occurs%20when,the%20difference%20between%20what%20the.*

[106] Cooper, Z. et al. ''Surprise! Out-of-Network Billing for Emergency Care in the United States.'' National Bureau of Economic Research: Working Paper 23623 (July 2017). *https://www.nber.org/papers/w23623.*

[107] Greaney, Thomas. ''Surprise Billing: a Window into the U.S. Health Care System.'' American Bar Association. (September 2020). *https://www.americanbar.org/groups/crsj/publications/human_rights_magazine_home/health-matters-in-elections/surprise-billing/#:~:text=The%20%E2%80%9Csurprise%E2%80%9D%20typically%20occurs%20when,the%20difference%20between%20what%20the.*

[108] 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.

[109] Centers for Medicare and Medicaid Services. ''Emergency Medical Treatment & Labor Act (EMTALA).'' (March 2021). *https://www.cms.gov/Regulations-and-Guidance/Legislation/EMTALA#:~:text=In%201986%2C%20Congress%20enacted%20the,regardless%20of%20ability%20to%20pay.*

[110] Brannon, Ike and David Kemp. ''The Potential Pitfalls of Combatting Surprise Billing.'' CATO Institute. (Fall 2019). *https://www.cato.org/sites/cato.org/files/2019-10/regulation-v42n3-1-updated.pdf.*

[111] Brannon, Ike and David Kemp. ''The Potential Pitfalls of Combatting Surprise Billing.'' CATO Institute. (Fall 2019). *https://www.cato.org/sites/cato.org/files/2019-10/regulation-v42n3-1-updated.pdf.* See also Polsky, D, Cidav Z., Swanson A. ''Marketplace Plans With Narrow Physician Networks Feature Lower Monthly Premiums Than Plans With Larger Networks.'' Health Affairs. (October 2016). *https://www.healthaffairs.org/doi/10.1377/hlthaff.2016.0693.*

[112] Zhu, Jane M., Lynn M. Hua, and Daniel Polsky. ''Private Equity Acquisitions of Physician Medical Groups across Specialties, 2013–2016.'' 323 *JAMA* 7 (2020): 663–665.

[113] Zhu, Jane M., Lynn M. Hua, and Daniel Polsky. ''Private Equity Acquisitions of Physician Medical Groups across Specialties, 2013–2016.'' 323 *JAMA* 7 (2020): 663–665.

[114] Konda S, Francis J, Motaparthi K, Grant-Kels JMGroup for Research of Corporatization and Private Equity in Dermatology. ''Future Considerations for Clinical Dermatology in the Setting of 21st Century American Policy Reform: Corporatization and the Rise of Private Equity in Dermatology.'' *Journal of the American Academy of Dermatology,* 2019;81(1):287–296.e8. *https://www.jaad.org/article/S0190-9622(18)32667-7/fulltext.*

[115] Appelbaum E, Batt R. ''Private Equity Buyouts in Healthcare: Who Wins, Who Loses?'' Institute for New Economic Thinking. (March 2020). *https://www.ineteconomics.org/research/research-papers/private-equity-buyouts-in-healthcare-who-wins-who-loses.*

[116] Appelbaum E, Batt R. ''Private Equity Buyouts in Healthcare: Who Wins, Who Loses?'' Institute for New Economic Thinking. (March 2020). *https://www.ineteconomics.org/research/research-papers/private-equity-buyouts-in-healthcare-who-wins-who-loses.*

[117] Offodile II, Anaeze C., et al. ''Private Equity Investments in Health Care: An Overview of Hospital and Health System Leveraged Buyouts, 2003–17.'' *Health Affairs,* Vol. 40(5), (May 2021). *https://www.healthaffairs.org/doi/10.1377/hlthaff.2020.01535.*

largest air ambulance transport companies were owned by private equity firms.[118]

In addition, some private equity firms may choose not to participate in plans' and issuers' networks in order to reap higher payments.[119] Private equity-owned hospitals have been found to charge higher prices.[120] According to one study, 204 private equity-owned hospitals had an annual net income averaging $8.5 million prior to their acquisition. After private equity groups purchased the hospitals, their net income rose to $12.9 million.[121] This represents a 52 percent increase in net income, on average. Another study found that the entry of two private equity firms into the hospital sector increased out-of-network billing rates by more than 30 and 80 percentage points, respectively, from 2011 to 2015.[122] The study also found that the payments that one private equity firm received for emergency department physicians from insurers increased by 122 percent and patient cost-sharing payments to emergency department (ED) physicians increased by 83 percent. Furthermore, some hospitals and providers do not accept private health insurance coverage. For example, one study found that 5 percent of physicians participated in cash-only practices in 2020.[123] When billing out-of-network, these providers who choose to remain out-of-network can charge much higher fees than what public or private payers typically allow.[124]

The Departments and OPM seek comment on how private equity ownership structures may be affected by the Federal IDR process.

Surprise billing represents a market failure, as often patients either do not have the option to seek care elsewhere or must make decisions based on incomplete information about the network status of providers and associated costs.[125] This market failure is exacerbated by the fact that patients must rely on the guidance of the provider, insurer, or plan, which have financial incentives that can be contrary to the patient's financial interests.[126]

As of February 28, 2021, 18 states had implemented comprehensive legislation [127] regulating surprise billing, 15 states had implemented limited legislation, and 14 states had implemented an IDR system regarding out-of-network payments.[128] However, even in states that have passed legislation, states cannot regulate health plans that are self-insured by employers.[129]

On December 27, 2020, the Consolidated Appropriations Act, 2021 (CAA), which includes the No Surprises Act, was enacted.[130] 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 bills arise most frequently. The No Surprises Act added new provisions applicable to group health plans and health insurance issuers offering group or individual health insurance coverage in Subchapter B of chapter 100 of the Code, Part 7 of ERISA, and Part D of title XXVII of the PHS Act. Section 102 of the No Surprises Act added Code section 9816, ERISA section 716, and PHS Act section 2799A–1, which contain limitations on cost sharing and requirements regarding the timing of initial payments for emergency services furnished by nonparticipating providers and emergency facilities, and for nonemergency services furnished by nonparticipating providers at certain participating health care facilities. Section 102 of the No Surprises Act also added 5 U.S.C. 8902(p) requiring FEHB carriers, facilities, and providers to comply with requirements described in applicable provisions with respect to FEHB covered individuals. Section 103 of the No Surprises Act amended Code section 9816, ERISA section 716, and PHS Act section 2799A–1 to establish a Federal IDR process that allows plans and issuers and nonparticipating providers and facilities to resolve disputes regarding out-of-network rates. Section 105 of the No Surprises Act created Code section 9817, ERISA section 717, and PHS Act section 2799A–2, which contain limitations on cost sharing and requirements for the timing of initial payments for nonparticipating providers of air ambulance services and allow plans and issuers and providers of air ambulance services to access the Federal IDR process described in Code section 9816, ERISA section 716, and PHS Act section 2799A–1. The No Surprises Act provisions that apply to health care providers and facilities, and providers of air ambulance services, such as 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.

On July 13, 2021, the Departments and OPM published the July 2021 interim final rules.[131] The July 2021 interim final rules implemented provisions of the No Surprises Act to 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.

These interim final rules build upon the protections in the July 2021 interim

[118] Appelbaum E, Batt R. ''Private equity buyouts in healthcare: Who wins, who loses?'' Institute for New Economic Thinking. (March 2020). *https://www.ineteconomics.org/research/research-papers/private-equity-buyouts-in-healthcare-who-wins-who-loses.*

[119] Cooper, Zack, Fiona Scott Morton, and Nathan Shekita. ''Surprise! Out-Of-Network Billing for Emergency Care in the United States.'' 128 Journal of Political Economy 9. (2020).

[120] Bruch, Joseph D., Suhas Gondi, and Zirui Song. ''Changes in Hospital Income, Use, and Quality Associated with Private Equity Acquisition.'' 180 JAMA Internal Medicine 11 (2020): 1428–1435.

[121] Bruch, Joseph D., Suhas Gondi, and Zirui Song. ''Changes in Hospital Income, Use, and Quality Associated with Private Equity Acquisition.'' 180 *JAMA Internal Medicine* 11 (2020): 1428–1435.

[122] Cooper, Zack, Fiona Scott Morton, and Nathan Shekita. ''Surprise! Out-Of-Network Billing for Emergency Care in the United States.'' 128 Journal of Political Economy 9. (2020).

[123] Oliver, Eric. ''What Percent Of Physicians are in a Cash-Only Practice?—9 Stats.'' *Becker's ASC Review* (2021). *https://www.beckersasc.com/benchmarking/what-percent-of-physicians-are-in-a-cash-only-practice-9-stats.html.*

[124] Cooper, Zack, Fiona Scott Morton, and Nathan Shekita. ''Surprise! Out-Of-Network Billing for Emergency Care in the United States.'' 128 Journal of Political Economy 9. (2020).

[125] Assistant Secretary for Planning and Evaluation. ''HHS Secretary's Report on: Addressing Surprise Medical Billing.'' Office of Health Policy. (July 2020). *https://aspe.hhs.gov/system/files/pdf/263871/Surprise-Medical-Billing.pdf.*

[126] Assistant Secretary for Planning and Evaluation. ''HHS Secretary's Report on: Addressing Surprise Medical Billing.'' Office of Health Policy. (July 2020). *https://aspe.hhs.gov/system/files/pdf/263871/Surprise-Medical-Billing.pdf.*

[127] The states that have passed comprehensive legislation include California, Colorado, Connecticut, Florida, Georgia, Illinois, Maine, Maryland, Michigan, New Hampshire, New Jersey, New Mexico, New York, Ohio, Oregon, Texas, Virginia, and Washington. The Commonwealth Fund. ''State Balance-Billing Protections.'' (February 2021). *https://www.commonwealthfund.org/sites/default/files/2021-03/Hoadley_state_balance_billing_protections_table_02052021.pdf.*

[128] The states that have passed limited legislation include Arizona, Delaware, Indiana, Iowa, Massachusetts, Minnesota, Mississippi, Missouri, Nebraska, Nevada, North Carolina, Pennsylvania, Rhode Island, Vermont, and West Virginia. The Commonwealth Fund. ''State Balance-Billing Protections.'' (February 2021). *https://www.commonwealthfund.org/sites/default/files/2021-03/Hoadley_state_balance_billing_protections_table_02052021.pdf.*

[129] The Commonwealth Fund. ''State Balance-Billing Protections.'' (November 2020). *https://www.commonwealthfund.org/sites/default/files/2020-12/Hoadley_state_balance-billing_protections_11302020.pdf.*

[130] Public Law 116–260 (December 27, 2020).

[131] 86 FR 36872 (July 13, 2021).

final rules and implement the Federal IDR provisions under Code sections 9816(c) and 9817(b), ERISA sections 716(c) and 717(b), PHS Act sections 2799A–1(c) and 2799A–2(b), and 5 U.S.C. 8902(p). The Federal IDR process will permit group health plans, health insurance issuers offering group or individual health insurance coverage, FEHB carriers, and nonparticipating providers, facilities, and providers of air ambulance services to determine the out-of-network rate for items and services that are emergency services, nonemergency services furnished by nonparticipating providers at participating facilities, and air ambulance services furnished by nonparticipating providers of air ambulance services, under certain circumstances.

Furthermore, these interim final rules extend the balance billing protections related to external reviews to grandfathered plans, including non-Federal governmental plans and individual market plans. The definitions of group health plan and health insurance issuer that are cited in section 110 of the No Surprises Act include both grandfathered and non-grandfathered plans and coverage. Accordingly, the practical effect of section 110 of the No Surprises Act is that grandfathered health plans must provide external review for adverse benefit determinations involving benefits subject to these surprise billing protections. Grandfathered and non-grandfathered plans must comply either with a state external review process or the Federal external review process. The disclosure requirements of the Federal external review process require: (1) A preliminary review by plans of requests for external reviews; (2) Independent Review Organizations (IROs) to notify claimants of eligibility and acceptance for external review; (3) the plan or issuer to provide IROs with documentation and other information considered in making adverse benefit determination; (4) the IRO to forward to the plan or issuer any information submitted by the claimant; (5) plans to notify the claimant and IRO if it reverses its decision; (6) the IRO to notify the claimant and plan of the result of the final external review; and (7) the IRO to maintain records for 6 years.

Additionally, these interim final rules implement provisions of the No Surprises Act that require health care providers and health care facilities to furnish good faith estimates upon request or upon the scheduling of items or services for uninsured (or self-pay) individuals. In order to implement these good faith estimate provisions under PHS Act section 2799B–6(1) and 2799B–6(2)(B), as added by section 112 of the No Surprises Act, HHS is adding 45 CFR 149.610 to establish requirements for providers and facilities to specifically inquire about an individual's health coverage status and establish requirements for providing a good faith estimate to uninsured (or self-pay) individuals.

PHS Act section 2799B–6(2) and these interim final rules specify that a provider or facility must provide a notification (in clear and understandable language) of the good faith estimate of the expected charges for furnishing such items or services (including any items or services that are reasonably expected to be provided in conjunction with such scheduled items or services and such items or services reasonably expected to be so provided by another health care provider or health care facility), with the expected billing and diagnostic codes (*i.e.,* ICD, CPT, HCPCS, DRG and/or NDC codes) for any such items or services. These interim final rules include definitions of certain terms, requirements for the providers and facilities, content requirements, and methods and manner requirements for issuing good faith estimates consistent with the provisions of PHS Act sections 2799B–6, 2799B–6(1), and 2799B–6(2)(B).

PHS Act section 2799B–7, as added by section 112 of the No Surprises Act, provides further protections for uninsured (or self-pay) individuals by requiring the Secretary of HHS to establish a process (in this section referred to as patient-provider dispute resolution) under which an uninsured (or self-pay) individual who received a good faith estimate of expected charges from a provider or facility, and who, after being furnished the item or service, is billed for charges that are substantially in excess of the estimate, may seek a determination from a SDR entity of the amount to be paid. HHS is adding new 45 CFR 149.620 to implement this patient-provider dispute resolution process including specific definitions related to the patient-provider dispute resolution process. HHS is also codifying provisions related to the eligibility of an item or service for the patient-provider dispute resolution process, certification and selection of SDR entities, fees associated with the patient-provider dispute resolution process, and deferral to state patient-provider dispute resolution processes.

Consistent with Executive Orders 13985 and 13988, and all civil rights laws and protections cited previously, these interim final rules include provisions designed to address and increase the HHS' understanding of barriers underserved and minority communities face in accessing the protections established in the No Surprises Act, including the provision of good faith estimates for uninsured (or self-pay) individuals, and the process for patient-provider dispute resolution.

The Departments seek comment from individuals from racial/ethnic minority and underserved communities, including individuals with vision, hearing, or language limitations, individuals with limited English proficiency, lesbian, gay, bisexual, transgender, and queer (LGBTQ+) persons, and individuals with health literacy needs, and providers who serve these individuals, to help identify emerging, persistent, or perceived barriers to individuals accessing and understanding these processes, rights, and protections, and other provisions of the No Surprises Act included in this rule, and policies to address and remove these barriers.

1.2. Summary of Impacts

Plans, issuers, FEHB carriers, health care providers, facilities, and providers of air ambulance services will incur costs to comply with the requirements in these interim final rules, as discussed later in this section of this preamble. However, the Departments and OPM have determined that the benefits of these interim final rules justify the costs.

The provisions in these interim final rules will help ensure that participants, beneficiaries, and enrollees with health coverage are protected from surprise medical bills. When plans, issuers, and FEHB carriers participate in the Federal IDR process, 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. One study found that surprise billing decreased by 34 percent in New York State between 2015 and 2018, when the state implemented an IDR process.[132] The study also found that New York's Out-of-Network Law [133] saved consumers over $400 million from the date of implementation with respect to emergency services alone.[134]

[132] Marion Mass. ''Surprise Billing Legislation Should Put Independent Dispute Resolution at Its Heart.'' *Morning Consult.* (March 2020). *https://morningconsult.com/opinions/surprise-billing-legislation-should-put-independent-dispute-resolution-at-its-heart/.*

[133] NY Fin Serv L § 605 (2014).

[134] New York State Department of Financial Services. ''New York's Surprise Out-Of-Network

The information regarding the good faith estimates furnished by providers and facilities will allow uninsured (or self-pay) individuals to have access to information about health care pricing before receiving care. This information will allow uninsured (or self-pay) individuals to evaluate options for receiving health care, make cost-conscious health care purchasing decisions, and reduce surprises in relation to their health care costs for those items and services. Additionally, uninsured (or self-pay) individuals may use the good faith estimate for comparison with actual billed charges received after items or services are furnished. If the billed charges are substantially in excess of the good faith estimate, an uninsured (or self-pay) individual may seek a determination from an SDR entity under the patient-provider dispute resolution process.

HHS will request information from uninsured (or self-pay) individuals in order to initiate the patient-provider dispute resolution process. This information will be used to help determine eligibility for the patient-provider dispute resolution process and is necessary for determining which provider or facility should be contacted for dispute resolution. Providers and facilities are required to submit information to an SDR entity to inform the SDR entity's payment determination decisions.

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 benefits of the Federal IDR process for the population with health coverage:

- Increased protection for participants, beneficiaries, and enrollees from surprise bills from out-of-network providers by creating a process for plans, issuers, FEHB carriers, and nonparticipating providers and facilities to resolve disputes regarding certain out-of-network rates. Note that, unless specified otherwise, providers include providers of air ambulance services.
- Increased awareness of expected charges for items or services, reduction in financial anxiety and out-of-pocket expenses for individuals with health coverage because individuals will be able to meet their deductibles and out-of-pocket maximum limits sooner.
- Increased access to care for individuals with health coverage that may have otherwise forgone or delayed needed treatment due to concerns over the potential for high out-of-pocket expenses.

Non-quantified benefits of the patient-provider dispute resolution process for uninsured (or self-pay) individuals:

- Increased awareness of expected charges for items or services, reduction in financial anxiety, more informed health care decisions, and protection for uninsured (or self-pay) individuals by requiring providers and facilities to furnish good faith estimates for scheduled or requested items and services.
- Improved access to care for uninsured (or self-pay) individuals that may have otherwise forgone or delayed needed treatment due to concerns over receiving unexpected large bills.
- Protection for uninsured (or self-pay) individuals from excessive surprise bills from providers or facilities by establishing a patient-provider dispute resolution process that may result in lower payments if the SDR entity determines the amount to be paid by the uninsured (or self-pay) individual to the provider or facility are lower than the billed charges.

Non-quantified benefits regarding external review:

- Increased access to benefits for some individuals.
- Reduced incidence of excessive delays and inappropriate denials, averting serious, avoidable lapses in access to quality health care and resultant injuries and losses to participants, beneficiaries, enrollees, and FEHB covered individuals.
- Potential increase in confidence and satisfaction among participants, beneficiaries, and enrollees in their health care benefits.
- Improved awareness among plans, issuers, and FEHB carriers of participant, beneficiary, enrollee, FEHB covered individuals, and provider concerns.

COSTS TO PLANS, ISSUERS, AND FEHB CARRIERS

Costs (in millions)	Estimate	Year dollar	Discount rate	Period covered
Annualized	$517.12	2021	7 percent	2022–2031
Monetized ($/Year)	491.44	2021	3 percent	2022–2031

The annualized cost estimates reflect estimated costs associated with the Federal IDR process for nonparticipating providers or nonparticipating emergency facilities, the Federal IDR process for providers of air ambulance services, IDR entity certification and reporting requirements, the Federal IDR process for the uninsured, SDR entity certification, and the extension of the external review to grandfathered plans and claims under certain provisions of the No Surprises Act. The Departments estimate a total cost of $760.95 million in the first year and $440.67 million going forward.

Costs to the Government:

The Federal Government will incur costs to build and maintain the Federal IDR portal and to implement and administer the patient-provider dispute resolution process. The maintenance costs for the Federal IDR portal are split between the Federal IDR process and the patient-provider dispute resolution process, based on anticipated volume for each program. The costs associated with the Federal IDR portal are estimated to be a one-time cost of $6 million in fiscal year 2021 and annual costs of $1 million going forward. The costs associated with the patient provider dispute resolution process are estimated to be a one-time cost of $10 million in fiscal year 2021 and an annual cost of $12 million going forward. Additionally, the costs associated with the Federal external review costs are estimated to be $1.16

Protection Law Report on the Independent Dispute Resolution Process.'' (September 2019).

million in fiscal year 2021 and $567,000 annually going forward.

Transfers:

Non-quantified transfers associated with the Federal IDR process for the population with health coverage:

- Potential transfers from providers who had previously balance billed for out-of-network claims to individuals who are no longer responsible for paying these balance bills.
- Potential transfers from plans, issuers, and FEHB carriers who were previously not responsible for out-of-network balance bills to providers and facilities that will submit out-of-network balance bills to plans, issuers, and FEHB carriers as a result of the interim final rules.
- Potential transfers from plans, issuers, and FEHB carriers to participants, enrollees, and beneficiaries if the Federal IDR process results in lower premiums.
- Potential transfers from participants, enrollees, and beneficiaries to plans, issuers, and FEHB carriers if the Federal IDR process results in higher premiums.
- Potential transfers to the Federal Government in the form of reduced Premium Tax Credits if the Federal IDR process results in the lower premiums.
- Potential transfers from the Federal Government to eligible enrollees, in the form of increased Premium Tax Credits payments if the Federal IDR process results in an increase in premiums.
- Potential transfers from individuals with health coverage who pay premiums to individuals with large out-of-network bills and uninsured individuals if the Federal IDR process results in an increase in premiums.
- Potential transfers from providers, facilities, and providers of air ambulance services to plans, issuers, and FEHB carriers if some providers, facilities, and providers of air ambulance services collect lower out-of-network payments.
- Potential transfers between providers, facilities, and providers of air ambulance services and individuals with health coverage, depending on the weight place on the QPA in payment determinations under the Federal IDR process. The presumption in favor of the QPA in the Federal IDR process may result in transfers from providers and facilities to participants, beneficiaries, and enrollees.

Non-quantified transfers associated with the patient-provider dispute resolution process for uninsured (or self-pay) individuals:

- Potential transfer of the patient-provider dispute resolution administrative fee from the provider or facility to the uninsured (or self-pay) individuals if the SDR entity makes a payment determination in favor of the uninsured (or self-pay) individual.
- Potential transfer from uninsured (or self-pay) individuals to providers or facilities if the SDR entity makes a payment determination that is higher than the good faith estimate.

Non-quantified transfers associated with external review:

- Potential transfer from plans, issuers, and FEHB carriers to participants, beneficiaries, and enrollees now receiving payment for denied benefits.

1.3. Affected Entities

These interim final rules will affect health care patients, health care providers, health care facilities, providers of air ambulance services, self-insured plans, issuers, and FEHB carriers.

In 2019, there were 1,553 issuers in the U.S. health insurance market, of which 1,298 issuers serve the individual market, 586 issuers serve the small group market, and 788 issuers serve the large group market.[135] Additionally, the Departments and OPM estimate that 46 issuers are FEHB carriers. While there is a significant amount of research that demonstrates the prevalence of surprise billing, as discussed in the July 2021 interim final rules, the Departments do not have data on what percentage of health insurance issuers cover individuals who experience surprise billing. However, given the size and scope of insurance companies, the Departments assume that all health insurance issuers will be affected by these interim final rules. The Departments estimate that 8.5 percent, or approximately 132 issuers are considered small under the Small Business Administration's (SBA) size standards.[136]

Of the plans that filed a Form 5500 in 2018, 25,500 plans were self-insured.[137] The Departments do not have data on what percentage of self-insured group health plans cover individuals who have received a surprise bill. The Departments request comment on how many group health plans will be affected by these interim final rules.

In 2018, 296.2 million individuals had health insurance. Of the 213.2 million individuals with private insurance, 178.4 million had employer-sponsored insurance and 34.8 million had other private insurance, including individual market coverage.[138] One study looked at claims data from a large commercial issuer for the period 2010–2016 and found that over 39 percent of emergency department visits to in-network hospitals resulted in an out-of-network bill, and 37 percent of inpatient admissions to in-network hospitals resulted in at least one out-of-network bill.[139] The Departments estimate that these interim final rules will directly affect individuals with private health coverage who visit an emergency room, visit a hospital, or are transported by an air ambulance.

The Departments expect that the Federal IDR process will have overflow effects of decreasing the incidence of surprise medical bills in general, even for patients who do not have a claim that goes to the Federal IDR process. The Federal IDR process relies on a ''baseball-style'' arbitration, in which each party submits their desired amount, and the certified IDR entity selects one of the two offers submitted. This differs from other types of arbitration, in which the arbitrator would often select a value between the two submissions. Accordingly, this process encourages each party to submit a reasonable offer. Further, the parties involved will need to weigh the costs associated with the Federal IDR process, including payment of the administrative fee and the certified IDR entity fee if their offer is not chosen. The Departments are of the view this may serve as an incentive to not only submit reasonable offers once the Federal IDR

[135] Centers for Medicare and Medicaid Services. ''Medical Loss Ratio Data and System Resources'' (2019). *https://www.cms.gov/CCIIO/Resources/Data-Resources/mlr.*

[136] The issuers affected by these interim final rules are expected to fall under the industry of Direct Health and Medical Insurer Carries, NAICS 524114. According to the SBA Table of Size Standards, an issuer is considered small if its annual receipts are less than $41.5 million. (*See* Small Business Administration. ''Table of Size Standards.'' (August 2019). *https://www.sba.gov/document/support--table-size-standards.*) Applying this standard to the 2017 County Business Patterns and Economic Census uniformly across establishments, the Departments estimate that 132, or 8.5 percent of issuers are small. (*See* Census Bureau. ''2017 SUSB Annual Data Tables by Establishment Industry, Data by Enterprise Receipt Size.'' (May 2021). *https://www.census.gov/data/tables/2017/econ/susb/2017-susb-annual.html.*)

[137] Stewart, Al. ''Report to Congress: Annual Report on Self-Insured Group Health Plans.'' (March 2021). *https://www.dol.gov/sites/dolgov/files/EBSA/researchers/statistics/retirement-bulletins/annual-report-on-self-insured-group-health-plans-2021.pdf.*

[138] Employee Benefits Security Administration. ''Health Insurance Coverage Bulletin.'' (March 2019). *https://www.dol.gov/sites/dolgov/files/EBSA/researchers/data/health-and-welfare/health-insurance-coverage-bulletin-2019.pdf.*

[139] 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.

process has been initiated, but also to conduct business in a way to avoid ending up in the Federal IDR process altogether. The Departments cannot estimate how large these overflow effects will be on a national basis; however, the experience in New York State provides a point of reference. In 2018, in New York State, surprise billing decreased by 34 percent after the IDR process was implemented.[140]

Surprise billing occurs more often in specialties that are not shopped.[141] A recent survey looked at 13.8 million visits to 35,000 unique providers in six specialties in 2017 to estimate the percent of providers with at least one out-of-network claim by specialty and whether the procedure was inpatient or outpatient. The survey found that less than half of specialist providers surveyed billed at least once on an out-of-network basis. Their findings are shown in the last four columns in Table 2.[142] The second column provides the number of active physicians in each specialty from the American Association of Medical Colleges.[143] As set forth in Table 2, the prevalence of providers who bill on an out-of-network basis and the average frequency of visits that are billed out-of-network among providers who do bill on an out-of-network basis varies by specialty.

The Departments estimate that 16,992 emergency and other health care facilities will be affected by these interim final rules, including 6,090 hospitals,[144] 29,227 diagnostic and medical laboratories,[145] 270 independent freestanding emergency departments,[146] 9,280 ambulatory surgical centers,[147] and 1,352 critical access hospitals. The Departments acknowledge that this estimate double counts some entities, particularly with regard to facilities that have laboratories in-house.

TABLE 2—PHYSICIANS WITH OUT-OF-NETWORK CLAIMS

	Number of active physicians[148]	Percent of providers with at least one out-of-network claim, 2017[149] (%)		Mean percent of visits with services billed out-of-network for providers who billed out-of-network at least once[150] (%)	
		Inpatient	Outpatient	Inpatient	Outpatient
Emergency	45,134	44.1	49.3	14.7	34.3
Pathology	12,640	44.0	33.0	44.3	31.4
Radiology	28,017	27.7	32.5	11.0	17.9
Anesthesiology	42,249	57.0	31.8	11.3	28.4
Behavioral Health/Psychiatry	38,778	29.8	14.9	21.4	24.4
Cardiovascular	22,514	17.9	17.0	6.8	8.3

As seen in Table 2, among the specialist providers considered, emergency physicians were most likely to bill on an out-of-network basis at least once; however, emergency physicians account for less than 5 percent of total physicians.[151] The Departments estimate that 15 percent, or 140,270, of physicians,[152] on average, bill on an out-of-network basis and will be affected by these interim final rules. The Departments estimate that 44.1 percent, or approximately 61,890 physicians, practice in a small business under the SBA size standards.[153] The Departments seek comment on these estimates.

Physician staffing companies, which allow for medical facilities to hire the services of a medical professional without hiring the medical professional

[140] Marion Mass. ''Surprise Billing Legislation Should Put Independent Dispute Resolution at Its Heart.'' *Morning Consult.* (March 2020). *https://morningconsult.com/opinions/surprise-billing-legislation-should-put-independent-dispute-resolution-at-its-heart/.*

[141] Greaney, Thomas. ''Surprise Billing: A Window into the U.S. Health Care System.'' American Bar Association. (September 2020). *https://www.americanbar.org/groups/crsj/publications/human_rights_magazine_home/health-matters-in-elections/surprise-billing/.*

[142] Fugelsten Biniek, Jean, et al. ''How Often Do Providers Bill Out of Network?'' Health Care Cost Institute. (May 2020). *https://healthcostinstitute.org/out-of-network-billing/how-often-do-providers-bill-out-of-network.*

[143] 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.*

[144] American Hospital Association. ''Fast Facts on U.S. Hospitals, 2021.'' (January 2021). *https://www.aha.org/statistics/fast-facts-us-hospitals.*

[145] IBIS World. Definitive Healthcare. ''Diagnostic & Medical Laboratories Industry in the US—Market Research Report?'' (May 2021). *https://www.ibisworld.com/industry-statistics/number-of-businesses/diagnostic-medical-laboratories-united-states/.*

[146] Emergency Medicine Network. ''2018 National Emergency Department Inventory.'' (2021). *https://www.emnet-usa.org/research/studies/nedi/nedi2018/.*

[147] Definitive Healthcare. ''How Many Ambulatory Surgery Centers are in the US?'' (April 2019). *https://www.definitivehc.com/blog/how-many-ascs-are-in-the-us.*

[148] *See* 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.*

[149] *See* Fugelsten Biniek, Jean, et al. ''How Often Do Providers Bill Out of Network?'' Health Care Cost Institute. (May 2020). *https://healthcostinstitute.org/out-of-network-billing/how-often-do-providers-bill-out-of-network.*

[150] *Id.*

[151] 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 percent).

[152] The Departments do not have data on the percentage of physicians who bill out of network across all specialties; however, it is likely lower than the percentage of physicians who bill out of network across the six specialties cited in the cited study. The six specialties cited account for approximately 20 percent of physicians. Based on the information presented in Table 2, the Departments estimate that on average, just over 30 percent of physicians in these specialties had at least one out-of-network claim. The Departments assumes that the other 80 percent of physicians bill on an out-of-network basis just 10 percent of the time. The Departments approximate the percent of physicians who bill on an out-of-network basis to be: (20 percent × 32 percent) + (10 percent × 80 percent) = 14.4 percent. As an approximation, the Departments round this to 15 percent.

[153] The physicians affected by these interim final rules are expected to fall under the industry of Offices of Physicians, NAICS 62111. According to the SBA Table of Size Standards, an office of physicians is considered small if its annual receipts are less than $12.0 million. (*See* Small Business Administration. ''Table of Size Standards.'' (August 2019). *https://www.sba.gov/document/support--table-size-standards.*) Applying this standard to the 2017 County Business Patterns and Economic Census uniformly across employees, the Departments estimate that 61,890, or 44.1 percent of physicians work in an office considered a small business. (*See* Census Bureau. ''2017 SUSB Annual Data Tables by Establishment Industry, Data by Enterprise Receipt Size.'' (May 2021). *https://www.census.gov/data/tables/2017/econ/susb/2017-susb-annual.html.*

themselves, may also be affected by these interim final rules, as they provide services in medical specialties that are not shopped, including emergency, radiology, and anesthesiology.[154] Physician staffing companies often bill patients directly for services rendered.[155] Within recent years, the growth of the health care staffing industry has accelerated, driven by staffing shortages in health care facilities as the population ages.[156] A survey of 200 health care executives found that 85 percent of surveyed health care facility managers used temporary physicians within the last year, and 72 percent were seeking more temporary physicians.[157] There are approximately 40 health care staffing firms providing these services.[158]

Furthermore, in 2014, it was estimated that there were 1,073 businesses in the air ambulance service industry.[159] One study estimated that between 2014 and 2017, 77 percent of air ambulance claims were out-of-network.[160] The Departments do not have data on the number of providers of air ambulance services that submit out-of-network claims; however, given the prevalence of out-of-network billing among providers of air ambulance services, the Departments assume that all businesses in the industry will be affected by these interim final rules. The Departments estimate that 59.2 percent, or approximately 635 providers of air ambulance services, are considered small under the SBA size standards.[161]

IDR entities must be certified under the standards and procedures set forth in guidance by the Departments. In order to be certified, an entity must have sufficient expertise in arbitration and claims administration, managed care, billing and coding, medical, and legal matters, with sufficient staffing to make determinations within 30 business days allowed for such payment determinations. Additionally, IDR entities must meet appropriate indicators of fiscal integrity and stability and maintain a current accreditation from a nationally recognized and relevant accrediting organization, such as URAC, or ensure that it otherwise possesses the requisite training to conduct payment determinations (for example, providing documentation that personnel employed by the IDR entity have completed arbitration training by the AAA, the AHLA, or a similar organization), among other requirements.

The National Association of Independent Review Organizations is an association of URAC-accredited independent review organizations, and in 2021, they had 29 members.[162] While this does not represent the entire pool of independent review organizations, this offers insight into the number of potential entities that may seek certification as IDR entities. In 2019, New York had certified three IDR entities to handle the state's IDR process.[163] In 2018, the state of New York accounted for 5.8 percent of the private insurance market.[164] The Departments recognize that the health care and surprise billing experiences across states are heterogeneous; however, if this proportion were uniform across the country, there would be approximately 52 IDR entities. Based on these two benchmarks, the Departments estimate that there will be 50 IDR entities that will seek certification by the Departments. Within these 50 entities, HHS estimates that there will be between one and three contracted SDR entities, depending on the anticipated volume of patient-provider dispute resolution cases and other factors necessary for administering an efficient program.

Health care providers and health care facilities are required to furnish a good faith estimate of expected charges to uninsured (or self-pay) individuals for scheduled items and services and upon request. In 2019, there were approximately 938,966 active physicians,[165] 6,090 hospitals,[166] 9,280 ambulatory surgical centers,[167] and 1,352 critical access hospitals.[168] As of 2019, there were approximately 29,349,300 uninsured individuals in the United States.[169] HHS estimates that approximately 3,498,942 uninsured (or self-pay) individuals will be impacted by this rule requirement[170] based on the

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[154] Appelbaum, Eileen and Rosemary Batt. ''Private Equity and Surprise Medical Billing.'' (2021). Institute for New Economic Thinking. *https://www.ineteconomics.org/perspectives/blog/private-equity-and-surprise-medical-billing.*

[155] Moody's Investor Service. ''Surprise Billing Ban to Constrain Physician Firms' Cash Flow, Curb Negotiating Clout for Air Ambulances.'' (2021). *https://www.moodys.com/research/Moodys-Surprise-billing-ban-to-constrain-physician-staffing-firms-cash--PBC_1263184.*

[156] Schwartz, Chris. ''Overview of the Temporary Healthcare Staffing Sector.'' Blue Pencil Strategies. *https://healthywork.uic.edu/wp-content/uploads/sites/452/2019/08/Temporary-Healthcare-Staffing-Fact-Sheet.pdf.*

[157] Gooch, Kelly. ''Temporary Physicians Staffing: Why and How Often It Occurs.'' Becker's Hospital Review. (2020). *https://www.beckershospitalreview.com/workforce/temporary-physician-staffing-why-and-how-often-it-occurs.html.*

[158] Schwartz, Chris. ''Overview of the Temporary Healthcare Staffing Sector.'' Blue Pencil Strategies. *https://healthywork.uic.edu/wp-content/uploads/sites/452/2019/08/Temporary-Healthcare-Staffing-Fact-Sheet.pdf.*

[159] IBIS World. ''Air Ambulance Service Industry in the US—Market Research Report.'' (December 2020). *https://www.ibisworld.com/united-states/market-research-reports/air-ambulance-services-industry/.*

[160] Brown, Erin, et al. ''The Unfinished Business of Air Ambulance Bills.'' Health Affairs Blog, March 26, 2021. *https://www.healthaffairs.org/do/10.1377/hblog20210323.911379/full/.*

[161] The providers of air ambulance services affected by these interim final rules are expected to fall under the industry of Ambulance Services, NAICS 621910. According to the SBA Table of Size Standards, an air ambulance service provider is considered small if its annual receipts are less than $16.5 million. (*See* Small Business Administration. ''Table of Size Standards.'' (August 2019). *https://www.sba.gov/document/support--table-size-standards.*) Applying this standard to the 2017 County Business Patterns and Economic Census uniformly across establishments, the Departments estimate that 635, or 59.2 percent of providers of air ambulance services are small. *See* Census Bureau. ''2017 SUSB Annual Data Tables by Establishment Industry, Data by Enterprise Receipt Size.'' (May 2021). *https://www.census.gov/data/tables/2017/econ/susb/2017-susb-annual.html.*

[162] Lacewell, Linda. ''New York's Surprise Out-of-Network Protection Law.'' Patient Choice Coalition.'' (September 2019). *http://www.patientchoicecoalition.com/blog/2019/11/22/report-on-the-independent-dispute-resolution-process/.*

[163] *Id.*

[164] In 2018, 10.5 million individuals had employer-sponsored insurance and 1.8 million individuals had other private insurance in New York State, while 178.4 million individuals had employer-sponsored insurance and 34.8 million individuals had other private insurance nationally. The Departments estimates New York accounts for 5.8 percent of the private insurance market ((10.5 + 1.8)/(178.4 + 34.8) = 5.8 percent). *See* Employee Benefits Security Administration. ''Health Insurance Coverage Bulletin.'' (March 2019). *https://www.dol.gov/sites/dolgov/files/EBSA/researchers/data/health-and-welfare/health-insurance-coverage-bulletin-2019.pdf.*

[165] *https://www.aamc.org/data-reports/workforce/interactive-data/active-physicians-us-doctor-medicine-us-md-degree-specialty-2019.*

[166] *https://www.aha.org/statistics/fast-facts-us-hospitals.*

[167] *https://blog.definitivehc.com/how-many-ascs-are-in-the-us#:~:text=Currently%2C%20there%20are%20more%20than,Healthcare's%20platform%20on%20surgery%20centers.*

[168] *https://www.flexmonitoring.org/historical-cah-data-0*).

[169] This figure includes those without health insurance and those who have coverage under the Indian Health Service only. Source: *https://www.kff.org/other/state-indicator/total-population/?dataView=1&currentTimeframe=0&selectedDistributions=uninsured&selectedRows=%7B%22wrapups%22:%7B%22united-states%22:%7B%7D%7D%7D&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D.*

[170] The number is estimated as follows: 51,744,200 nonemergency elective procedures (surgical and non-surgical) performed annually × 9.2% uninsured rate = 4,760,466. HHS assumes that some uninsured populations will forego elective procedures because of costs. Therefore, a 30% decrease adjustment was included resulting in 3,332,326. HHS also assumes a 5% adjustment for good faith estimate inquires only resulting in a final value of 3,498,942. *See* Squitieri, Lee et al. ''Resuming Elective Surgery during Covid–19: Can Inpatient Hospitals Collaborate with Ambulatory Surgery Centers?.'' *Plastic and reconstructive*

number of nonemergency elective procedures (surgical and non-surgical) performed annually multiplied by the percentage of uninsured (or self-pay) individuals (9.2%), and HHS assumes that some uninsured individuals will forego elective procedures because of cost. HHS also assumes that a certain number of good faith estimates will be furnished only upon request, increasing the number of good faith estimates from that of the total for scheduled items and services.

These interim final rules also implement a patient-provider dispute resolution process that applies to uninsured (or self-pay) individuals whose billed charges exceed the expected charges in the good faith estimate for a provider or facility by $400 or greater. HHS does not have data on the percentage of how many uninsured (or self-pay) individuals will initiate the patient-provider dispute resolution process. For the purposes of the estimates in this section, HHS relied on the experience of New York State. From 2015 to 2018, New York State had a total of 1,486 disputes involving surprise bills submitted to the state IDR process, and 31% of these disputes (457 in all) were found ineligible for IDR for various reasons including 8% (approximately 36 cases) due to being self-insured.[171] For the purposes of this analysis, HHS assumes that, going forward, New York State will continue to see 40 IDR adjudications each year involving surprise medical bills for self-insured individuals. Accordingly, HHS estimates that there will be 26,659 claims that result in patient-provider dispute resolution cases each year. [172] These interim final rules establish requirements that an SDR entity must meet the same certification standards as a certified IDR entity. HHS estimates that there will be between one and three contracted SDR entities depending on the anticipated volume of patient-provider dispute resolution cases and other factors necessary for administering an efficient program. HHS will assess if a potential SDR entity meets the certification standards as part of the contracting process.

Furthermore, the interim final rules extend the balance billing protections related to external review to grandfathered plans. Prior to the interim final rules, the Departments estimate that there are approximately 8.1 million participants in ERISA-covered plans in states that have no external review laws or whose laws do not meet the Federal minimum requirements.[173] These estimates lead to a total of 92.5 million participants not having access to external review. Among the 92.5 million participants, 80.5 million participants in non-grandfathered plans and 12 million participants in grandfathered plans will be required to be covered by the external review requirement.

The Departments estimate that there are approximately 1.3 external reviews for every 10,000 participants [174] and that there will be approximately 12,304 external reviews annually. Experience from North Carolina indicates that about 75 percent of requests for external reviews are actually eligible to proceed to an external review.[175] Therefore, the Departments expect that there will be about 15,942 requests for external review.[176]

1.4. Benefits

Federal IDR Process

In the past, information asymmetries regarding health care costs and provider or facility network status between individuals and plans, issuers, and providers have left individuals vulnerable to surprise billing. These interim final rules will provide a structure to guide the resolution of pricing disparities in a way that will prevent a patient's information asymmetry from resulting in a surprise bill, thus alleviating the market failure.

As a result of these interim final rules, individuals with health coverage will only be liable for their in-network cost-sharing amounts when receiving care from nonparticipating providers at participating facilities (in certain circumstances), nonparticipating emergency facilities, and nonparticipating providers of air ambulance services. Accordingly, these individuals are likely to see lower out-of-pockets costs, reduced anxiety, reduced financial stress, and lower medical debt. Further, these payments will now count towards their deductible and maximum out-of-pocket limits, allowing individuals to reach those limits sooner. A significant number of individuals forgo or delay care due to the cost of care.[177] 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.

Further, these interim final rules create a system in which disputes may be resolved in a consistent and efficient manner. These interim final rules are intended to minimize reliance on the Federal IDR process and encourage parties to submit reasonable offers and allow for more efficient price discovery. By requiring the non-prevailing party to pay the certified IDR entity fees, these interim final rules increase the financial stakes for parties that submit an offer that is unreasonably high or low. However, if the parties agree upon a settlement, after initiation, but prior to determination by the certified IDR entity, each party must pay half of the certified IDR entity's fees, unless the parties agree otherwise on a method for allocating the fees. Thus, parties have an incentive to choose a settlement compared to the Federal IDR process. During negotiations, providers may be more willing to accept a lower price and similarly, plans, issuers, and FEHB carriers may be more willing to offer a higher price.

Similarly, these interim final rules are intended to encourage the settlement of multiple claims. Under these interim final rules, the party that initiates the Federal IDR process is suspended from taking the same party to arbitration for an item or service that is the same or similar item or service as the qualified

surgery. Global open vol. 9,2 e3442. 18 Feb. 2021, doi:10.1097/GOX.0000000000003442 (The study estimates 4,297,850 nonemergency elective procedures (surgical and non-surgical) are performed each month. This value was multiplied by 12 months = 51,574,200. HHS adjusted by approximately one-third of one percent to account annual increase in volume since study publication resulting in 51,744,200). See also KFF Health Insurance Coverage of the Total Population.

[171] *https://www.dfs.ny.gov/system/files/documents/2019/09/dfs_oon_idr.pdf.*

[172] The number is estimated as follows: 51,744,200 nonemergency elective procedures (surgical and non-surgical) performed annually × 9.2% uninsured rate = 4,760,466. HHS assumes that some uninsured (or self-pay) individuals will forego elective procedures because of costs. Therefore, a 30% decrease adjustment was included resulting in 3,332,326. HHS assumes that 10% of uninsured (or self-pay) individuals who undergo a nonemergency elective procedure will receive a billed charge that is $400 or more than the total expected charges in the good faith estimate for the provider or facility, therefore 3,332,326 × 10% = 333,232. HHS assumes that 8% will engage the provider-patient dispute resolution process, therefore 333,232 × 8% = 26,659.

[173] These states are Alabama, Florida, Georgia, Pennsylvania, Texas, and Wisconsin. See Affordable Care Act: Working with States to Protect Consumers, available at *https://www.cms.gov/CCIIO/Resources/Files/external_appeals.html.*

[174] AHIP Center for Policy and Research, ''An Update on State External Review Programs, 2006,'' July 2008.

[175] North Carolina Department of Insurance. ''Health Insurance Smart NC: Annual Report on External Review Activity 2013.'' *https://digital.ncdcr.gov/digital/collection/p249901coll22/id/730531.*

[176] 12,304/0.75 = 15,942.

[177] According to a Kaiser Family Foundation analysis of National Health Interview Survey data, in 2019, 10.5 percent of adults reported forgoing or delaying medical care due to costs. Reference: Krutika, Amin, Gary Claxton, Giorlando Ramirez, and Cynthia Cox (2021). ''How Does Cost Affect Access to Care?'' Peterson-KFF Health System Tracker. Available at *https://www.healthsystemtracker.org/chart-collection/cost-affect-access-care/.*

IDR item or service already subject to a certified IDR entity's determination for 90 calendar days following a payment determination. Furthermore, these interim final rules permit multiple qualified IDR items and services to be batched together in a single payment determination proceeding to encourage efficiency; however, the batched items and services must involve the same provider or group of providers, the same facility, the same provider of air ambulance services, the same plan or issuer, treatments involving the same or similar items or services (as determined by service codes), and have to occur within a single 30-business-day period (or during the 90-calendar-day suspension period). By batching similar qualified IDR items and services, these interim final rules may reduce the per-service cost of the Federal IDR process and potentially the aggregate administrative costs, since the Federal IDR process is likely to exhibit at least some economies of scale.[178] For example, the per-service cost of a payment determination involving ten services is likely to be lower than the per-service cost of a payment determination involving five services. Thus, these interim final rules may result in cost savings for plans, issuers, and providers. The Departments do not have data or a way to estimate how prevalent batching will be, and thus the potential cost savings that may result, in comparison to a hypothetical IDR process without batching. The Departments seek comment and data on this topic, if available.

In addition, these interim final rules prohibit conflicts of interest in the selection of certified IDR entities. The selected certified IDR entity cannot be a group health plan; a health insurance issuer offering group health insurance coverage, individual health insurance coverage or short-term, limited-duration insurance; an FEHB carrier; or a provider, a facility or a provider of air ambulance services. Additionally, the selected certified IDR entity cannot be an affiliate of a group health plan; a health insurance issuer offering group health insurance coverage, individual health insurance coverage or short-term, limited-duration insurance; an FEHB carrier; or a provider, a facility or a provider of air ambulance services. The selected certified IDR entity cannot be an affiliate or subsidiary of a professional or trade association representing group health plans; health insurance issuers; FEHB carriers; or providers, facilities, or providers of air ambulance services. Also, the selected certified IDR entity and its personnel cannot have a material familial, financial, or professional relationship with a party to the payment determination being disputed. By prohibiting conflicts of interest, these interim final rules will help ensure that the selected certified IDR entity will take both parties into full consideration during arbitration and ensure that the resolution of the dispute is conducted fairly.

Furthermore, these interim final rules dictate what factors the certified IDR entities may consider for their decisions. Specifically, these interim final rules require that certified IDR entities consider the QPA and requires them to consider other relevant factors, to the extent credible information is provided by the parties, while not allowing for the consideration of usual and customary rates, billed charges of the provider, or public payor rates, such as those of Medicare, Medicaid, the Children's Health Insurance Program, TRICARE, chapter 17 of title 38, United States Code, or demonstration projects under title XI of the Social Security Act.

The Departments seek comment addressing the benefits that will be associated with these interim final rules. The Departments also seek comment on how the interim final rules will affect individuals from minority and underserved communities and providers who serve these individuals.

Protections for the Uninsured

Health insurance and health care costs are critical determinants of access to health care and are central reasons for existing health inequities.[179] In the past decade, while overall rates of health insurance coverage have increased, the rates of health insurance coverage among most minority groups continue to be disproportionately lower than among non-minority groups. Estimates from the Centers for Disease Control and Prevention (CDC) National Health Interview Survey (NHIS), suggest that approximately 30 million U.S. residents lacked health insurance in the first half of 2020.[180] Prior to the COVID–19 pandemic, according to information collected in the Current Population Survey Annual Social and Economic Supplement (CPS ASEC) and the American Community Survey (ACS), in 2019, 8.0% of people, or 26.1 million individuals, did not have health insurance at any point during the year.[181] Additionally, the most recent ACS data documents the largest annual increase in the number of uninsured children from 2018 to 2019 since the survey began asking about health insurance in 2008. The child uninsured rate increased from 5.2% in 2018 to 5.7% in 2019.[182]

The provisions in these interim final rules will protect uninsured (or self-pay) individuals by allowing them to obtain a good faith estimate of expected charges from providers and facilities prior to receiving scheduled items and services and upon request. With this information, uninsured (or self-pay) individuals may be more likely to consider and compare costs across providers or facilities prior to or upon scheduling an item or service to help inform decisions regarding costs for an item or service. Additionally, these interim final rules protect these uninsured (or self-pay) individuals from receiving excessive surprise bills from providers and facilities, and allow an uninsured (or self-pay) individual to seek a determination through the patient-provider dispute resolution process if billed charges for items or services from a provider or facility are substantially in excess of the expected charges listed on the good faith estimate.

The patient-provider dispute resolution process further protects uninsured (or self-pay) individuals as the process may result in lower payments. During the dispute resolution process, the SDR entity must review any documentation submitted by the uninsured (or self-pay) individual or their authorized representative, or a provider or facility, and must make a determination as to whether the health care provider or health care facility has provided credible information for each billed item or service, including an item or service that did not originally appear on the good faith estimate, to demonstrate that the difference between the billed charge and the expected

[178] Fielder, Matthew, Loren Adler, and Benedic, Ippolito. ''Recommendations for Implementing the No Surprises Act.'' U.S.C.-Brookings Schaeffer on Health Policy. (March 2021). *https://www.brookings.edu/blog/usc-brookings-schaeffer-on-health-policy/2021/03/16/recommendations-for-implementing-the-no-surprises-act/.*

[179] ''Mirror, Mirror 2021: Reflecting Poorly.'' The Commonwealth Fund (2021). *https://www.commonwealthfund.org/publications/fund-reports/2021/aug/mirror-mirror-2021-reflecting-poorly.*

[180] ''Trends in the US Uninsured Population 2010–2020.'' APSE Office of Health Policy (2020). *https://aspe.hhs.gov/system/files/pdf/265041/trends-in-the-us-uninsured.pdf.*

[181] Keisler-Starkey, Katherine and Lisa N. Bunch. ''Health Insurance Coverage in the United States: 2019.'' (2020) *https://www.census.gov/library/publications/2020/demo/p60-271.html.*

[182] ''Census Data Show Largest Annual Increase in Number of Uninsured Children in More Than a Decade.'' *https://ccf.georgetown.edu/2020/09/15/census-data-show-decades-largest-annual-increase-in-number-of-uninsured-children/.*

charge in the good faith estimate reflects the costs of a medically necessary item or service and is based on unforeseen circumstances that could not have reasonably been anticipated by the provider or facility when the good faith estimate was provided. HHS is of the view that this helps ensure that the SDR entity review is comprehensive and that the facts and circumstances for the billed charge for each item or service are considered by the SDR entity. HHS is also of the view that this approach ensures that the uninsured (or self-pay) individual is only billed charges that reflect medically necessary items or services and are based on unforeseen circumstances that could not have reasonably been anticipated by the provider or facility when the good faith estimate was provided. This dispute resolution process protects the uninsured (or self-pay) individual from unexpected charges in cases where there are extra charges based on items or services that are not medically necessary, or could have been reasonably foreseen and thus included on the good faith estimate.

These provisions also provide protections when an uninsured (or self-pay) individual receives a bill that includes providers or facilities that were not included in the good faith estimate, specifically if a co-provider or co-facility is replaced at the last moment by a different co-provider or co-facility. These interim final rules provide important consumer protections that are aimed to protect uninsured (or self-pay) individuals from unexpected medical bills by not allowing a provider or facility to essentially circumvent these protections simply due to not being directly represented on the good faith estimate. Therefore, HHS is of the view that it is necessary and appropriate for billed items or services of providers or facilities to be eligible for dispute resolution if the billed charge is substantially in excess of the total expected charges included in the good faith estimate for the original co-provider or co-facility. If the replacement provider or facility provides the uninsured (or self-pay) individual with an updated good faith estimate in accordance with 45 CFR 149.610(b)(2) then the determination of whether an item or service billed by the replacement co-provider or co-facility is eligible for dispute resolution is based on whether the total billed charges for the replacement co-provider or co-facility is substantially in excess of the total expected charges included in the good faith estimate provided by the replacement co-provider or co-facility. HHS recognizes that these particular situations may be more complex for an uninsured (or self-pay) individual to determine eligibility for dispute resolution since the provider or facility may not be reflected in the good faith estimate.

HHS is of the view that requiring an uninsured (or self-pay) individual to pay the entire cost of dispute resolution in cases where the provider or facility prevails in dispute resolution could be prohibitive for such an uninsured (or self-pay) individual to access the dispute resolution process. HHS is also concerned that requiring a provider or facility to pay dispute resolution costs when they do not prevail could impose a burden on the provider or facility and potentially provide an incentive for the provider or facility to raise prices on uninsured (or self-pay) individuals to account for potential dispute resolution costs or avoid treating uninsured (or self-pay) individuals altogether. Therefore, HHS is adopting an approach in which HHS will cover dispute resolution costs through contracts with SDR entities for the patient-provider dispute-resolution process. HHS estimates that the total costs to be paid for patient-provider dispute resolution to SDR entities to be $10,633,600.[183] Such an approach ensures that the uninsured (or self-pay) individual would not be required to pay dispute resolution costs and as a result would not face a barrier to accessing the dispute resolution process. Additionally, as the provider or facility would not be required to pay dispute resolution costs, such approach would reduce the provider's or facility's incentives to increase prices or restrict an uninsured (or self-pay) individual's access to needed care.

In addition, PHS Act section 2799B–7 requires that the Secretary of HHS establish an administrative fee to participate in the patient-provider dispute resolution process in such a manner as to not create a barrier to an uninsured (or self-pay) individual to participate in such process. HHS intends to establish an administrative fee in guidance in a manner that will not create a barrier to an uninsured (or self-pay) individual's access to the patient-provider dispute resolution process. For the first year, HHS expects the fee to be no more than $25.

Although HHS is of the view that requiring all parties to the dispute resolution to pay an administrative fee to offset some of the Federal costs for administering the patient-provider dispute resolution program is appropriate, only the non-prevailing party will be required to pay the administrative fee (either as a payment made directly to the SDR entity in the case of the uninsured (or self-pay) individual, or in a reduction in the final payment determination amount as in the case of the provider or facility). In cases where the SDR entity determines the payment amount the uninsured (or self-pay) individual pays is less than the billed charge, the SDR entity would apply a reduction equal to the administrative fee amount paid by the uninsured (or self-pay) individual to the payment amount to calculate the final payment determination amount to be paid by the uninsured (or self-pay) individual for the items or services. HHS is of the view that requiring the SDR entity to apply a reduction equal to the administrative fee paid by the uninsured (or self-pay) individual to the payment amount is the appropriate approach as it simplifies the number of transactions. HHS anticipates collecting $666,475 [184] in administrative fees from an anticipated 26,659 cases, which will offset some of the costs of the patient-provider dispute resolution process, which is estimated to be $12.6 million (which includes IDR portal system maintenance and contracting fees for SDRs) beginning in 2022, resulting in a total cost to the Federal Government of approximately $12 million.

External Review Requirements

These interim final rules will help transform the external review process

[183] The number is estimated as follows: 51,744,200 nonemergency elective procedures (surgical and non-surgical) performed annually × 9.2% uninsured rate = 4,760,466. HHS assumes that some uninsured (or self-pay) individuals will forgo elective procedures because of costs. HHS assumes that 333,232 of uninsured (or self-pay) individuals who undergo a nonemergency elective procedure will receive a billed amount that is $400 or greater more than the total expected charges listed in the good faith estimate for the provider or facility, therefore 3,332,326 × 10% = 333,232. The Department assumes that 8% of these individuals will engage the provider-patient dispute resolution process, therefore 333,232 × 8% = 26,659. For the first year, HHS expects the SDR fee per arbitration to be about $400 therefore $400 × 26,659 = $10,633,600.

[184] The number is estimated as follows: 51,744,200 nonemergency elective procedures (surgical and non-surgical) performed annually × 9.2% uninsured rate = 4,760,466. HHS assumes that some uninsured (or self-pay) individuals will forego elective procedures because of costs. HHS assumes that 333,232 of uninsured (or self-pay) individuals who undergo a nonemergency elective procedure will receive a billed charge that is at least $400 more than the total expected charges listed in the good faith estimate for the provider or facility, therefore 3,332,326 × 10% = 333,232. The Department assumes that 8% will engage the provider-patient dispute resolution process, therefore 333,232 × 8% = 26,659. For the first year, HHS expects the SDR fee per arbitration to be $25 therefore $25 × 26,659 = $666,475.

into a more uniform and structured process. As stated earlier in this preamble, these interim final rules extend the balance billing protections related to external review to grandfathered plans. Grandfathered health plans must provide external review for adverse benefit determinations involving benefits subject to these surprise billing protections. Additionally, for non-grandfathered health plans these interim final rules clarify that, to the extent not already covered, that any adverse determination that involves consideration of whether a plan or issuer is complying with PHS Act section 2799A–1 or 2799A–2, ERISA section 716 or 717, or Code section 9816 or 9817 is eligible for external review. Grandfathered and non-grandfathered plans must comply either with a state external review process or the Federal external review process. A more uniform external review process will provide a broad range of direct and indirect benefits that will accrue to varying degrees to all affected parties. In general, the Departments expect that these interim final rules will improve the extent to which group health plans, issuers, and FEHB carriers provide benefits consistent with the established terms of individual plans or coverages. This change will cause some participants to receive benefits that they might otherwise have been denied. Furthermore, expenditures by plans may be reduced as a fuller system of claims and appeals processing helps facilitate enrollee acceptance of cost management efforts.

Furthermore, the more uniform standards for handling appeals and external review provided by these interim final rules will reduce the incidence of inappropriate denials, averting serious, avoidable lapses in access to health care and resultant injuries and losses to participants, beneficiaries, and enrollees. These changes also will enhance participants', beneficiaries', and enrollees' level of confidence in and satisfaction with their health care benefits and improve plans' awareness of participant, beneficiary, enrollee, and provider concerns. These changes could prompt plan and issuer responses that improve health care quality.

1.5. Costs

These interim final rules seek to protect patients from surprise billing, while also seeking to minimize the costs to providers, facilities, plans, issuers, and individuals.

The ultimate effect of the Federal IDR process on health care costs is uncertain. Discussions of the uncertainty and potential transfers that the Departments expect are included in the Transfers and Uncertainty sections.

1.5.1. Federal IDR Process for Nonparticipating Providers or Nonparticipating Emergency Facilities

The Departments and OPM do not have data on how many claims will be submitted to the Federal IDR process. For the purposes of the estimates in this section, the Departments and OPM rely on the experience of New York State. In 2018, New York State had 1,014 IDR decisions, up from 650 in 2017 and 396 in 2016.[185] The Departments do not know what is causing the increasing trend or whether the trend is likely to continue to increase. The Departments seek comments on this trend for analytic purposes. In 2018, the state of New York accounted for 5.8 percent of the private insurance market.[186] For purposes of this analysis, the Departments assume that, going forward, New York State will continue to see 1,000 IDR cases each year and that the number of Federal IDR cases will be proportional to that in New York State by share of covered individuals in the private health coverage market. Accordingly, the Departments estimate that there will be approximately 17,000 claims that are submitted to the Federal IDR process each year.[187] The Departments seek comment on this estimate.

Surprise billing decreased by 34 percent in New York State between 2015 and 2018 when the state implemented an IDR process.[188] While the number of IDR cases has been trending up, the decline in surprise billing is likely to result in a decline in IDR cases. Additionally, the usage and cost of certified IDR entities is likely to decrease when certified IDR entities use the QPA as the rebuttable presumption in payment determination, particularly after the first instance of using the QPA. The Departments do not have any data or experiences on which to base an estimate of how much use of the Federal IDR process will decline over time. Accordingly, in these estimates, prevalence of the use of the Federal IDR process is assumed to be constant; however, the Departments recognize that this is likely an overestimate.

The Departments estimate that the cost associated with the Federal IDR process for nonparticipating providers or nonparticipating emergency facilities will be $38.4 million. This includes an estimated cost of $21.1 million for paperwork requirements. For more details, please refer to the Paperwork Reduction Act section of this preamble.

In addition to the paperwork costs for the Federal IDR process, the Departments estimate that it will take, a medical and health services manager 2 hours and a clerical worker 15 minutes on average to prepare materials for open negotiation for each plan, issuer, or FEHB carrier and provider or facility. The Departments estimate that 25 percent of disputes will be resolved in open negotiation before entering the Federal IDR process. The Departments request data or comments on this assumption. Accordingly, the Departments estimate that 23,111 claims will go through open negotiation.[189] This results in a cost of $10.3 million.[190]

If the plan, issuer, or FEHB carrier and the provider or facility fail to select a certified IDR entity, the Departments will select a certified IDR entity through a random selection method. The Departments assume that in 25 percent of IDR payment determinations, a certified IDR entity will not be selected by the parties. The Departments request comment on this assumption.

Furthermore, the party whose offer was not chosen by the certified IDR entity must pay the certified IDR entity fee, in addition to the administrative fee (required to be paid by both parties upon initiation of the IDR process). However, if the parties agreed upon an out-of-network rate, the certified IDR entity fee must be divided equally

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[185] Adler, Loren. ''Experience with New York's Arbitration Process for Surprise Out-of-Network Bills.'' U.S.C.-Brookings Schaeffer on Health Policy. (October 2019). *https://www.brookings.edu/blog/usc-brookings-schaeffer-on-health-policy/2019/10/24/experience-with-new-yorks-arbitration-process-for-surprise-out-of-network-bills/.*

[186] In 2018, 10.5 million individuals had employer-sponsored insurance and 1.8 million individuals had other private coverage in New York State, while 178.4 million individuals had employer-sponsored coverage and 34.8 million individuals had other private coverage nationally. The Departments estimate that New York accounts for 5.8 percent of the private insurance market ((10.5 + 1.8)/(178.4 + 34.8) = 5.8 percent). *See* Employee Benefits Security Administration. ''Health Insurance Coverage Bulletin.'' (March 2019). *https://www.dol.gov/sites/dolgov/files/EBSA/researchers/data/health-and-welfare/health-insurance-coverage-bulletin-2019.pdf.*

[187] This is calculated as: 1,000/0.058 = 17,333.

[188] Marion Mass. ''Surprise Billing Legislation Should Put Independent Dispute Resolution at Its Heart.'' Morning Consult. (March 2020). *https://morningconsult.com/opinions/surprise-billing-legislation-should-put-independent-dispute-resolution-at-its-heart/.*

[189] This is calculated 17,333/(1 − 0.25) = 23,111.

[190] The burden is estimated as follows: 23,111 claims × 2 hours + 23,111 claims × 0.25 hour = 51,999 hours. A labor rate of $105.01 is used for a medical and health services manager and a labor rate of $55.23 is used for a clerical worker. The labor rates are applied in the following calculation: 23,111 claims × 2 hours × $105.01 + 23,111 claims × 0.5 hour × $55.23 = $5,172,803. 2 × $5,172,803 = $10,345,605. Labor rates are EBSA estimates.

between the parties, unless otherwise agreed to by the parties. In New York, IDR entities included independent review organizations who contracted with board certified physicians and other insurance contract experts.[191] The fees charged by IDR entities in New York ranged from $300 to $600.[192] In Texas, the state contracted with individual attorneys to provide IDR entities. In Texas, fixed fees ranged from $270 to $6,000.[193] Based on these ranges, the Departments estimate that on average the certified IDR entity fees will be approximately $400. This results in a cost of $6.9 million.[194]

1.5.2. IDR Process for Air Ambulances

In 2018, 178.4 million individuals had employer-sponsored health insurance and 34.8 million individuals had other private insurance, including individual market coverage.[195] In 2017, the Health Cost Institute (HCCI) estimated that, on average, there were 33.3 air ambulance uses per 100,000 people,[196] and the Government Accountability Office (GAO) estimated that approximately 69 percent of air transports resulted in an out-of-network bill.[197] The Departments do not have data on what percent of out-of-network bills will proceed to the Federal IDR process; however, given the nature of air ambulances services, the Departments assume that it will be substantially higher than for hospital or emergency department claims. The Departments assume that 10 percent of out-of-network claims for air ambulance services will be submitted to the Federal IDR process,[198] which would result in nearly 4,900 air transport payment determinations in the Federal IDR process each year.[199] The Departments seek comment on this estimate.

The Departments estimate that the cost associated with the Federal IDR process for nonparticipating providers or nonparticipating providers of air ambulance services will be $11.1 million. This includes an estimated cost of $5.3 million for paperwork requirements. For more details, please refer to the Paperwork Reduction Act section.

In addition to the paperwork costs, the Departments estimate that it will take, a medical and health services manager 2 hours and a clerical worker 15 minutes on average to prepare materials for open negotiation for each plan, issuer, or FEHB carrier and provider of air ambulance services. The Departments estimate that 25 percent of disputes will be resolved in open negotiation before entering the Federal IDR process. The Departments request data or comments on this assumption. Accordingly, the Departments estimate that 6,532 claims will go through open negotiation.[200] This results in a cost of $3.8 million.[201]

As stated above, if the plan, issuer, or FEHB carrier, and the nonparticipating provider of air ambulance services fail to select a certified IDR entity, the Departments will select a certified IDR entity through a random selection method. The Departments estimate that in 25 percent of IDR payment determinations, a certified IDR entity will not be selected by the parties.

Furthermore, the party whose offer was not chosen by the certified IDR entity must pay the certified IDR entity fee, in addition to the administrative fee (initially required to be paid by both parties upon initiation of the Federal IDR process). However, if the parties agree upon an out-of-network rate, the costs must be divided equally between the parties, unless otherwise agreed to by the parties. In New York, IDR entities included independent review organizations that contracted with board certified physicians and other insurance contract experts.[202] The fees charged by IDR entities in New York ranged from $300 to $600.[203] In Texas, the state contracted with individual attorneys to provide IDR entities. In Texas, fixed fees per case ranged from $270 to $6,000.[204] Based on these ranges, the Departments estimate that on average the certified IDR entity fees will be approximately $400. This results in a cost of approximately $2 million.[205] This results in a cost of approximately $2 million.[206]

1.5.3. Requests Extension of Time Periods for Extenuating Circumstances

A plan, issuer, FEHB carrier, provider, facility, or provider of air ambulance services may request an extension regarding the time periods set forth in these interim final rules, other than for the timing of the payments, including payments to the provider, facility, or air ambulance services, under extenuating circumstances. To request an extension, entities will need to submit the Request for Extension due to Extenuating Circumstances form through the Federal IDR portal, if the extension is necessary to address delays due to matters beyond the control of the parties or for good cause. Additionally, they must attest that prompt action will be taken to ensure that the required action is made as soon as administratively practicable. The Departments estimate that the costs associated with requests for the extension of time periods will be $1,381 annually. For more details, please refer to the Paperwork Reduction Act section of this preamble.

[191] Kaiser Family Foundation. ''Surprise Medical Bills: New Protections for Consumers Take Effect in 2022.'' (2019). *https://www.kff.org/private-insurance/fact-sheet/surprise-medical-bills-new-protections-for-consumers-take-effect-in-2022/.*

[192] The Commonwealth Fund. ''How States are Using Independent Dispute Resolution to Resolve Out-of-Network Payments in Surprise Billing.'' (February 2020). *https://www.commonwealthfund.org/blog/2020/how-states-are-using-independent-dispute-resolution-resolve-out-network-payments-surprise.*

[193] Kaiser Family Foundation. ''Surprise Medical Bills: New Protections for Consumers Take Effect in 2022.'' (2019). *https://www.kff.org/private-insurance/fact-sheet/surprise-medical-bills-new-protections-for-consumers-take-effect-in-2022/.*

[194] The cost is estimated as follows: (17,333 × $400) = $6,933,200.

[195] Employee Benefits Security Administration. ''Health Insurance Coverage Bulletin.'' (March 2019). *https://www.dol.gov/sites/dolgov/files/EBSA/researchers/data/health-and-welfare/health-insurance-coverage-bulletin-2019.pdf.*

[196] Hargraves, John and Aaron Bloschichak. ''Air Ambulances-10-Year Trends in Costs and Use.'' Health Care Cost Institute. (2019). *https://healthcostinstitute.org/emergency-room/air-ambulances-10-year-trends-in-costs-and-use.*

[197] Government Accountability Office. ''Air Ambulance: Available Data Show Privately-Insured Patients are at Financial Risk.'' (2019). *https://www.gao.gov/assets/gao-19-292.pdf.*

[198] The Departments utilize 10 percent as an assumption to estimate the overall number of physicians billing out-of-network at least once in a year.

[199] The Departments estimate that of the 213.2 million individuals with employer-sponsored and other private health insurance (178.4 million individuals with employer-sponsored health insurance and 34.8 million individuals with other private insurance), there are 33.3 air transports per 100,000 individuals, of which 69 percent result in an out-of-network bill. The Departments assume that 10 percent of the out-of-network bills will end up in IDR. (213,200,000 × 0.000333 × 0.69 × 0.1= 4,899).

[200] This is calculated 4,899/(1 − 0.25) = 6,532.

[201] The burden is estimated as follows: 6,532 claims × 2 hours + 6,532 claims × 0.25 hour = 39,190 hours. A labor rate of $105.01 is used for a medical and health services manager and a labor rate of $55.23 is used for a clerical worker. The labor rates are applied in the following calculation: 6,532 claims × 2 hours × $105.01 + 6,532 claims × 0.5 hour × $55.23 = $1,895,077. 2 × $1,895,077 = $3,790,154. Labor rates are EBSA estimates.

[202] Kaiser Family Foundation. ''Surprise Medical Bills: New Protections for Consumers Take Effect in 2022.'' (2019). *https://www.kff.org/private-insurance/fact-sheet/surprise-medical-bills-new-protections-for-consumers-take-effect-in-2022/.*

[203] The Commonwealth Fund. ''How States are Using Independent Dispute Resolution to Resolve Out-of-Network Payments in Surprise Billing.'' (February 2020). *https://www.commonwealthfund.org/blog/2020/how-states-are-using-independent-dispute-resolution-resolve-out-network-payments-surprise.*

[204] Kaiser Family Foundation. ''Surprise Medical Bills: New Protections for Consumers Take Effect in 2022.'' (2019). *https://www.kff.org/private-insurance/fact-sheet/surprise-medical-bills-new-protections-for-consumers-take-effect-in-2022/.*

[205] The cost is estimated as follows: (4,899 × $400) = $1,959,600.

[206] The cost is estimated as follows: (4,899 × $400) = $1,959,600.

1.5.4. Requirements for Certified IDR Entities

An IDR entity must be certified under standards and procedures set forth in these interim final rules and in guidance promulgated by the Departments. For each month, certified IDR entities will be required to report information on their activity to the Departments. The Departments estimate that there will be 50 entities seeking IDR certification, as discussed earlier in this analysis of economic and paperwork burdens.

The Departments estimate that the cost associated with the IDR entity certification process and reporting requirements will be $149,616 in the first year and $124,491 in the subsequent years. For more details, please refer to the Paperwork Reduction Act section.

1.5.5. External Review Requirements

The interim final rules require grandfathered health plans to provide external review for adverse benefit determinations involving benefits subject to these surprise billing protections.

The Departments estimate that there are approximately 84.4 million participants in self-insured ERISA-covered plans. Prior to the interim final rules, the Departments estimate that there were approximately 8.1 million participants in ERISA-covered plans in the states which currently have no external review laws or whose laws do not meet the Federal minimum requirements. These estimates lead to a total of 92.5 million participants. Among the 92.5 million participants, 80.5 million participants in non-grandfathered plans and 12 million participants in grandfathered plans will be required to be covered by the external review requirement.

The Departments estimate that there are approximately 1.3 external reviews for every 10,000 participants and that there will be approximately 12,304 external reviews annually. Experience from North Carolina indicates that about 75 percent of requests for external review are actually eligible to proceed to an external review.[207] Therefore, the Departments expect that there will be about 15,942 requests for external review. The Departments estimate that the cost associated with the external review requirements for ERISA-covered plans will be $3.3 million.

Additionally, HHS estimates that there are approximately 13.5 million individual market enrollees and 19.3 million non-Federal governmental plans enrollees.[208] These estimates lead to a total of 32.8 million total enrollees in individual market and non-Federal Government plans. Among the 32.8 million participants, 2.6 million are in grandfathered plans and 30.1 million are in non-grandfathered plans. HHS also added a 2 percent increase in the number of out-of-networks claims to capture the increase in burden on non-grandfathered plans resulting from the surprise billing and cost sharing protections of the external review requirements, resulting in an adjusted total of 30.7 million participants for non-grandfathered plans and an adjusted total of 33.3 million participants for all individual market and non-Federal Government plans.

HHS also estimates there are an estimated 1.3 external reviews for every 10,000 participants and that there will be approximately 4,337 total external reviews annually for individual market and non-Federal Government plans. This amount includes 3,994 reviews for non-grandfathered plans and 343 for grandfathered plans. Experience from North Carolina indicates that about 75 percent of requests for external reviews are actually eligible to proceed to an external review, therefore it is expected that there will be about 5,783 requests for external review. This amount includes 5,326 requests for non-grandfathered plans and 457 requests for grandfathered plans. HHS estimates that the cost associated with the external review requirements for individual market and non-Federal Government plans will be $241,850.

In summary, the Departments estimate that the total annual cost associated with the External Review for DOL will be $3.3 million and the total annual cost associated with the External Review for HHS will be will be $0.2 million. For more details, see the Paperwork Reduction Act section.

1.5.6. Protections for the Uninsured

These interim final rules seek to protect uninsured (or self-pay) individuals from surprise billing through two mechanisms: The provision of good faith estimates from providers and facilities and the patient-provider dispute resolution process to resolve billing disputes when an uninsured (or self-pay) individual receives a bill for charges that are substantially in excess of the expected charges listed in the good faith estimates.

1.5.7. Good Faith Estimates

As discussed in the Paperwork Reduction Act section of this preamble, HHS estimates the total annual burden to convening providers or facilities to notify uninsured (or self-pay) individuals of the availability of good faith estimates to be approximately 2,743,283 hours with an equivalent cost of $320,250,167. HHS estimates the annual cost to a convening provider or facility to provide a good faith estimate of expected charges to uninsured (or self-pay) individuals for scheduled items and services and upon requests between 2022 and 2024 to be $356,727,765 and total burden hours of 3,538,305.

1.5.8. Patient-Provider Dispute Resolution Process

As discussed in the Paperwork Reduction Act section of this preamble, HHS estimates the total annual burden associated with the patient-provider dispute resolution process for uninsured (or self-pay) individuals and health care providers and health care facilities to be approximately 255,524 hours with an equivalent cost of $29,764,646.

1.5.9. Patient-Provider SDR Entity Certification

As discussed in the Paperwork Reduction Act section of this preamble, HHS estimates the total annual burden associated with the SDR entity certification to be 16 hours with an equivalent cost of $1,873 in the first year. In subsequent years, the total hour burden associated with the SDR entity certification or recertification is 2.25 hours with an equivalent cost of $257. HHS seeks comment on the assumptions and calculations made in the corresponding Information Collection Request (ICR). The Departments also seek comment on the estimates presented in this section and on any additional costs incurred by patients, providers, providers of air ambulance services, facilities and uninsured (or self-pay) individuals.

1.5.10. Summary

The Departments estimate the total cost burden associated with these interim final rules to be $760.95 million in the first year, with $38.43 million attributable to the Federal IDR process for nonparticipating providers or nonparticipating emergency facilities or

[207] North Carolina Department of Insurance. ''Health Insurance Smart NC: Annual Report on External Review Activity 2013.'' *https://digital.ncdcr.gov/digital/collection/p249901coll22/id/730531.*

[208] Individual market based on data from MLR annual report for the 2019 MLR reporting year, available at *https://www.cms.gov/CCIIO/Resources/Data-Resources/mlr.* Non-federal government plans data from Agency for Healthcare Research and Quality, Center for Financing, Access and Cost Trends. 2019 Medical Expenditure Panel Survey-Insurance Component.

group health plans or health insurance issuers offering health insurance coverage, $11.08 million attributable to the Federal IDR process for air ambulance services; $149,616 attributable to costs associated with certification and recordkeeping requirements for certified IDR entities, $4.02 million attributable to the external review process, and $706.7 million attributable to the patient-provider dispute resolution process.

The Departments seek comment addressing the costs that will be associated with these interim final rules. The Departments also seek comment on how these interim final rules will affect individuals from minority and underserved communities, and providers and facilities who serve these individuals.

1.6. Transfers

These interim final rules will protect patients from surprise bills for emergency and nonemergency medical services and air ambulance services. The Departments and OPM recognize this as transfers between individuals, plans, issuers, FEHB carriers, and providers, facilities, and providers of air ambulance services. The Departments and OPM expect that these interim final rules will result in some transfers from providers, facilities, and providers of air ambulance services to individuals, some transfers from plans, issuers, and FEHB carriers to providers, facilities, and providers of air ambulance services, and some transfers from individuals to plans, issuers, and FEHB carriers and providers, facilities, and providers of air ambulance services. The magnitude of each of these transfers is uncertain, and as such, the ultimate effect of the Federal IDR process on each of entity is largely uncertain.

These interim final rules may result in lower out-of-pocket spending by individuals, as these interim final rules are expected to decrease surprise billing. This result would follow from two types of transfers: Transfers from providers, facilities, and providers of air ambulance services who had previously balance billed individuals for out-of-network claims to individuals who would have received those balance bills, and transfers from plans, issuers, and FEHB carriers who were previously not responsible for out-of-network bills to providers who would submit out-of-network bills to plans, issuer, and FEHB carriers as a result of these interim final rules. The Departments request comment or data on how large each of these transfers might be.

As shown in Table 3, the mean provider charges relative to Medicare payment rates differ across physician specialties, and the ratios for specialties in which surprise billing is more common have a higher ratio of mean provider charges relative to Medicare payments rates than those specialties for which surprise billing is less common. These higher rates have been linked to the fact that patients are not able to select providers in these specialties, leaving patients more vulnerable to surprise billing.[209] The Departments expect that the proposed interim final rules will lead to the ratio of mean provider charges to Medicare payment rates to converge with specialties with comparatively infrequent surprise billing.

TABLE 3—RATIO OF MEAN PROVIDER CHARGES TO MEDICARE PAYMENT RATES BY SPECIALTY

Specialty	Mean ratios, 2018[210]
Specialties with infrequent surprise billing	
Family Practice	2.1
Internal Medicine	2.2
Primary Care	2.2
Dermatology	2.1
Specialties with frequent surprise billing	
Anesthesiology	7.0
Emergency Medicine	5.7
Diagnostic Radiology	4.0
Pathology	2.7

Further, research finds that New York's Out-of-Network Law[211] has saved consumers over $400 million from the date of implementation, March 2015, through the end of 2018 with respect to emergency services alone.[212] These savings have been realized in part through a reduction in costs associated with emergency services and an increased incentive for network participation. By establishing an IDR process for out-of-network emergency services, the Out-of-Network Law reduced out-of-network billing by 34 percent and lowered in-network emergency physician payments by 9 percent.[213]

The interim final rules are expected to have an effect on premiums, although there is uncertainty around how premiums will ultimately be affected. The Congressional Budget Office estimated the provisions in the No Surprises Act are likely to reduce premiums by 0.5 percent to 1 percent in most years.[214] In comparison, the CMS's Office of the Actuary (OACT) estimated the provisions are likely to increase premiums by 0.00 percent to 0.35 percent.[215] Neither of these estimates isolate the effect attributable to the Federal IDR process.

The ultimate effect on premiums will depend on how much plans, issuers, FEHB carriers, and providers, facilities, and providers of air ambulance services will use the Federal IDR process and how the Federal IDR process affects plan, issuer, and FEHB carrier liability. If payments to providers decrease, this change may result in a decrease in premiums. This decrease in premiums will result in a transfer from providers and facilities to participants, enrollees, or beneficiaries through plans, issuers, and FEHB carriers. Additionally, this could result in a transfer from eligible enrollees to the Federal Government in the form of reduced payment of the Premium Tax Credits (PTC). Conversely, if payments to providers increase, the expenditures for plans, issuers, and FEHB carriers may be passed on to consumers in the form of increased premiums. This could result in three types of transfers: (1) From the participants, enrollees, and beneficiaries to the plans, issuers, and FEHB carriers; (2) from the Federal Government to

[209] *See* Hannick, Kathleen and Loren Adler. ''Provider Charges Relative to Medicare Rates, 2012–2018.'' USC-Brookings Schaeffer on Health Policy. (May 2021). *https://www.brookings.edu/blog/usc-brookings-schaeffer-on-health-policy/2021/05/03/provider-charges-relative-to-medicare-rates-2012-2018/.*

[210] *See* Hannick, Kathleen and Loren Adler. ''Provider Charges Relative to Medicare Rates, 2012–2018.'' USC-Brookings Schaeffer on Health Policy. (May 2021). *https://www.brookings.edu/blog/usc-brookings-schaeffer-on-health-policy/2021/05/03/provider-charges-relative-to-medicare-rates-2012-2018/.*

[211] NY Fin Serv L § 605 (2014).

[212] 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). *https://www.pacep.net/assets/documents/NYReportontheIDRProcess.pdf.*

[213] Cooper, Zack, Fiona Scott Morton, and Nathan Shekita. ''Surprise! Out-Of-Network Billing for Emergency Care in the United States.'' 128 Journal of Political Economy 9. (2020).

[214] Congressional Budget Office. ''Estimate for Divisions O Through FF. H.R. 133, Consolidated Appropriations Act, 2021. Public Law 116–260.'' *https://www.cbo.gov/system/files/2021-01/PL_116-260_div%20O-FF.pdf.*

[215] The OACT analysis assumed that an individuals' cost-sharing is limited to their in-network cost-sharing amounts and that plans and issuers are responsible for any excess of the allowed amounts for nonparticipating providers over in-network reimbursement rates. OACT assumed that that the average allowed amounts for services provided by nonparticipating providers will remain higher than in-network reimbursement rates after the No Surprises Act takes effect. OACT estimated a range of values for out-of-network allowed charges between 125 percent and 150 percent of average network rates. OACT assumed that these estimated levels reflected the Federal IDR process but did not make any explicit assumptions about the separate impact of the Federal IDR process.

eligible enrollees in the form of increased PTC; and (3) from insured individuals who pay premiums to individuals with large out-of-network bills.

In addition, these interim final rules may affect in-network and out-of-network rates received by physicians. It is possible that the out-of-network rates collected by some providers, facilities, and providers of air ambulance services will be lower than they would have been if not for the provisions in these interim final rules. There is also uncertainty around how these interim final rules will affect the negotiation dynamics between providers, facilities, plans, issuers, and FEHB carriers regarding health care costs.

As evidenced in states where arbitrators are directed to base their determinations on billed charges, there have been increased health care costs as a result of the out-of-network payment standard being higher than that in-network rate.[216] However, as noted in an analysis by the USC.-Brookings Schaeffer Initiative for Health Policy, if certified IDR entities base their determinations on median in-network rates, which are typically lower than billed charges, the IDR process could place downward pressure on health care costs and premiums. If certified IDR entities choose amounts that are above median in-network rates, this could result in a potential increase in costs and premiums.[217] For example, in New York, providers prevailed in IDR at nearly twice the rate that issuers prevailed. In the state, arbiters are told to consider the 80th percentile of billed charges in their decision process. A study found that even when deciding in favor of health plans, arbitrations averaged just 11 percent below the 80th percentile of charges, which is consistently above the typical in-network or out-of-network rates. This result implies that plans, issuers, and FEHB carriers only won in arbitration when paying above-market rates.[218]

Further, in the Federal IDR process, certified IDR entities are required to consider credible information about additional factors such as providers' expertise and patient characteristics after beginning with a presumption in favor of the QPA, making it beneficial for a provider or facility to initiate the process when they expect to be paid more than the median in-network rate. A report from the Congressional Budget Office noted that some providers, particularly those with more specialized services, may be able to negotiate for larger payments from insurers by threatening to initiate the Federal IDR process.[219] This outcome could result in a transfer from plans, issuers, and FEHB carriers to providers. Furthermore, this outcome could also result in higher premiums, which could ultimately result in a transfer from patients to providers.[220]

In addition, these interim final rules may affect provider and facility payments and revenue. It is possible that the payments collected by some providers and facilities will be lower than they would have been if not for the provisions in these interim final rules. These interim final rules set standards requiring certified IDR entities to consider the QPA (typically the median in-network rate) when making payment determinations; the Departments expect this approach to have a downward impact on health care costs, potentially resulting in transfers from providers and facilities to individuals with health coverage.

Furthermore, the external review requirements of these interim final rules may result in a transfer from plans, or issuers to participants and beneficiaries now receiving payment for denied benefits. These transfers will improve equity, because incorrectly denied benefits will be paid.

These interim final rules also establish requirements for the uninsured (or self-pay) individual to submit an administrative fee payment when initiating the patient-provider dispute resolution process as provided in 45 CFR 149.620(g) and described in section IV.B.8 of this preamble. This requirement may result in a transfer to the uninsured (or self-pay) individual from the provider or issuer if the uninsured (or self-pay) individual prevails in the dispute resolution process. Under such circumstances, the SDR entity must apply a reduction equal to the administrative fee amount paid by the individual to the final determination amount for charges to be paid by the individual for the items or services.

1.7. Regulatory Alternatives

Section 6(a)(3)(C)(iii) of Executive Order 12866 requires an economically significant regulation to include an assessment of the costs and benefits of potentially effective and reasonable alternatives to the planned regulation. The Departments considered whether the certified IDR entity was required to consider the QPA and permitted to consider other statutory factors only when a party presents clear and convincing evidence that the value of the qualified IDR item or service materially differs from the QPA due to those factors, or whether the certified IDR entity should be required to consider all factors equally.

The Departments are of the view, however, that applying a clear and convincing evidence standard does not afford enough weight to the statutory requirement that certified IDR entities consider the additional permissible factors. Such a standard could result in a certified IDR entity failing to consider credible information a party provides, even where it clearly demonstrates that the QPA is materially different from the appropriate out-of-network rate. On the other hand, permitting consideration of all permissible factors equally disregards the weight that the No Surprises Act places on the QPA. For example, Code section 9816(c)(7)(B)(iii)–(iv), ERISA section 716(c)(7)(B)(iii)–(iv), and PHS Act section 2799A–1(c)(7)(B)(iii)–(iv) require the Departments to report the offers as a percentage of the QPA and the amount of the offer selected, expressed as a percentage of the QPA. The statute also provides strict rules for calculating the QPA and creates disclosure and audit requirements regarding the QPA.

The Departments, therefore, are of the view that starting with a rebuttable presumption that the QPA is the appropriate payment amount properly emphasizes the QPA while requiring the consideration of the permissible additional factors when appropriate. The QPA generally is based on the median of contracted rates, which are the product of contract negotiations between providers and facilities and plans (and their service providers) and issuers, and therefore generally reflect market rates. The statute sets out detailed rules for calculating the QPA, including a requirement that when

[216] Ollove, Michael. Laws to Curb Surprise Medical Bills Might Be Inflating Health Care Costs. PEW. (2021. *https://www.pewtrusts.org/en/research-and-analysis/blogs/stateline/2021/05/20/laws-to-curb-surprise-medical-bills-might-be-inflating-health-care-costs.*

[217] Adler, Loren, et al. ''Understanding the No Surprises Act.'' USC-Brookings Schaeffer on Health Policy. (2021). *https://www.brookings.edu/blog/usc-brookings-schaeffer-on-health-policy/2021/02/04/understanding-the-no-surprises-act/.*

[218] Adler, Loren. ''Experience with New York's Arbitration Process for Surprise Out-of-Network Bills.'' USC-Brookings Schaeffer on Health Policy. (October 2019). *https://www.brookings.edu/blog/usc-brookings-schaeffer-on-health-policy/2019/10/24/experience-with-new-yorks-arbitration-process-for-surprise-out-of-network-bills/.*

[219] Congressional Budget Office Cost Estimate. ''H.R. 2328, Reauthorizing and Extending America's Community Health Act.'' (September 2019). *https://www.cbo.gov/system/files/2019-09/hr2328.pdf.*

[220] Congressional Budget Office Cost Estimate. ''H.R. 2328, Reauthorizing and Extending America's Community Health Act.'' (September 2019). *https://www.cbo.gov/system/files/2019-09/hr2328.pdf.*

plans, issuers, and FEHB carriers do not have sufficient information to calculate their own median contracted rates, they utilize a database free of conflicts of interests.[221] Plans, issuers, and FEHB carriers must provide specific information on how the QPA is calculated to nonparticipating providers and facilities, ensuring that they are aware of how this rate was calculated.[222] Plans, issuers, and FEHB carriers are also subject to audit requirements that will be enforced by the Departments and OPM to ensure that they follow these standards.[223] The Departments are also required to report how the out-of-network rates compare to the QPA, suggesting that Congress saw it as an appropriate analogue for the out-of-network rate.[224] Moreover, starting with the QPA as the rebuttable presumption for the appropriate payment amount will increase the predictability of dispute resolution outcomes which may encourage parties to reach an agreement outside of the Federal IDR process to avoid the administrative costs and will aid in reducing prices that may have been inflated due to the practice of surprise billing prior to the No Surprises Act. Finally, the Departments are of the view that this approach will protect participants, beneficiaries, and enrollees from excessive costs, either through reduced costs for items and services or through decreased premiums. Therefore, in determining which offer to select, these interim final rules provide that the certified IDR entity must begin with the presumption that the QPA for the applicable year is the appropriate payment amount for the qualified IDR items or services. The certified IDR entity must, however, consider the other factors when a party provides credible information, and must choose the offer closest to the QPA, unless the credible evidence submitted by the parties clearly demonstrates that the QPA is materially different from the appropriate out-of-network rate.

As noted previously, emphasizing the QPA will allow for predictability. As mentioned earlier in this preamble, when the recognized amount is the QPA, plans, issuers, and FEHB carriers must provide the QPA to providers and facilities when submitting an initial payment amount or denial of payment, and must provide additional information regarding the QPA upon request. Thus, even before beginning negotiations, all parties involved will know that the QPA is the primary factor that the certified IDR entity will always consider (while other factors may be considered, depending on the circumstances). This certainty will encourage plans, issuers, providers, and facilities to make offers that are closer to the QPA, and to the extent another factor could support deviation from the QPA, to focus on evidence concerning that factor. This certainty may also encourage parties to avoid the Federal IDR process altogether and reach an agreement during the open negotiation period. Finally, it is anticipated that focusing on the QPA will help mitigate costs and reduce government expenditures once the Federal IDR process is fully implemented, as projected by the Congressional Budget Office.[225] Therefore, after carefully considering both interpretations, the Departments chose to emphasize the QPA.

Furthermore, as discussed earlier in this preamble, the Departments considered how to select a certified IDR entity if the parties fail to do so. Academic literature is inconclusive regarding whether the selection process of an arbitrator has an effect on the arbitration results. One study found significant consistency between factors affecting an arbitrator's decision,[226] suggesting that the selection of a certified IDR entity by parties to the IDR, or the selection process of a certified IDR entity by the government if the parties fail to select a certified IDR entity, should not have a significant effect on the outcome. Contrarily, another study found large differences among arbitrator decisions; however, the authors attributed these differences to information disparities between parties.[227] As the parties in the Federal IDR process under these interim final rules are all professionals with specialized knowledge in health care, these information disparities are expected to be minimal in the context of the Federal IDR process.

Although the academic literature suggests that the selection of an IDR entity is unlikely to have a significant effect on the IDR entity's determination, the Departments explored options to minimize this risk. The Departments considered alternative approaches, including whether the Departments should consider the specific fee of the certified IDR entity, or look to other factors, such as how often the certified IDR entity chooses the amount closest to the QPA. However, looking to how often the certified IDR entity chooses the amount closest to the QPA could unfairly penalize certified IDR entities that have correctly handled decisions when there is credible information clearly demonstrating that the QPA is materially different from the appropriate out-of-network rate. Using this as a factor in assigning certified IDR entities could incentivize decisions that do not adequately take into account the other factors set forth in the statute and these interim final rules, even when there is credible information clearly demonstrating that the QPA is materially different from the appropriate out-of-network rate. Moreover, the consideration of other factors may encourage plans, issuers, FEHB carriers, or providers and facilities, to decline to agree to a particular certified IDR entity, thinking that the Departments will favor certain criteria. Given the cost controls applicable to the certification process, it is unlikely that the cost of a specific certified IDR entity will be a significant factor in the inability of the parties to choose a certified IDR entity.

Thus, after carefully considering the alternatives, the Departments have chosen to use a random selection method to select a certified IDR entity with a fee within the allowed range. If there is an insufficient number of certified IDR entities with a fee within the allowed range available to arbitrate the case, the Departments will use a random selection method to select a certified IDR entity that has received approval from the Departments to charge a fee outside of the allowed range.

External Review

The Departments considered different amendments to the regulations for external review to address the scope for non-grandfathered plans and issuers in light of section 110 of the No Surprises Act. Under the existing rules, a claim is eligible for external review under the Federal external review process if it involves medical judgement. The Departments note that the scope of

[221] Code section 9816(a)(2), (3)(E); ERISA section 716(a)(2), (3)(E) and PHS Act section 2799A–1(a)92), (3)(E); 26 CFR 54.9816–6T, 29 CFR 2590.716–6, and 45 CFR 149.140.

[222] Id.

[223] 86 FR 36872, 36899 (July 13, 2021).

[224] Code section 9816(c)(7)(A)(v), (B)(iii) and (iv); ERISA section 716(c)(7)(A)(v), (B)(iii) and (iv); and PHS Act section 2799A–1(c)(7)(A)(v), (B)(iii) and (iv).

[225] Congressional Budget Office, Estimate for Divisions O Through FF, H.R. 133, Consolidated Appropriations Act, 2021, Public Law 116–260, Enacted on December 27, 2020. *https://www.cbo.gov/publication/56962.*

[226] Farber, Henry and Max Bazerman. ''The General Basis of Arbitrator Behavior: An Empirical Analysis of Conventional and Final-Offer Arbitration.'' *The Econometric Society.* Vol. 54(4) (July 1986). *https://www.jstor.org/stable/1912838.*

[227] Egan, Mark, Gregor Matvos, and Amit Seru. ''Arbitration with Uniformed Consumers.'' National Bureau of Economic Research. (October 2018). *https://www.nber.org/system/files/working_papers/w25150/w25150.pdf.*

claims that are eligible for external review in general is broad, as many adverse benefit determinations involve medical judgment. The examples the Departments have provided of questions involving medical judgement (described in more detail earlier in the preamble) include questions involving health care setting, level of care, or effectiveness of a covered benefit, whether treatment involved ''emergency care'' or ''urgent care,'' affecting coverage, and how a claim is coded. The Departments note that the state external review process also extends to questions involving the requirements for medical necessity, appropriateness, health care setting, level of care, or effectiveness of a covered benefit. The Departments are of the view that many claims that result in an adverse benefit determination involving items and services subject to the surprise billing and cost-sharing protections under the No Surprises Act generally would be eligible for external review under the current scope as specified in the 2015 final regulations. However, as stated above, section 110 of the No Surprises Act directs the Departments to require the external review process under PHS Act section 2719 to apply with respect to *any* adverse determination by a plan or issuer under PHS Act section 2799A–1 or 2799A–2, ERISA section 716 or 717, or Code section 9816 or 9817, including with respect to whether an item or service that is subject to such a determination is an item or service to which the respective section applies. The Departments are of the view that it is important to ensure that consumers can avail themselves of external review in these situations and ensure that they are afforded full protection against surprise medical costs (including cost sharing), as intended by the No Surprises Act. Accordingly, these interim final rules amend the 2015 final rules to broaden the scope of external review requirements and explicitly require, to the extent not already covered, that any adverse determination that involves consideration of whether a plan or issuer is complying with PHS Act section 2799A–1 or 2799A–2, ERISA section 716 or 717, or Code section 9816 or 9817 is eligible for external review.

HHS considered certain other approaches to furnishing good faith estimates to uninsured (or self-pay) individuals. HHS considered notification of the availability of good faith estimates using only broad outreach efforts and not, in addition to, specifically requiring that providers or facilities inform uninsured (or self-pay) individuals of the availability of good faith estimates. However, HHS is of the view that uninsured (or self-pay) individuals are more acutely aware of and concerned about health care costs when engaging with providers and facilities. Not requiring providers or facilities to notify uninsured (or self-pay) individuals of the availability of good faith estimates would potentially deprive uninsured (or self-pay) individuals of the ability to avail themselves of these important consumer protections under the No Surprises Act.

HHS considered requiring good faith estimates for each instance of a recurring item or service with the same expected charges. HHS is of the view that to do so would unnecessarily increase the burden on providers and facilities, particularly for those items and services furnished weekly or more than once per week, without adding additional informational value for the uninsured (or self-pay) individual. HHS is of the view that, while a single good faith estimate for certain recurring items and services is sufficient, establishing certain limitations is necessary in order to confirm and periodically evaluate the accuracy of the information included in the good faith estimate. For instance, HHS includes requirements that limit the applicability of a good faith estimate for recurring items and services to no longer than 12 months. If additional recurrences of furnishing such items or services are expected beyond 12 months, a convening provider or convening facility must provide an uninsured (or self-pay) individual with a new good faith estimate.

HHS also considered requiring the use of standardized notices for good faith estimates issued to uninsured (or self-pay) individuals. However, HHS is of the view that requiring the use of such model notices for good faith estimates would not allow providers or facilities necessary flexibilities to develop notices that would be most effective for their patient populations.

HHS also considered basing the substantially in excess threshold as equal to only a percentage of the expected charges in the good faith estimate; however HHS has concerns that such an approach could make dispute resolution easier to access for items or services where the expected charges are small, which would include circumstances where the difference between the billed charge and the expected charges in the good faith estimate is too small to justify the costs of dispute resolution. Alternatively, when the total expected charges in the good faith estimate are very high, few items or services could be subject to dispute resolution, despite significant unexpected charges. HHS also considered other approaches to defining the ''substantially in excess'' standard, including setting it as the lesser of a specific percentage of the total expected charges in the good faith estimate or a flat maximum dollar amount, or based on a percentage of the expected charges in the good faith estimate that varies depending on the expected costs of the items or service. Although these approaches would mitigate some of the concerns discussed previously and would make it easier for higher cost items or services to meet the substantially in excess threshold, these approaches would increase concerns that dispute resolution for lower cost services could be overused, thus potentially increasing costs for providers and facilities and potentially increasing costs for such items or services. As an alternative, HHS also considered an approach for determining ''substantially in excess'' based on an amount that is the greater of either a percentage of the total amount of expected charges in the good faith estimate or a flat minimum dollar amount. However, HHS remains concerned that such an approach could effectively put dispute resolution out of reach for uninsured (or self-pay) individuals in situations where the expected charges for the item or service are high, particularly for those who need to undergo more complex procedures. Finally, HHS considered a tiered approach, either a flat dollar amount that would increase as the total expected charges in the good faith estimate increases or a percentage that would decrease as the total of expected charges in the good faith estimate increases, but HHS is of the view that such an approach would add undue complexity and could be confusing for uninsured (or self-pay) individuals, providers, facilities, and other stakeholders.

Lastly, HHS considered basing the definition of ''substantially in excess'' on billed charges that exceed a certain percentage for the same or similar services using an independent database. However, HHS is of the view that such a mechanism is inconsistent with the statute which contemplates items or services to be determined to be ''substantially in excess'' based on the good faith estimate provided, rather than being based on a specific benchmark, such as that provided by an independent database.

As HHS obtains additional experience with the patient-provider dispute resolution process, HHS intends to review data on the use of the dispute

resolution process and may propose adjustments to the definition of ''substantially in excess'' in the future.

HHS considered whether to base eligibility for patient-provider dispute resolution on whether an individual item or service listed on a good faith estimate is billed an amount substantially in excess to the expected charge in the good faith estimate. However, HHS is concerned that such an approach would add complexity as each item or service on the good faith estimate would need to be assessed separately for eligibility. HHS also considered basing the eligibility on the total of all billed charges for all items or services and all providers or facilities listed on the good faith estimate, however such an approach would be significantly more complex given that the good faith estimate could consist of estimates of multiple providers and facilities who would bill the uninsured (or self-pay) individual separately. This approach could also potentially increase the burden on the uninsured (or-self pay) individual who would likely need to submit multiple bills from multiple providers or facilities for dispute resolution. Additionally, such an approach could require a provider or facility to respond to a notice requesting additional documentation from an SDR entity due to the billing of other providers, even when the provider or facility did not bill an uninsured (or self-pay) individual an amount substantially in excess of the good faith estimate. As a result, HHS is of the view that it is appropriate to base eligibility for dispute resolution on each provider or facility listed on the good faith estimate.

HHS considered not requiring co-providers or co-facilities that are not represented on a good faith estimate due to replacing an original co-provider or co-facility that was represented in a good faith estimate to be subject to the patient-provider dispute resolution process due to not having provided estimates of expected charges with which to base whether the billed charges substantially exceed the estimate. However, HHS is of the view that such requirements should still apply in these circumstances as they provide important consumer protections that are aimed to protect uninsured (or self-pay) individuals from unexpected medical bills, and allowing a replacement co-provider or co-facility to essentially circumvent these protections simply due to not being directly represented on the good faith estimate would weaken these consumer protections.

HHS considered requiring the Federal IDR portal be used by an uninsured (or self-pay) individual to initiate a patient-provider dispute resolution process rather than making the use of the Federal IDR portal optional. However, HHS was concerned that such a requirement could pose an unreasonable barrier for uninsured (or self-pay) individuals, particularly those with limited or no access to the internet.

HHS considered not providing a mechanism for the uninsured (or self-pay) individual to settle on a payment amount for an item or service prior to an SDR entity issuing a payment determination. However, HHS is of the view that providing an opportunity for the uninsured (or self-pay) individual and the provider or facility to come to terms on a payment amount that is mutually agreeable for the parties involved is appropriate as it can help resolve payment disputes quickly without the need for a determination by an SDR entity. Such a process can also incentivize a provider or facility to accept a lower payment amount or to provide financial assistance to the uninsured (or self-pay) individual.

HHS considered whether to allow the SDR entity to have discretion to determine a payment amount lower than the expected charges listed in the good faith estimate. However, HHS is of the view that such an approach would result in less transparency and predictability for the uninsured (or self-pay) individuals, providers and facilities regarding the outcomes of the patient-provider dispute resolution process. Therefore, HHS is of the view that the good faith estimate represents charges the uninsured (or self-pay) individual would likely expect to pay for the items or services, and as a result the consumer protections established in the patient-provider dispute resolution process serve as an important backstop that protects an uninsured (or self-pay) individual from unexpected billed charges that substantially exceed the good faith estimate.

HHS considered allowing an SDR entity to use a different standard for conducting determinations, other than that the information submitted by the provider must provide credible information that the difference between the billed charge and the expected charge for the item or service in the good faith estimate reflects the costs of a medically necessary item or service and is based on unforeseen circumstances that could not have reasonably been anticipated by the provider or facility when the good faith estimate was provided. However, HHS is of the view is that such an approach would not align with the standard utilized in the Federal IDR processes discussed in section III of this preamble. This approach would result in adding undue complexity to the patient-provider dispute resolution process and the use of a different standard from the Federal IDR process could potentially lead to confusion for uninsured (or self-pay) individuals, providers and facilities.

When an SDR entity determines that the provider or facility has provided credible information that the difference between the billed charge and the expected charge for the item or service in the good faith estimate reflects the costs of a medically necessary item or service and is based on unforeseen circumstances that could not have reasonably been anticipated by the provider or facility when the good faith estimate was provided, HHS considered requiring that the SDR determine that the payment amount be equal to the billed charge, rather than the lesser of the billed charge or the payment amount for the same or similar services contained on an independent database (or if applicable, the good faith estimate). However, HHS is concerned that such an approach may increase the incentive for providers and facilities to inflate their billed charges, particularly in cases where the provider or facility believes they can justify the billed charges.

HHS considered not requiring an SDR entity determination to be binding upon the parties involved, in the absence of a fraudulent claim or evidence of misrepresentation of facts presented to the IDR entity involved. However, HHS was concerned that not having the process be binding could lead to a provider or facility not abiding by the SDR entity determination and holding the uninsured (or self-pay) individual liable for the entire billed charge even if the SDR entity determined that the uninsured (or self-pay) individual pay a lower amount. HHS is of the view that without making the determination binding, the consumer protections established in PHS Act section 2799B–7 would be significantly diminished and that the cost for administering the program may outweigh the benefit.

HHS considered various approaches to paying for the costs of the patient-provider dispute resolution process. HHS considered requiring the uninsured (or self-pay) individual to pay the patient-provider dispute resolution costs (*e.g.,* SDR entity costs) in cases where the individual does not prevail in dispute resolution. However, such an approach could place a significant burden on the uninsured (or

self-pay) individuals, especially low-income individuals. Such a requirement would also not be in alignment with the requirements in PHS Act section 2799B–7 that the administrative fee be set so as not to create a burden to participation. HHS also considered requiring the provider or facility to pay for dispute resolution costs when the provider or facility does not prevail. However, HHS has concerns that such an approach would impose a burden on the providers and facilities and could potentially provide an incentive for the providers and facilities to increase the prices on uninsured (or self-pay) individuals to account for potential patient-provider dispute resolution costs or avoid treating uninsured (or self-pay) individuals altogether.

HHS considered using an open certification process for SDR entities rather than contracting with a limited number of SDR entities that meet the certification requirements outlined in 45 CFR 149.620(d). However, HHS is of the view that an open certification process would increase the administrative burden associated with certifying SDR entities and would not allow for the same level of administrative oversight, monitoring, and audit potential as opposed to contracting with the SDR entities directly.

HHS considered not providing a mechanism to defer to a state that implements a parallel patient-provider dispute resolution process that meets certain minimum Federal requirements. However, such an approach would not allow for states to establish processes which meet Federal minimum standards that are specifically tailored for the state's residents and providers and facilities in the state. Allowing a state to establish a process that meets or exceeds the Federal minimum standards is also consistent with other provisions of the No Surprises Act such as allowing the application of a state law to determine the total amount payable to out-of-network providers and facilities.

1.8. Uncertainty

It is unclear what percentage of participants, beneficiaries, and enrollees experience surprise billing. The frequency of surprise billing may differ among small and large health issuers.

Furthermore, among individuals who experience surprise billing, the percentage of claims that would be resolved by the Federal IDR process is unclear. It is possible that some claims would be resolved through early settlement before they proceed to the Federal IDR process. It is also possible that some claims would be determined to be ineligible for the Federal IDR process. While there is some data from New York regarding these questions, it is uncertain whether other states' trends will be similar to New York's or whether New York's experience can be extrapolated to other states.

Additionally, these interim final rules permit multiple qualified IDR items and services to be batched in a single payment determination to encourage efficiency. In order for qualified IDR items or services to be batched, they must involve the same service code or comparable code under different procedural systems. Batching by service code will allow parties to group together qualified IDR items and services that are medically similar, promoting efficiency by allowing the certified IDR entity to consider similar qualified IDR items and services, and more efficiently focus on where the value of the qualified IDR items or services is consistently materially different from the QPA. Additionally, the Departments require batching to be done by provider or group of providers, the same facility, or the same provider of air ambulance services sharing the same NPI or TIN. By allowing groupings of providers with the same TIN, this will allow group practices to batch together qualified IDR items or services. Due to the uncertainty surrounding how often and how many payment determinations will consider batched items and services, the Departments acknowledge the high degree of uncertainty around the estimates of how many disputes will result in the Federal IDR process each year.

Additionally, it is unclear how these interim final rules will alter the experiences of everyone involved in the health care system, beyond the individuals and entities that are involved in the Federal IDR process. For example, research finds that New York's Out-of-Network law [228] reduced surprise billing by 34 percent and lowered in-network emergency physician payments by 9 percent via shifting the billing costs to emergency department physicians who bill on an out-of-network basis.[229] Research also finds that New York's Out-of-Network law increased the incentive for physicians providing emergency services to participate in health plan networks.[230]

It is unclear to what degree providers and facilities may adjust their pricing for items and services in order to pay for the anticipated costs of providing a good faith estimate. It also is unclear if providers and facilities will provide higher estimates than the amounts they intend to charge in order to avoid the patient-provider dispute resolution process, and what impact this practice might have on an individual's decision to seek necessary care. For example, some providers and facilities may overestimate the costs for items or services, up-code to a more expensive service, or add additional unnecessary services, which could circumvent the intended consumer protections. These actions could impact whether some patients defer or delay needed care on the basis of perceived costs or have a pathway to dispute bills through the patient-provider dispute resolution process.

Among uninsured (or self-pay) individuals who receive billed charges that are substantially in excess of the expected charges in the good faith estimate, it is unclear to what extent such bills will be resolved using the patient-provider dispute resolution process, or to what extent such bills will be resolved in other ways such as a settlement where the provider or facility would offer a lower bill, discount, or an offer of financial assistance.≤

Last, the Departments are uncertain whether the policies adopted in these interim final rules could ultimately lead to inflation of health care costs or could result in a reduction in uninsured (or self-pay) individuals' access to needed care. One study, which examined the arbitration decisions in New Jersey, where billed charges or usual and customary rates are taken into consideration in the IDR process, found that the median payments awarded were 5.7 times higher than the median in-network rates for the same services. The study concluded that basing arbitration decisions on provider-billed charges would likely increase health care costs.[231] In New York State, state guidance directs arbiters to consider the 80th percentile of billed charges and the New York Department of Financial Services has found that arbitration decisions resulted in, on average, charges 8 percent higher than the

[228] NY Fin Serv L § 605 (2014).

[229] 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.*

[230] 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). *https://www.pacep.net/assets/documents/NYReportontheIDRProcess.pdf.*

[231] Chartock, B.L., Adler, L., Ly, B., Duffy, E., & Trish, E. (2021). Arbitration over Out-Of-Network Medical Bills: Evidence from New Jersey Payment Disputes: Study Examines Arbitration Decisions to Resolve Payment Disputes Between Issuers and Out-Of-Network Providers in New Jersey. 40 *Health Affairs* 1, 130–137. *https://www.healthaffairs.org/doi/abs/10.1377/hlthaff.2020.00217.*

eightieth percentile of billed charges.[232] By considering the offer closest to the QPA and prohibiting certified IDR entities from considering billed charges, these interim final rules will likely limit potential inflationary effects even if arbitration leads to payment determinations that are above the amounts plans and issuers typically pay to in-network providers.[233] Thus, these interim final rules may constrain inflationary effects, but the degree to which they may do so is uncertain.

1.9. Conclusion and Summary of Economic Impacts

The Departments are of the view that these interim final rules will help ensure that consumers are protected from unexpected out-of-network medical costs by creating a process for plans, issuers, FEHB carriers and nonparticipating providers, facilities, and providers of air ambulance services to resolve disputes regarding out-of-network rates. These interim final rules provide a market-based approach that will allow these entities to agree upon reasonable payment rates.

The Departments expect a significant reduction in the incidence of surprise billing, potentially resulting in significant savings for consumers. There may be a potential transfer from providers, facilities, and providers of air ambulance services 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. Overall, these interim final rules provide a mechanism to effectively resolve disputes between plans, issuers, and FEHB carriers and providers and facilities, while protecting patients.

HHS is of the view that the provisions in these interim final rules will protect uninsured (or self-pay) individuals from surprise medical costs by allowing them to obtain a good faith estimate of expected charges from providers and facilities prior to receiving scheduled items and services and upon request. With this information, uninsured (or self-pay) individuals may be more likely to consider and compare costs across providers or facilities prior to or upon scheduling an item or service to help inform decisions regarding costs for an item or service. These benefits, however, are predicated on the good faith estimate being a reasonably predictive and accurate document that can be understood by patients and their representatives. Additionally, these interim final rules protect these uninsured (or self-pay) individuals by allowing an uninsured (or self-pay) individual to seek a determination through the patient-provider dispute resolution process if actual billed charges for items or services from a provider or facility are substantially in excess of the expected charges listed in the good faith estimate. Moreover, HHS is of the view that uninsured (or self-pay consumers) will also benefit from being able to take advantage of the patient-provider dispute resolution process as an intermediary step in resolving outstanding medical bills, which will delay providers sending these outstanding bills to collection agencies.

The patient-provider dispute resolution process further protects uninsured (or self-pay) individuals as the process may result in lower payments if an SDR entity determines that information submitted by a provider or facility does not provide credible information that the billed charge for an item or service reflects the costs of a medically necessary item or service and is based on unforeseen circumstances that could not have reasonably been anticipated by the provider or facility when the good faith estimate was provided, in which case the SDR entity must determine as the payment amount the expected charge for the item or service (or in the case of a new item or service, $0) to be paid by the uninsured (or self-pay) individual to the provider or facility.

The Departments estimate that these interim final rules will impose incremental costs of approximately $760.95 million in the first year and $440.67 million in subsequent years. Over 10 years, the associated costs will be approximately $3.62 billion with an annualized cost of $517.12 million, using a 7 percent discount rate.[234]

C. Paperwork Reduction Act

Contemporaneously with the publication of these interim final rules, the Departments are each submitting a request for a new ICR containing the information collection requirements for the Federal IDR process, and the patient-provider dispute resolution process for HHS, created by the No Surprises Act be processed as an Emergency Clearance Request in accordance with section 5 CFR 1320.13 of the Paperwork Reduction Act, Emergency Processing. The Departments and OPM 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. 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. To obtain a copy of the ICR go to *https://www.RegInfo.gov.*

The Departments will be requesting approval of the emergency review requests by the effective date of the interim final rules. The Departments will be seeking approval of the ICRs for 180 days, the maximum allowed for an ICR approved using an emergency review. As part of the emergency review request, the Departments will be requesting that OMB waive the notice requirement set forth in 5 CFR 1320.13(d). Once the emergency submission is approved, the Departments will initiate an ICR Revision, the process required under the PRA to seek up to three (3) years of approval for the information collections. As part of the process, the Departments and OPM will open a 60-day and 30-day comment period for each ICR.

The Departments are particularly interested in comments that:

- Evaluate whether the collection of information is necessary for the functions of the Departments, including whether the information will have practical utility;
- Evaluate the accuracy of the Departments' estimate of the burden of the collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology (for example permitting electronically delivered responses).

[232] Adler, Loren. ''Experience with New York's Arbitration Process for Surprise Out-of-Network Bills.'' U.S.C.-Brookings Schaeffer on Health Policy. (October 2019). *https://www.brookings.edu/blog/usc-brookings-schaeffer-on-health-policy/2019/10/24/experience-with-new-yorks-arbitration-process-for-surprise-out-of-network-bills/.*

[233] Fielder, Matthew, Loren Adler, and Benedic Ippolito. ''Recommendations for Implementing the No Surprises Act.'' U.S.C.-Brookings Schaeffer on Health Policy. (March 2021). *https://www.brookings.edu/blog/usc-brookings-schaeffer-on-health-policy/2021/03/16/recommendations-for-implementing-the-no-surprises-act/.*

[234] The costs would be $4.19 billion over 10-year period with an annualized cost of $491.44 million, applying a 3 percent discount rate.

Comments on these topics may also be submitted to the Departments during the open comment period for these interim final rules. See the **ADDRESSES** section in this rule on where to send comments.

1. Labor Cost Estimates

TABLE 4—WAGE ESTIMATES

Occupation title	Occupational code	Hourly total compensation ($/hour)	Overhead cost ($/hour)	Total hourly labor costs ($/hour)
Secretaries and Administrative Assistants, Except Legal, Medical, and Executive	43–6014	$28.96	$26.27	$55.23
Lawyer	23–1011	105.28	35.68	140.96
Computer Programmers	15–1251	67.62	46.15	113.77
Medical Secretaries and Administrative Assistants	43–6013	27.94	18.13	46.07
Human Resources Specialists	13–1071	49.09	42.74	91.83
Business Operations Specialist	13–1198	59.60	41.72	101.32
General and Operations Manager	11–1021	88.25	34.30	122.55
Compensation and Benefits Manager	11–3111	96.97	24.81	121.78
Computer and Information Systems Managers	11–3021	113.52	53.38	166.90
Medical and Health Services Manager	11–9110	83.39	21.62	105.01
Physician (all other)	29–1228	154.74	14.66	169.40
All occupations	00–0000	39.40	24.92	64.32

Group health plans, health insurance issuers, and FEHB carries are responsible for ensuring compliance with these interim final rules. Accordingly, in the following ICR sections, the Departments refer to costs on plans, issuers, and FEHB carriers. However, it is expected that most self-insured group health plans will work with a TPA to meet the requirements of these interim rules. The Departments recognize the potential that some of the largest self-insured plans may seek to meet the requirements of these interim final rules in house and not use a TPA or other third party, in such cases those plans will incur the estimated burden and cost directly.

2. ICRs Regarding IDR Process for Nonparticipating Providers or Nonparticipating Emergency Facilities (26 CFR 54.9816–8T, 29 CFR 2590.716–8, and 45 CFR 149.510)

As discussed in the Regulatory Impact Analysis, the Departments estimate that 17,333 claims will be submitted as part of the Federal IDR process each year.

The Departments estimate that 25 percent of disputes will be resolved in open negotiation before entering the Federal IDR process. The Departments request data or comments on this assumption. Accordingly, the Departments estimate that 23,111 claims will go through open negotiation.[235] The Departments estimate that it will take, on average, a medical and health services manager 2 hours to write each notice of open negotiation and a clerical worker 15 minutes to prepare and send the notice. The burden for each plan, issuer, and FEHB carrier would be 2.25 hours, with an equivalent cost of approximately $224. As shown in Table 5, for all 23,111 payment determinations subject to these interim final rules proceeding through the Federal IDR process, the annual burden would be 51,999 hours, with an associated equivalent cost of $5.2 million.[236] The open negotiation notice must be sent within 30 business days beginning on the day the provider or facility receives an initial payment or a notice of denial of payment from the plan or issuer regarding such item or service. The Departments assume that 5 percent of these notices would be mailed and will incur a printing cost of $0.05 per page and $0.55 for postage. Thus, the mailing cost is estimated to be $693.[237]

TABLE 5—ANNUAL BURDEN AND COSTS TO PREPARE AND SEND THE NOTICE OF OPEN NEGOTIATION PROCESS FOR NONPARTICIPATING PROVIDERS OR NONPARTICIPATING EMERGENCY FACILITIES STARTING IN 2022

Estimated number of responses	Total annual burden (hours)	Total estimated labor cost	Mailing costs	Total estimated cost
23,111	51,999	$5,172,803	$693	$5,173,496

[235] This is calculated 17,333/(1 − 0.25) = 23,111.

[236] The burden is estimated as follows: 23,111 claims × 2 hours + 23,111 claims × 0.25 hour = 51,999 hours. A labor rate of $105.01 is used for a medical and health services manager and a labor rate of $55.23 is used for a clerical worker. The labor rates are applied in the following calculation: 23,111 claims × 2 hours × $105.01 + 23,111 claims × 0.5 hour × $55.23 = $5,172,803. Labor rates are EBSA estimates.

[237] This is calculated 23,111 × 0.05 × ($0.05 + $0.55) = $693.

The Departments estimate that it will take 2 hours for a legal professional to write the Notice of IDR Initiation and 15 minutes for a clerical worker to prepare and send the initiating notice. The burden for each plan, issuer, and FEHB carrier would be 2.25 hours, with an equivalent cost of approximately $224. As shown in Table 6, for the 17,333 claims initiating the Federal IDR process, the annual burden would be 38,999 hours, with an annual equivalent cost estimate of $3.9 million.[238] The initiating party may furnish the Notice of IDR Initiation to the other party electronically if the initiating party has a good faith belief that the electronic method is readily accessible by the other party and the notice is provided in paper form free of charge upon request; the Departments assume that these notices 5 percent of notices would be mailed and will incur a printing cost of $0.05 per page and $0.55 for postage. Thus, the mailing cost is estimated to be $520.[239]

TABLE 6—ANNUAL BURDEN AND COST TO PREPARE AND SEND THE NOTICE OF IDR INITIATION FOR NONPARTICIPATING PROVIDERS OR NONPARTICIPATING EMERGENCY FACILITIES STARTING IN 2022

Estimated number of responses	Total annual burden (hours)	Total estimated labor cost	Mailing and printing costs	Total estimated cost
17,333	38,999	$3,879,602	$520	$3,880,122

If the parties to the Federal IDR process agree on an out-of-network rate for a qualified IDR item or service after providing notice to the Departments of initiation of the Federal IDR process, but before the certified IDR entity has made its payment determination, the initiating party must send a notification to the Departments and to the certified IDR entity (if selected) electronically through the Federal IDR portal, in a form and manner specified by the Departments, as soon as possible, but no later than 3 business days after the date of the agreement. This notification should include the out-of-network rate for the qualified IDR item or service and signatures from authorized signatories for both parties. The Departments assume that 1 percent of IDR payment determinations will be resolved by an agreement on an out-of-network rate after the Federal IDR process has been initiated. The Departments request comment on this assumption. The Departments estimate that it will take, on average, a medical and health services manager 30 minutes to write each notice of open negotiation and a clerical worker 15 minutes to submit the notice to the Federal IDR portal. The burden for each plan, issuer, and FEHB carrier would be 45 minutes, with an equivalent cost of approximately $66. As shown in Table 7, for the 173 payment determinations resolved in this manner, the annual burden would be 130 hours, with an associated equivalent cost of $11,472.[240]

TABLE 7—ANNUAL BURDEN AND COST TO PREPARE AND SEND THE NOTICE OF AGREEMENT ON AN OUT-OF-NETWORK RATE STARTING IN 2022

Estimated number of responses	Total annual burden (hours)	Total estimated labor cost	Mailing and printing costs	Total estimated cost
173	130	$11,472	$0	$11,472

If the plan, issuer, or FEHB carrier and the nonparticipating provider or nonparticipating emergency facility select a certified IDR entity, or if they fail to select a certified IDR entity, they must notify the Departments of their selection no later than 1 business day after such selection or failure to select. To the extent the non-initiating party does not believe that the Federal IDR process applies, the non-initiating party must also provide information that demonstrates the lack of applicability by the same date that the notice of selection or failure to select must be submitted.

The Departments estimate that in 75 percent of IDR payment determinations, a certified IDR entity will be selected by the disputing parties. The Departments request comments on this assumption. Additionally, the Departments assume that it will take 1 hour for a legal professional to write the notice and 15 minutes for a clerical worker to prepare and send the notice. The burden for each plan, issuer, and FEHB carrier would be 1.25 hours, with an equivalent cost of approximately $119. As shown in Table 8, for the 13,000 claims that will have a certified IDR entity selected by the disputing parties, the annual burden would be 16,250 hours, with an annual equivalent cost estimate of $1.5 million.[241] The Departments assume that 5 percent of notices would be mailed and will incur a printing cost of $0.05 per page and $0.55 for postage. Thus, the mailing cost is estimated to be $390.[242]

[238] The burden is estimated as follows: 17,333 claims × 2 hours + 17,333 claims × 0.25 hours = 38,999 hours. A labor rate of $105.01 is used for a medical and health services manager and a labor rate of $55.23 is used for a clerical worker. The labor rates are applied in the following calculation: 17,333 claims × 0.25 hours × $105.01 + 17,333 claims × 2 hours × $55.23 = $3,879,602. Labor rates are EBSA estimates.

[239] This is calculated 17,333 × 0.05 × ($0.05 + $0.55) = $520.

[240] The burden is estimated as follows: 17,300 claims × 1 percent × 0.5 hours + 17,300 claims × 1 percent × 0.25 hours = 130 hours. A labor rate of $105.01 is used for a medical and health services manager and a labor rate of $55.23 is used for a clerical worker. The labor rates are applied in the following calculation: 17,300 claims × 1 percent × 0.5 hours × $105.01 + 17,300 claims × 1 percent × 0.25 hours × $55.23 = $11,472. Labor rates are EBSA estimates.

[241] The burden is estimated as follows: (13,000 claims × 75 percent × 1 hour) + (13,000 claims × 75 percent × 0.25 hours) = 16,250 hours. A labor rate of $105.01 is used for a medical and health services manager and a labor rate of $55.23 is used for a clerical worker. The labor rates are applied in the following calculation: (13,000 claims × 75 percent × 0.25 hours × $105.01) +13,000 claims × 75 percent × 1 hours × $55.23) = $1,544,628. Labor rates are EBSA estimates.

[242] This is calculated 13,000 × 0.05 × ($0.05 + $0.55) = $390.

TABLE 8—ANNUAL BURDEN AND COST TO SELECT A CERTIFIED IDR ENTITY AND NOTIFY THE DEPARTMENTS OF SELECTION FOR NONPARTICIPATING PROVIDERS OR NONPARTICIPATING EMERGENCY FACILITIES STARTING IN 2022

Estimated number of responses	Total annual burden (hours)	Total estimated labor cost	Mailing and printing costs	Total estimated cost
13,000	16,250	$1,544,628	$390	$1,545,018

If the plan, issuer, or FEHB carrier and the nonparticipating provider or nonparticipating emergency facility fail to select a certified IDR entity, the Departments will select a certified IDR entity that charges a fee within the allowed range of IDR entity costs (or has received approval from the Departments to charge a fee outside of the allowed range) through a random selection method. The Departments estimate that in 25 percent of IDR payment determinations, a certified IDR entity will not be selected by the parties.

Additionally, no later than 10 business days after the date of selection of the certified IDR entity with respect to a payment determination for a qualified IDR item or service, the provider or facility and the plan or issuer must submit to the certified IDR entity an offer for a payment amount for the qualified IDR item or service furnished by such provider or facility though the Federal IDR portal. The Departments estimate for providers and issuers, it will take an average of 2.5 hours for a medical and health services manager to write the offer and 30 minutes for a clerical worker to prepare and send the offer. The burden for each plan, issuer, and FEHB carrier would be 3 hours, with an equivalent cost of approximately $290. As shown in Table 9, for the 17,333 payment determinations that will go through submission of offer, the annual burden would be 103,998 hours, with an annual equivalent cost estimate of $10.1 million.[243] The Departments assume that 5 percent of notices would be mailed and will incur a printing cost of $0.05 per page and $0.55 for postage. Thus, the mailing cost is estimated to be $1,040.[244]

TABLE 9—ANNUAL BURDEN AND COST TO PREPARE AND SUBMIT OFFER FOR NONPARTICIPATING PROVIDERS OR NONPARTICIPATING EMERGENCY FACILITIES STARTING IN 2022

Estimated number of responses	Total annual burden (hours)	Total estimated labor cost	Mailing and printing costs	Total estimated cost
17,333	103,998	$10,057,993	$1,040	$10,059,033

After the selected certified IDR entity has reviewed the offer, the certified IDR entity must notify the provider or facility and the plan, issuer, or FEHB carrier of the payment determination and the reason for such determination, in a form and manner specified by the Departments.[245] The cost of preparing and delivering this notice is assumed to be included in the certified IDR entity fee paid by the plan or issuer, or provider or facility, to conduct the review.[246]

If the certified IDR entity does not choose the offer closest to the QPA, the certified IDR entity's written decision must include an explanation of the credible information that the certified IDR entity determined demonstrated that the QPA was materially different from the appropriate out-of-network rate, based on the permitted considerations, with respect to the qualified IDR item or service. The cost of preparing and delivering this written decision is included in the certified IDR entity fee paid by the provider, facility, plan, issuer, or FEHB carrier. When determining the out-of-network rate, the certified IDR entity must consider the QPA and must consider the other statutory factors when a party presents credible information relating to those factors clearly demonstrating the QPA is materially different from the appropriate out-of-network rate, or where the offers are equally distant from the QPA but in opposing directions.

Additionally, the selected certified IDR entity must provide the payment determination and the reasons for such to the Departments. The Departments also assume that the cost of preparing and delivering this written decision is included in the certified IDR entity fee paid by the provider, facility, plan, issuer, or FEHB carrier.

After a final determination, the certified IDR entity must maintain records of all claims and notices associated with the Federal IDR process for 6 years. The certified IDR entity must store the documents in a manner necessary to meet the requirements of these interim final rules. The certified IDR entities must make such records available for examination by the plan, issuer, FEHB carrier, provider, facility, or state or Federal oversight agency upon request, except where such disclosure would violate state or Federal privacy laws. The Departments assume it will take 30 minutes for a clerical worker to establish the records for each IDR payment determinations. The burden for each certified IDR entity would be 30 minutes, with an equivalent cost of approximately $28. As shown in Table 10, for the maintenance and recordkeeping of 17,333 claims, the annual burden would be 8,667 hours, with an annual

[243] The burden is estimated as follows: (17,333 claims × 2.5 hours + 17,333 claims × 0.5 hours) + (17,333 claims × 2.5 hours + 17,333 claims × 0.5 hours) = 103,998 hours for providers and issuers. A labor rate of $105.01 is used for a medical and health services manager and a labor rate of $55.23 is used for a clerical worker. The labor rates are applied in the following calculation: (17,333 claims × 2.5 hours × $105.01 + 17,333 claims × 0.5 hours × $55.23) + (17,333 claims × 2.5 hours × $105.01 + 17,333 claims × 0.5 hours × $55.23) = $10,057,993. Labor rates are EBSA estimates.

[244] This is calculated (17,333 × 0.05 × ($0.05 + $0.55) + (17,333 × 0.05 × ($0.05 + $0.55) = $1,040.

[245] IDR Payment Determination Notification (ERISA 716(c)(5)(A)).

[246] Under Section 103 of the No Surprises Act, the party whose offer was not chosen by the certified IDR entity is responsible for paying the IDR entity's fee.

equivalent cost burden estimate of $0.5 million.[247]

TABLE 10—ANNUAL BURDEN AND COST FOR THE CERTIFIED IDR ENTITY TO MAINTAIN RECORDS FOR NONPARTICIPATING PROVIDERS OR NONPARTICIPATING EMERGENCY FACILITIES STARTING IN 2022

Estimated number of responses	Total annual burden (hours)	Total estimated labor cost	Other costs	Total estimated cost
17,333	0	$0	$478,651	$478,651

Summary

The total hour burden associated with the Federal IDR process for hospital and emergency department claims is 211,376 hours with an equivalent cost of $20,666,498. The total cost associated with the Federal IDR process for hospital and emergency claims is $481,294.

Half of the burden associated with the Federal IDR process for hospital and emergency departments is estimated to be allocated to health care plans, issuers, and FEHB carriers, and the other half is estimated be allocated to health care providers and facilities. As shown in Tables 11 through 13, HHS, DOL, the Department of the Treasury, and OPM share jurisdiction, HHS will account for 45 percent of the burden, or approximately, 95,119 hours at an equivalent cost of $9,299,924 and a cost burden of $216,582. DOL and the Department of the Treasury will each account for 25 percent of the burden, or approximately 52,844 hours at an equivalent cost of $5,166,624 and a cost burden of $120,324. OPM will account for 5 percent of the burden or approximately 10,569 hours at an equivalent cost of $1,033,325 and a cost burden of $24,065.

TABLE 11—HHS SUMMARY ANNUAL COST AND BURDEN OF IDR PROCESS FOR NONPARTICIPATING PROVIDERS OR NONPARTICIPATING EMERGENCY FACILITIES STARTING IN 2022

Estimated number of responses	Total annual burden (hours)	Total estimated labor cost	Mailing and printing cost	Other costs	Total estimated cost
49,477	95,119	$9,299,924	$1,189	$215,393	$9,516,506

TABLE 12—DOL AND DEPARTMENT OF THE TREASURY'S SUMMARY ANNUAL COST AND BURDEN OF IDR PROCESS FOR NONPARTICIPATING PROVIDERS OR NONPARTICIPATING EMERGENCY FACILITIES STARTING IN 2022

Estimated number of responses	Total annual burden (hours)	Total estimated labor cost	Mailing and printing cost	Other costs	Total estimated cost
27,487	52,844	$5,166,624	$661	$119,663	$5,286,948

TABLE 13—OPM'S SUMMARY ANNUAL COST AND BURDEN OF IDR PROCESS FOR NONPARTICIPATING PROVIDERS OR NONPARTICIPATING EMERGENCY FACILITIES STARTING IN 2022

Estimated number of responses	Total annual burden (hours)	Total estimated labor cost	Mailing and printing cost	Other costs	Total estimated cost
5,497	10,569	$1,033,325	$132	$23,933	$1,057,390

3. ICRs Regarding Federal IDR Process for Air Ambulance (26 CFR 54.9817–2T, 29 CFR 2590.717–2, and 45 CFR 149.520)

According to the March 2019 Health Insurance Coverage Bulletin, in 2018, 213.2 million individuals had private health insurance.[248] In 2017, HCCI estimated that, on average, there were 33.3 air ambulance uses per 100,000 people,[249] and the GAO estimated that approximately 69 percent of air transports resulted in an out-of-network bill.[250] The Departments do not have data on what percent of out-of-network bills will proceed to the Federal IDR process; however, given the nature of air ambulance services, the Departments assume that the percentage will be substantially higher than for hospital or emergency department claims. The Departments assume that 10 percent of out-of-network claims for air transport will end up in the Federal IDR process.

Accordingly, the government estimates there will be 4,899 air

[247] The burden is estimated as follows: (17,333 claims × 30 minutes) = 8,667 hours for providers and issuers. A labor rate of $55.23 is used for a clerical worker. The labor rates are applied in the following calculation: (17,333 claims × 30 minutes × $55.23) = $478,651. Labor rates are EBSA estimates.

[248] Employee Benefits Security Administration. ''Health Insurance Coverage Bulletin.'' (March 2019). *https://www.dol.gov/sites/dolgov/files/EBSA/researchers/data/health-and-welfare/health-insurance-coverage-bulletin-2019.pdf.*

[249] Hargraves, John and Aaron Bloschichak. ''Air Ambulances-10-Year Trends in Costs and Use.'' Health Care Cost Institute. (2019). *https://healthcostinstitute.org/emergency-room/air-ambulances-10-year-trends-in-costs-and-use.*

[250] Government Accountability Office. ''Air Ambulance: Available Data Show Privately-Insured Patients are at Financial Risk.'' (2019). *https://www.gao.gov/assets/gao-19-292.pdf.*

ambulance service claims submitted to the Federal IDR process each year.[251]

In these interim final rules, air ambulance services are subject to the same requirements for hospital and emergency services in 26 CFR 54.9816–8T, 29 CFR 2590.716–8, and 45 CFR 149.510 (as applicable), except that the items and services for which the requirements of (b)(1) of that section apply shall be understood to be out-of-network air ambulance services, and ''qualified IDR items and services'' are understood to be air ambulance services.

The Departments estimate that 4,899 air transport disputes will be handled by the Federal IDR process each year, but the Departments estimate that 25 percent of disputes will be resolved in open negotiation before entering the Federal IDR process. Accordingly, the Departments estimate that 6,532 transport payment determinations will enter into open negotiation.[252] The Departments estimate that it will take an average of 2 hours for a medical and health services manager to write each notice of open negotiation and 15 minutes for a clerical worker to prepare and send the notice. The burden for each plan, issuer, and FEHB carrier would be 2.25 hours, with an equivalent cost of approximately $224. As shown in Table 14, for the 6,532 payment determinations that will enter into open negotiation, the annual burden would be 14,696 hours, with an annual equivalent cost estimate of $1.5 million.[253] The open negotiation notice must be sent within 30 business days beginning on the day the provider of air ambulance services receives an initial payment or a notice of denial of payment from the plan, issuer, or FEHB carrier regarding such item or service. The Departments assume that 5 percent of notices would be mailed and will incur a printing cost of $0.05 per page and $0.55 for postage. Thus, the mailing cost is estimated to be $196.[254]

TABLE 14—ANNUAL BURDEN AND COSTS TO PREPARE AND SEND THE NOTICE OF OPEN NEGOTIATION PERIOD FOR PROVIDERS OF AIR AMBULANCE SERVICES STARTING IN 2022

Estimated number of responses	Total annual burden (hours)	Total estimated labor cost	Mailing and printing cost	Total estimated cost
6,532	14,696	$1,461,951	$196	$1,462,147

For the estimated 4,899 payment determinations that are submitted to the Federal IDR process, the Departments estimate that it will take 2 hours for a legal professional to write the Notice of IDR Initiation and 15 minutes for a clerical worker to prepare and send the initiating notice. The burden for each plan, issuer, and FEHB carrier would be 2.25 hours, with an equivalent cost of approximately $224. As shown in Table 15, for the 4,899 payment determinations that will have selected a certified IDR entity, the annual burden would be 11,022 hours, with an annual equivalent cost estimate of $1.1 million.[255] The initiating party may furnish the Notice of IDR Initiation to the other party electronically if the initiating party has a good faith belief that the electronic method is readily accessible by the other party and the notice is provided in paper form free of charge upon request. The Departments assume that 5 percent of notices would be mailed and will incur a printing cost of $0.05 per page and $0.55 for postage. Thus, the mailing cost is estimated to be $147.[256]

TABLE 15—ANNUAL BURDEN AND COST TO PREPARE AND SEND THE NOTICE OF IDR INITIATION FOR PROVIDERS OF AIR AMBULANCE SERVICES STARTING IN 2022

Estimated number of responses	Total annual burden (hours)	Total estimated labor cost	Mailing and printing cost	Total estimated cost
4,899	11,022	$1,096,463	$147	$1,096,610

If the parties to the Federal IDR process agree on an out-of-network rate for a qualified IDR item or service after providing a Notice of IDR Initiation to the Departments, but before the certified IDR entity has made its payment determination, the initiating party must send a notification to the Departments and to the certified IDR entity (if selected) electronically through the Federal IDR portal, in a form and manner specified by the Departments, as soon as possible, but no later than 3 business days after the date of the agreement. This notification should include the out-of-network rate for the qualified IDR item or service and signatures from authorized signatories for both parties. The Departments assume that 1 percent of payment determinations will be resolved by an agreement on an out-of-network rate after the Federal IDR process has been initiated. The Departments request comment on this assumption. The Departments estimate that it will take, on average, a medical and health services manager 30 minutes to write each notice of open negotiation and a clerical worker 15 minutes to submit the

[251] The Departments estimate that of the 213.2 million individuals with employer-sponsored health insurance, there are 33.3 air transports per 100,000 individuals, of which 69 percent result in an out-of-network bill. The Departments assume that 10 percent of the out-of-network bills will end up in IDR. (213,200,000 × 0.000333 × 0.69 × 0.1= 4,899).

[252] This is calculated as 4,899/(1 − 0.25) = 6,532.

[253] The burden is estimated as follows: 6,532 claims × 2 hours + 6,532 claims × 0.25 hours = 14,696 hours. A labor rate of $105.01 is used for a medical and health services manager and a labor rate of $55.23 is used for a clerical worker. The labor rates are applied in the following calculation: 6,532 claims × 0.25 hours × $105.01 + 6,532 claims × 2 hours × $55.23 = $1,461,951. Labor rates are EBSA estimates.

[254] This is calculated 6,532 × 0.05 × ($0.05 + $0.55) = $196.

[255] The burden is estimated as follows: 4,899 claims × 2 hours + 4,899 claims × 0.25 hours = 11,022 hours. A labor rate of $105.01 is used for a medical and health services manager and a labor rate of $55.23 is used for a clerical worker. The labor rates are applied in the following calculation: 4,899 claims × 0.25 hours × $105.01 + 4,899 claims × 2 hours × $55.23 = $1,096,463. Labor rates are EBSA estimates.

[256] This is calculated 4,899 × 0.05 × ($0.05 + $0.55) = $147.

notice to the Federal IDR portal. The burden for each plan, issuer, and FEHB carrier would be 45 minutes, with an equivalent cost of approximately $66. As shown in Table 16, for the 49 payment determinations resolved in this manner, the annual burden would be 37 hours, with an associated equivalent cost of $3,249.[257]

TABLE 16—ANNUAL BURDEN AND COST TO PREPARE AND SEND THE NOTICE OF AGREEMENT ON AN OUT-OF-NETWORK RATE STARTING IN 2022

Estimated number of responses	Total annual burden (hours)	Total estimated labor cost	Mailing and printing cost	Total estimated cost
49	37	$3,249	$0	$3,249

If the plan, issuer, or FEHB carrier and the nonparticipating provider of air ambulance services select or fail to select a certified IDR entity, they must notify the Departments of their selection or failure to select a certified IDR entity no later than 1 day after such selection or failure. The Departments estimate that in 75 percent of payment determinations, a certified IDR entity will be selected. The Departments request comment on this assumption. Additionally, the Departments assume that it will take one hour for a legal professional to write the notice and 15 minutes for a clerical worker to prepare and send the notice. The burden for each plan, issuer, and FEHB carrier would be 1.25 hours, with an equivalent cost of approximately $119. Due to the tight turnaround, the Departments assume this notice will be sent electronically through the Federal IDR portal. As shown in Table 17, for the 3,674 payment determinations that will have a selected a certified IDR entity, the annual burden would be 4,593 hours, with an annual equivalent cost estimate of $0.4 million.[258] The Departments assume that 5 percent of notices would be mailed and will incur a printing cost of $0.05 per page and $0.55 for postage. Thus, the mailing cost is estimated to be $110.[259]

TABLE 17—ANNUAL BURDEN AND COST TO SELECT CERTIFIED IDR ENTITY AND NOTIFY THE DEPARTMENTS OF SELECTION FOR PROVIDERS OF AIR AMBULANCE SERVICES STARTING IN 2022

Estimated number of responses	Total annual burden (hours)	Total estimated labor cost	Mailing and printing cost	Total estimated cost
3,674	4,593	$436,535	$110	$436,646

If the plan, issuer, or FEHB carrier and the nonparticipating provider of air ambulance services fail to select a certified IDR entity, the Departments will select a certified IDR entity that charges a fee within the allowed range of certified IDR entity costs (or has received approval from the Departments to charge a fee outside of the allowed range if there are an insufficient number of certified IDR entities) through a random selection method. The range of certified IDR entity fees and the administrative fee paid to the Departments by the plan, issuer, or FEHB carrier and the provider of air ambulance services will be addressed in later guidance by the Departments. The Departments estimate that in 25 percent of IDR payment determinations, a certified IDR entity will not be selected by the parties.

Additionally, no later than 10 business days after the date of selection of the certified IDR entity with respect to a determination for a qualified IDR item or service, the provider of air ambulance services, plan, issuer, or FEHB carrier must submit to the certified IDR entity: (1) An offer for a payment amount for the qualified IDR item or service furnished by the provider of air ambulance services, expressed both as a dollar amount and as a percentage of the QPA; and (2) information as requested by the certified IDR entity relating to the offer. With the information requested by the certified IDR entity, the parties must include: (A) The coverage area of the plan, issuer, or FEHB carrier; the relevant geographic region for purposes of the QPA; (B) whether the coverage is fully-insured or fully or partially self-insured), if applicable; and (C) the QPA. The parties may also submit to the certified IDR entity any information relating to the offer submitted by either party, except that the information may not include information on factors described in paragraph 26 CFR 54.9816–8T(c)(4)(v), 29 CFR 2590.716–8(c)(4)(v), and 45 CFR 149.510(c)(4)(v). The Departments estimate for providers of air ambulance services, issuers, plans, and FEHB carriers, it will take an average of 2 hours for a medical and health services manager to write the offer and 15 minutes for a clerical worker to prepare and send the offer. The burden for each plan, issuer, and FEHB carrier would be 2.25 hours, with an equivalent cost of approximately $224. As shown in Table 18, for the 4,899 claims that will go through submission of offers, the annual burden would be 22,044 hours, with an annual equivalent cost estimate of $2.2 million.[260] The Departments assume

[257] The burden is estimated as follows: 4,899 claims × 1 percent × 0.5 hours + 4,899 claims × 1 percent × 0.25 hours = 37 hours. A labor rate of $105.01 is used for a medical and health services manager and a labor rate of $55.23 is used for a clerical worker. The labor rates are applied in the following calculation: 4,899 claims × 1 percent × 0.5 hours × $105.01 + 4,899 claims × 1 percent × 0.25 hours × $55.23 = $3,249. Labor rates are EBSA estimates.

[258] The burden is estimated as follows: (4,899 claims × 75 percent × 1 hour) + (4,899 claims × 75 percent × 0.25 hours) = 4,593 hours. A labor rate of $105.01 is used for a medical and health services manager and a labor rate of $55.23 is used for a clerical worker. The labor rates are applied in the following calculation: (4,899 claims × 75 percent × 0.25 hours × $105.01) + (4,899 claims × 75 percent × 1 hours × $55.23) = $436,535. Labor rates are EBSA estimates.

[259] This is calculated 3,674 × 0.05 × ($0.05 + $0.55) = $110.

[260] The burden is estimated as follows: (4,899 claims × 2 hours + 4,899 claims × 0.25 hours) + (4,899 claims × 2 hours + 4,899 claims × 0.25 hours) = 22,044 hours for providers and issuers. A labor rate of $105.01 is used for a medical and health

Continued

that 5 percent of notices would be mailed and will incur a printing cost of $0.05 per page and $0.55 for postage. Thus, the mailing cost is estimated to be $294.[261]

TABLE 18—ANNUAL BURDEN AND COST TO PREPARE AND SUBMIT OFFER FOR PROVIDERS OF AIR AMBULANCE SERVICES STARTING IN 2022

Estimated number of responses	Total annual burden (hours)	Total estimated labor cost	Mailing and printing cost	Total estimated cost
4,899	22,044	$2,192,926	$294	$2,193,220

After the certified IDR entity has reviewed the offer, the certified IDR entity must notify the provider of air ambulance services and the plan, issuer, or FEHB carrier of the payment determination.[262] The cost of preparing and delivering this notice is included in the $25 administrative fee paid by the provider of air ambulance services, plan, issuer, or FEHB carrier to conduct the review.

Certified IDR entities also need to notify the provider of air ambulance services and the plan, issuer, or FEHB carrier of the payment determination and the written decision explaining such determination. If the certified IDR entity does not choose the offer closest to the QPA, the certified IDR entity's written decision must include an explanation of the credible information that the certified IDR entity determined demonstrated that the QPA amount was materially different from the appropriate out-of-network rate, based on the required considerations, with respect to the qualified IDR item or service.

Additionally, the certified IDR entity must provide the payment determination and the reasons for such determination to the Departments. The Departments also assume that the cost of preparing and delivering this written decision is included in the certified IDR entity fee paid by the provider of air ambulance services, plan, issuer, or FEHB carrier.

After a final determination, the certified IDR entity must maintain records of all claims and notices associated with the Federal IDR process for 6 years. The certified IDR entity must make such records available for examination by the plan, issuer, FEHB carrier, provider of air ambulance services, or state or Federal oversight agency upon request, except where such disclosure would violate state or Federal privacy laws. The Departments assume it will take 30 minutes for a clerical worker to establish the records for each determination under the Federal IDR process necessary to meet the requirements. The cost burden for each certified IDR entity would be 30 minutes, with an equivalent cost of approximately $28. As shown in Table 19, for the maintenance and recordkeeping of 4,899 claims, the annual burden would be 2,449 hours, with an estimated annual equivalent cost burden of $0.1 million.[263]

TABLE 19—ANNUAL BURDEN AND COST FOR THE CERTIFIED IDR ENTITY TO MAINTAIN RECORDS FOR PROVIDERS OF AIR AMBULANCE SERVICES STARTING IN 2022

Estimated number of responses	Total annual burden (hours)	Total estimated labor cost	Other costs	Total estimated cost
4,899	2,499	$0	$135,278	$135,278

Summary

The total hour burden associated with the Federal IDR process for air ambulance services is 52,392 hours with an equivalent cost of $5,191,124. The total cost burden associated with the Federal IDR process for air ambulance services is $136,025. Half of the burden associated with the Federal IDR process for air ambulance services is estimated to be allocated to health plans, issuers, or TPAs, and the other half is estimated be allocated to health care providers. The burden associated with the Federal IDR process for air ambulance services is assumed to be shared by the Departments and OPM. HHS is assumed to cover 45 percent of the burden, while DOL and the Department of the Treasury will each cover 25 percent of the burden and OPM will cover 5 percent of the burden. As shown in Table 20, the hour burden associated with HHS requirements is estimated to be approximately 23,576 hours at an equivalent cost of $2,336,006. The total cost burden associated with HHS requirement is estimated to be $61,211. As shown in Table 21, the hour burden associated with DOL and the Department of the Treasury requirements is estimated to be approximately 13,089 hours at an equivalent cost of $1,297,781 each. The total cost burden associated with DOL and the Department of the Treasury requirement is estimated to be $34,006. As shown in Table 22, the hour burden associated with OPM requirements is estimated to be approximately 2,620 hours at an equivalent cost of $259,556 each. The total cost burden associated with OPM requirement is estimated to be $6,801.

services manager and a labor rate of $55.23 is used for a clerical worker. The labor rates are applied in the following calculation: (4,899 claims × 2 hours × $105.01 + 4,899 claims × 0.25 hours × $55.23) + (4,899 claims × 2 hours × $105.01 + 4,899 claims × 0.25 hours × $105.01) = $2,192,926. Labor rates are EBSA estimates.

[261] This is calculated (4,899 × 0.05 × ($0.05 + $0.55)) + (4,899 × 0.05 × ($0.05 + $0.55)) = $294.

[262] IDR Payment Determination Notification (ERISA 716(c)(5)(A)).

[263] The burden is estimated as follows: (4,899 claims × 30 minutes) = 2,449 hours for providers and issuers. A labor rate of $55.23 is used for a clerical worker. The labor rates are applied in the following calculation: (4,899 claims × 30 minutes × $55.23) = $135,278. Labor rates are EBSA estimates.

TABLE 20—HHS SUMMARY COST AND BURDEN OF FEDERAL IDR PROCESS FOR PROVIDERS OF AIR AMBULANCE SERVICES STARTING IN 2022

Estimated number of responses	Total annual burden (hours)	Total estimated labor cost	Mailing and printing cost	Other costs	Total estimated cost
16,188	23,576	$2,336,006	$336	$60,875	$2,397,217

TABLE 21—DOL AND DEPARTMENT OF THE TREASURY'S SUMMARY COST AND BURDEN OF FEDERAL IDR PROCESS FOR PROVIDERS OF AIR AMBULANCE SERVICES STARTING IN 2022

Estimated number of responses	Total annual burden (hours)	Total estimated labor cost	Mailing and printing cost	Other costs	Total estimated cost
8,993	13,098	$1,297,781	$187	$33,819	$1,331,787

TABLE 22—OPM'S SUMMARY COST AND BURDEN OF FEDERAL IDR PROCESS FOR PROVIDERS OF AIR AMBULANCE SERVICES STARTING IN 2022

Estimated number of responses	Total annual burden (hours)	Total estimated labor cost	Mailing and printing cost	Other costs	Total estimated cost
450	2,620	$259,556	$37	$6,734	$266,357

3. ICRs Regarding the Request of Extension of Time Periods for Extenuating Circumstances (26 CFR 54.9816–8T, 29 CFR 2590.716–8, and 45 CFR 149.510)

The Departments do not have data on how often entities will request an extension; however, the Departments are of the view that extenuating circumstances will be rare. The Departments assume that 100 plans, issuers, FEHB carriers, health care and air ambulance service providers, or facilities will annually request an extension starting in 2022 by completing the ''Request for Extension due to Extenuating Circumstances'' form and attesting that prompt action will be taken to ensure the payment determination under this section is made as soon as administratively practical. The Departments request comment on how many entities are likely to make such a request. The Departments estimate that it will take a clerical worker 15 minutes to prepare and send the notice. As shown in Table 23, the annual burden would be 25 hours, with an associated equivalent cost of $1,381.[264] The Departments expect these requests to be submitted through the Federal IDR portal, and therefore have not estimated an associated mailing cost.

TABLE 23—ANNUAL BURDEN AND COSTS TO REQUEST AN EXTENSION OF TIMES PERIODS FOR EXTENUATING CIRCUMSTANCES STARTING IN 2022

Estimated number of responses	Total annual burden (hours)	Total estimated labor cost	Mailing cost	Total estimated cost
100	25	$1,381	$0	$1,381

Summary

The total hour burden associated with requests for extension is 25 hours with an equivalent cost of $1,381. Half of the burden is estimated to be allocated to health plans, issuers, or TPAs, and the other half is estimated be allocated to health care providers. The burden is assumed to be shared by the Departments and OPM. HHS is assumed to cover 45 percent of the burden, while DOL and the Department of the Treasury will each cover 25 percent of the burden and OPM will cover 5 percent of the burden. As shown in Table 24, the hour burden associated with HHS requirements is estimated to be approximately 11 hours at an equivalent cost of $621. As shown in Table 25, the hour burden associated with DOL and the Department of the Treasury requirements is estimated to be approximately 6 hours at an equivalent cost of $345 each. As shown in Table 26, the hour burden associated with OPM requirements is estimated to be approximately 1 hour at an equivalent cost of $69.

[264] The burden is estimated as follows: 100 requests × 0.25 hour = 25 hours. A labor rate of $55.23 is used for a clerical worker. The labor rates are applied in the following calculation: 100 requests × 0.25 hours × $55.23 = $1,381. Labor rates are EBSA estimates.

TABLE 24—HHS'S ANNUAL BURDEN AND COSTS REQUEST AN EXTENSION OF TIMES PERIODS FOR EXTENUATING CIRCUMSTANCES STARTING IN 2022

Estimated number of responses	Total annual burden (hours)	Total estimated labor cost	Mailing cost	Total estimated cost
45	11	$621	$0	$621

TABLE 25—DOL AND DEPARTMENT OF THE TREASURY'S ANNUAL BURDEN AND COSTS TO REQUEST AN EXTENSION OF TIMES PERIODS FOR EXTENUATING CIRCUMSTANCES STARTING IN 2022

Estimated number of responses	Total annual burden (hours)	Total estimated labor cost	Mailing cost	Total estimated cost
25	6	$345	$0	$345

TABLE 26—OPM'S ANNUAL BURDEN AND COSTS TO REQUEST AN EXTENSION OF TIMES PERIODS FOR EXTENUATING CIRCUMSTANCES STARTING IN 2022

Estimated number of responses	Total annual burden (hours)	Total estimated labor cost	Mailing cost	Total estimated cost
5	1.25	$69	$0	$69

5. ICRs Regarding IDR Entity Certification and IDR Entity Monthly Reporting (26 CFR 54.9816–8T, 29 CFR 2590.716–8, and 45 CFR 149.510)

An IDR entity must be certified under standards and procedures set forth in guidance promulgated by the Departments. The Departments estimate that there will be 50 entities that seek IDR certification.

To be certified as a certified IDR entity, the entity will need to submit an application through the Federal IDR portal, demonstrating that it meets the requirements described in these interim final rules. An IDR entity must provide written documentation to the Departments regarding general company information (such as contact information, TIN, and website), as well as the applicable service area in which the IDR entity intends to conduct payment determinations under the Federal IDR process. The IDR entity must have (directly or through contracts or other arrangements) sufficient arbitration and claims administration, managed care, billing and coding, medical, legal, and other expertise, and sufficient staffing. The IDR entity must also establish processes to ensure against conflicts of interest, including to attesting that such conflicts do not exist, as defined under these interim final rules. The IDR entity will also need to demonstrate its financial stability and integrity. The corresponding paperwork (including 3 years of financial statements) will be submitted through the Federal IDR portal. Finally, each IDR entity that the Departments certify must enter into an agreement with the Departments. That agreement will include specified provisions encompassed by these interim final rules, including, but not limited to, the requirements applicable to certified IDR entities when making payment determinations as well as the requirements for certification and revocation (such as specifications for wind down activities and reallocation of certified IDR entity fees, where warranted).

The Departments estimate that on average it will take a medical and health services manager 5.10 hours and a clerical worker 15 minutes to satisfy the requirement. The burden for each IDR entity would be 5.35 hours, with an equivalent cost of approximately $548. As shown in Table 27, for the 50 IDR entities that will go through certification, this results in a cost burden of $27,468 in the first year.[265]

TABLE 27—ONE TIME AND ANNUAL BURDEN AND COSTS TO CERTIFY AND RECERTIFY

Year	Estimated number of responses	Total annual burden (hours)	Total estimated labor cost	Other costs	Total estimated cost
2022	50	0	$0	$27,468	$27,468
2033	10	0	0	2,343	2,343
2024	10	0	0	2,343	2,343
3 Year Average	23.33	0	0	10,718	10,718

Upon selection of a certified IDR entity, the certified IDR entity must submit the administrative fee to the Departments on behalf of patient and the provider or facility. The Departments estimate that the time required to complete the information collection is estimated to average a clerical worker 18 hours annually,

[265] The burden is estimated as follows: (50 IDR entities × 5.10 hours) + (50 IDR entities × 0.25 hours) = 268 hours. A labor rate of $105.01 is used for a medical and health services manager and a labor rate of $55.23 is used for a clerical worker. The labor rates are applied in the following calculation: (50 IDR entities × 5.10 hours × $105.01) + (50 IDR entities × 0.25 hours × $55.23) = $27,468.

including the time to review instructions, search existing data resources, gather required data, and complete and review information collection. As shown in Table 28, this results in a cost burden of $49,707.[266]

TABLE 28—ANNUAL BURDEN AND COSTS TO SUBMIT ADMINISTRATIVE FEE STARTING IN 2022

Estimated number of IDR entities participating	Total annual burden (hours)	Total estimated labor cost	Other cost	Total estimated cost
50	0	$0	$49,707	$49,707

Certified IDR entities are required to be recertified every 5 years. The Departments estimate that on average one-fifth of certified IDR entities will need to be recertified each year. Similar to the initial certification process, the IDR entities must ensure the processes are established and complete the corresponding paperwork, including the certification agreement, through the Federal IDR portal. The Departments estimate that, on average, it will take a medical and health services manager 2.10 hours and a clerical worker 15 minutes to satisfy the requirement. The burden for each certified IDR entity would be 2.35 hours, with an equivalent cost of approximately $224. As shown in Table 30, for the 10 certified IDR entities that will go through recertification, this results in a cost burden of $2,238 in subsequent years.[267] Table 29 summarizes these costs over time.

TABLE 29—ONE TIME AND ANNUAL BURDEN AND COSTS TO CERTIFY AND RECERTIFY

Year	Estimated number of responses	Total annual burden (hours)	Total estimated labor cost	Other costs	Total estimated cost
2022	50	0	$0	$27,468	$27,468
2023	10	0	0	3,343	2,343
2024	10	0	0	2,343	2,343
3 Year Average	23.33	0	0	10,718	10,718

These interim final rules permit an individual, provider, facility, provider of air ambulance services, or group health plan, health insurance issuer offering group or individual health insurance coverage, or FEHB carrier to petition for a denial of a certification or a revocation of a certification with respect to an IDR entity seeking certification or certified IDR entity for failure to meet certain requirements set forth in the interim final rules. The Departments do not have data on how often such a petition might occur; however, the Departments assume that such a petition will be a rare occurrence. The Departments assume that there will be 3 petitions each year, and it will take on average a medical and health services manager 2 hours and a clerical worker 15 minutes to prepare the petition. The burden for each IDR entity seeking certification or certified IDR entity would be 2.25 hours, with an equivalent cost of approximately $224. As shown in Table 30, for the three petitions, this results in a cost burden of $560.[268]

TABLE 30—ANNUAL BURDEN AND COSTS ASSOCIATED WITH THE PETITION FOR DENIAL OR WITHDRAWAL OF IDR ENTITY CERTIFICATION STARTING IN 2022

Estimated number of responses	Total annual burden (hours)	Total estimated labor cost	Other costs	Total estimated cost
3	0	$0	$560	$560

For each month, certified IDR entities will be required to report information on their activities to the Departments. The required information will include the number of Notices of IDR Initiation submitted to the certified IDR entity under the Federal IDR process during the immediately preceding month; the number of such Notices of IDR Initiation with respect to which a final determination was made; the size of the provider practices and the size of the facilities submitting Notices of IDR Initiation; the number of times the payment amount determined or agreed to exceeded the QPA, specified by items and services; and the total amount of certified IDR entity fees paid to the certified IDR entity.

Additionally, for each Notice of IDR Initiation, the certified IDR entity must provide a description of the qualified IDR items and services included with respect to the Notice of IDR Initiation, including the relevant billing and

[266] The burden is estimated as follows: (18 hours × $55.23) = $994.14 each IDR entity. A labor rate of $55.23 is used for a clerical worker. The labor rates are applied in the following calculation: (50 × 18 hours × $55.23) = $49,707. Labor rates are EBSA estimates.

[267] The burden is estimated as follows: (50 IDR entities × ⅕ × 2.1 hours) + (50 IDR entities × ⅕ × 0.25 hours) = 24 hours. A labor rate of $105.01 is used for a medical and health services manager and a labor rate of $55.23 is used for a clerical worker. The labor rates are applied in the following calculation: (50 IDR entities × ⅕ × 2.1 hours × $105.01) + (50 IDR entities × ⅕ × 0.25 hours × $55.23) = $2,343.

[268] The burden is estimated as follows: (3 IDR entities × 2 hours) + (3 IDR entities × 0.25 hours) = 6 hours. A labor rate of $105.01 is used for a medical and health services manager and a labor rate of $55.23 is used for a clerical worker. The labor rates are applied in the following calculation: (3 IDR entities × 2 hours × $105.01) + (3 IDR entities × 0.25 hours × $55.23) = $560.

service codes; the relevant geographic region for purposes of the QPA; the amount of the offer submitted by the plan or issuer (as applicable) and by the provider or facility (as applicable) expressed as a dollar amount and as a percentage of the QPA; whether the offer selected by the certified IDR entity was the offer submitted by the plan or issuer (as applicable) or by the provider or facility (as applicable); the amount of the selected offer expressed as a dollar amount and a percentage of the QPA; the rationale for the certified IDR entity's decision; the practice specialty or type of each provider or facility (as applicable) involved in furnishing each qualified IDR item or service; the identity for each plan or issuer, and provider or facility, with respect to the determination; and for each determination, the number of business days elapsed between selection of the certified IDR entity and the determination of the out-of-network rate by the certified IDR entity.

For each month, certified IDR entities will be required to report information on their activities to the Departments relating to air ambulance services. The certified IDR entities will be required to provide the number of Notices of IDR Initiation submitted under the Federal IDR process that pertain to air ambulance services during the month submitted to the certified IDR entity; the number of such Notices of IDR Initiation with respect to which a final determination was made; the number of times the payment amount exceeded the QPA; and the total amount of certified IDR entity fees paid to the certified IDR entity during the month that data was collected with regard to air ambulance services.

With respect to each Notice of IDR Initiation involving air ambulance claims, the certified IDR entity must also provide a description of each air ambulance service, the point of pick-up (as defined in 42 CFR 414.605) for which the services were provided, the amount of the offer submitted by the group health plan, health insurance issuer, or FEHB carrier and by the nonparticipating provider of air ambulance services expressed as a dollar amount and a percentage of the QPA; whether the offer selected by the certified IDR entity was the offer submitted by such plan, issuer, or FEHB carrier or by the provider or facility; the amount of the offer so selected expressed as a dollar amount and a percentage of the QPA, including the rationale for the certified IDR entity's decision; the air ambulance vehicle type; the identity of the plan, issuer, FEHB carrier, or provider of air ambulance services with respect to such determination; and the number of business days elapsed between selection of the certified IDR entity and the determination of the payment amount by the certified IDR entity.

For each month, certified IDR entities will be required to report the information on their activity to the Departments. The report will be submitted through the Federal IDR portal. The Departments estimate it will take a medical and health services manager 1 hour, on average, to prepare the reports and a clerical worker 15 minutes to prepare and send the report to the Departments each month. The burden for each certified IDR entity would be 1.25 hours, with an equivalent cost of approximately $118. For the 600 IDR entities, the annual burden would be 750 hours, with an equivalent cost burden of $71,291 each year.[269]

TABLE 31—ANNUAL BURDEN AND COST FOR THE IDR MONTHLY REPORT STARTING IN 2022

Estimated number of responses	Total annual burden (hours)	Total estimated labor cost	Other costs	Total estimated cost
600	0	0	$71,291	$71,291

The certified IDR entities are required, following the discovery of a breach of unsecured IIHI, to notify of the breach the provider, facility, or provider of air ambulance services; the plan or issuer; the Departments; and each individual whose unsecured IIHI has been, or is reasonably believed to have been, subject to the breach, to the extent possible. The Departments estimate that three certified IDR entities will have a breach each year. In addition, the Departments estimate that it will take a medical and health services manager 1 hour, on average, to handle the initial breach and follow the required protocols, and that it will take a general and operations manager 45 minutes, on average, to ensure the protocol is executed and adapt policies accordingly. The burden for each certified IDR entity would be 1.75 hours, with an equivalent cost of approximately $197. For the three certified IDR entities, this results in a cost burden of $591 each year.[270] The Departments assume that 5 percent of notices would be mailed and will incur a printing cost of $0.05 per page and $0.55 for postage. Thus, the mailing cost is estimated to be $0.09.[271] The Departments seek comment addressing the costs that will be associated with these interim final rules.

TABLE 32—ANNUAL BURDEN AND COST FOR BREACH NOTIFICATION STARTING IN 2022

Estimated number of responses	Total annual burden (hours)	Total estimated labor cost	Other costs	Total estimated cost
3	0	$0.09	$591	$591.09

[269] The burden is estimated as follows: (50 IDR entities × 1 hour × 12 reports annually) + (50 IDR entities × 0.25 hours × 12 reports annually) = 750 hours. A labor rate of $105.01 is used for a medical and health services manager and a labor rate of $55.23 is used for a clerical worker. The labor rates are applied in the following calculation: (200 IDR entities × 1 hour × 12 reports × $105.01) + (200 IDR entities × 0.25 hours × 12 reports × $55.23) = $71,291.

[270] The burden is estimated as follows: (3 certified IDR entities × 1 hour) + (3 certified IDR entities × 0.75 hour) = 5 hours. A labor rate of $105.01 is used for a medical and health services manager and a labor rate of $55.23 is used for a clerical worker. The labor rates are applied in the following calculation: (3 certified IDR entities × 1 hour × $105.01) + (3 certified IDR entities × 0.75 hour × $122.55) = $591.

[271] This is calculated 3 × 0.05 × ($0.05 + $0.55) = $0.09.

Summary

In the first year, the total cost burden associated with the IDR entity certification process is $149,616. In subsequent years, the total cost burden associated with the IDR entity certification process is $124,491. The three-year average cost burden associated with the IDR entity certification is $132,866. The burden associated with the IDR entity certification is shared by HHS, DOL, the Department of the Treasury, and OPM. As shown in Tables 33 through 35, it is estimated that 45 percent of the burden will be accounted for by HHS, 25 percent of the burden will be accounted for by DOL and the Department of the Treasury each, and 5 percent will be accounted for by OPM. Therefore, the cost burden associated with HHS requirements is $67,327 in the first year and $56,021 in subsequent years. The three-year average cost burden associated with HHS requirements is $59,790. The cost burden associated with each of the DOL and the Department of the Treasury requirements is $37,404 in the first year and $31,123 in subsequent years. The three-year average cost burden associated with DOL and the Department of the Treasury is $33,217 each. The cost burden associated with OPM requirements is $7,481 in the first year and $6,225 in subsequent years. The three-year average cost burden associated with OPM requirements is $6,643. The Departments seek comment on the assumptions and calculations made in this ICR.

TABLE 33—HHS SUMMARY COST AND BURDEN OF IDR ENTITY CERTIFICATION STARTING IN 2022

Estimated number of responses	Total annual burden (hours)	Total estimated labor cost	Other costs	Total estimated cost
305	$0	$0	$59,790	$59,790

TABLE 34—DOL AND THE DEPARTMENT OF THE TREASURY'S SUMMARY COST AND BURDEN OF IDR ENTITY CERTIFICATION STARTING IN 2022

Estimated number of responses	Total annual burden (hours)	Total estimated labor cost	Other costs	Total estimated cost
170	0	$0	$33,217	$33,217

TABLE 35—OPM'S SUMMARY COST AND BURDEN OF IDR ENTITY CERTIFICATION STARTING IN 2022

Estimated number of responses	Total annual burden (hours)	Total estimated labor cost	Other costs	Total estimated cost
34	0	$0	$6,643	$6,643

ICRs Regarding Notice of the Right to Good Faith Estimates for Uninsured (or Self-Pay) Individuals (45 CFR 149.610)

Convening providers and facilities are required under 45 CFR 149.610(b) to inform uninsured (or self-pay) individuals of the availability of good faith estimates of expected charges. The notice regarding the availability of good faith estimates for uninsured (or self-pay) individuals must be written in a clear and understandable manner and made available in accessible formats and in the language(s) spoken by individual(s) seeking items and services with such convening provider or convening facility. Additionally, the notice must be prominently displayed (and easily searchable from a public search engine), on the convening provider's or convening facility's website, in the convening provider's or convening facility's office, and on-site where scheduling or questions about the cost of items and services occur. These ICRs estimate the information collection burdens for three groups of provider types: (1) Providers associated with health care facilities, (2) individual physician practitioners, and (3) wholly physician-owned private practices. For all three groups of providers, the ICRs apply the same methodology to estimate the burden, consisting of the following steps:

- Drafting notices informing uninsured (or self-pay) individuals of their right to receive a good faith estimate of expected charges.
- Displaying the notices on the provider's website, in the provider's office, and on-site where scheduling or questions about the cost of items or services occur.
- Posting a single page notice in at least two prominent locations.
- Printing and materials costs for posting notices.

Details about the requirements of the steps that apply to all 3 provider groups are described once for providers associated with health care facilities and apply equally to the other two provider groups. Any specific differences in estimating the burden to comply with these requirements are detailed for the specific provider group below. HHS invites comment on the assumptions and calculations made in these ICRs.

Providers Associated With Health Care Facilities

Unique to providers associated with health care facilities, HHS assumes that such providers will enter into agreements with their associated health care facility to provide notice of the availability of good faith estimates of expected charges to uninsured (or self-pay) individuals on their behalf. HHS estimates that for each health care facility it will take an average of 2 hours for a lawyer to draft an agreement and a medical secretary and administrative assistant 2 hours to provide electronic copies to all associated convening providers to sign. As shown in Table 36, this results in an equivalent cost estimate of approximately $91,770,384 to be incurred as one-time cost in 2021.[272] HHS cannot estimate how

[272] The burden is estimated as follows: 245,336 health care facilities × 2 hours = 490,672 hours. A

Continued

many providers will incur burden to sign the agreement, but assumes the burden to providers will be minimal; the use of electronic signature portals may reduce the burden to the convening provider. In future years, this agreement can be included in the contract between the facilities and providers at no additional cost.

TABLE 36—ESTIMATED ONE-TIME AND HOUR BURDEN FOR PROVIDERS ASSOCIATED WITH FACILITIES TO ENTER INTO AGREEMENTS TO PROVIDE NOTICE OF RIGHT TO A GOOD FAITH ESTIMATE

Year	Estimated number of respondents	Estimated number of responses	Burden per response (hours)	Total burden (hours)	Total estimated cost
2021	245,336	245,336	4	981,344	$91,770,384

HHS assumes that the associated facility will draft the notices informing uninsured (or self-pay) individuals of their right to receive a good faith estimate of expected charges. Information regarding the availability of good faith estimates for uninsured (or self-pay) individuals must be written in a clear and understandable manner and made available in accessible formats and in the language(s) spoken by individual(s) seeking items and services with such convening provider. Additionally, the notices must be prominently displayed on the convening provider's website, and in the convening provider's office, and on-site where scheduling or questions about the cost of items or services occur. Providers may satisfy this requirement by utilizing the language in the standard notice anticipated to be issued by HHS. HHS estimates that for each health care facility, it will take an average of two hours for a lawyer to read and understand the anticipated notice and draft any additions in clear and understandable language, a medical secretary and administrative assistant 30 minutes to prepare the document for posting within the facility, and a computer programmer 1 hour to post the information on each providers' website on behalf of the facility. As shown in Table 37, this results in an equivalent cost of approximately $102,754,069 to be incurred as a one-time cost in 2021.[273]

TABLE 37—ESTIMATED ONE-TIME COST AND HOUR BURDEN FOR HEALTH CARE FACILITIES (INCLUDING ON BEHALF OF HEALTH CARE PROVIDERS ASSOCIATED WITH HEALTH CARE FACILITIES) TO DRAFT AND POST NOTICE OF GOOD FAITH ESTIMATE

Year	Estimated number of respondents	Estimated number of responses	Burden per response (hours)	Total burden (hours)	Printing and materials costs	Total estimated cost
2021	245,336	245,336	2.5	858,676	$25,752	$102,754,069

HHS assumes that each health care facility will post a single page document in at least 2 prominent locations so uninsured (or self-pay) individuals are provided reasonable notice of their right to a good faith estimate of expected charges. A prominent location in the health care facility may include patient appointment check-in kiosks, reception front-desks, patient appointment scheduling locations, and where patients pay bills. The notices should be drafted in clear and understandable language, shorter in length, and printed in legible font size. HHS assumes that each facility will incur a printing cost of $0.05 per page and materials for a total equivalent cost of $0.10. Hospitals may have a greater number of posting locations because of building size, therefore, HHS anticipates that hospitals will post four additional notices on average and incur an additional cost of $0.20 each. This results in a one-time equivalent cost of approximately $24,534 to all non-hospital health care facilities and an overall one-time cost of approximately $25,752 when including hospitals.

HHS estimates that the one-time burden for providers and facilities to enter into agreements and for facilities to develop, prepare, print, and post the notices and update their respective websites will be approximately 1,840,020 total burden hours with an associated equivalent cost of approximately $194,524,453, as shown in Table 38.

labor rate of $140.96 is used for a lawyer. The labor rate is applied in the following calculation: 245,336 health care facilities × 2 hours × $140.96 = $69,165,125. 245,336 health care facilities × 2 hours = 490,672 hours. A labor rate of $46.07 is used for a medical secretary and administrative assistant. The labor rate is applied in the following calculation: 245,336 health care facilities × 2 hours × $46.07 = $22,605,259. Therefore, 490,672 hours + 490,672 hours = 981,344 total burden hours and $69,165,125 + $22,605,259 = $91,770,381 total annual respondent time cost.

[273] The burden is estimated as follows: 245,336 health care facilities × 2 hours = 490,672 hours. A labor rate of $140.96 is used for a lawyer. The labor rate is applied in the following calculation: 245,336 health care facilities × 2 hours × $140.96 = $69,165,125. 245,336 health care facilities × 0.5 hours = 122,668 hours. A labor rate of $46.07 is used for a medical secretary and administrative assistant. The labor rate is applied in the following calculation: 245,336 health care facilities × 0.5 hours × $46.07 = $5,651,315. 245,336 health care facilities × 1 hours = 245,336 hours. A labor rate of $113.77 is used for a computer programmer. The labor rate is applied to the following calculation: 245,336 health care facilities × 1 hour × $113.77= $27,911,877. Therefore, 490,672 hours + 122,668 hours + 245,336 hours = 858,676 total burden hours. Additionally, one-time printing and material costs are estimated using the following calculation: .05 × 2 pages × 245,336 impacted health care facilities = 25, 752 total one-time cost for printing and materials. The total respondent time costs are $69,165,125 + $5,651,315 + $27,911,877 + $25,752 = $102,754,069.

TABLE 38—TOTAL ESTIMATED ONE-TIME COST AND HOUR BURDEN FOR HEALTH CARE FACILITIES (INCLUDING ON BEHALF OF HEALTH CARE PROVIDERS ASSOCIATED WITH HEALTH CARE FACILITIES) TO PROVIDE NOTICE OF RIGHT TO A GOOD FAITH ESTIMATE [274]

Year	Estimated number of respondents	Estimated number of responses	Burden per response (hours)	Total annual burden (hours)	Printing and materials costs	Total estimated cost
2021	245,336	245,336	7.5	1,840,020	$25,752	$194,524,453

Individual Physician Practitioners

HHS estimates that 145,887 individual physician practitioners will incur burden and cost to comply with this provision.[275] HHS estimates an average of 2 hours and 30 minutes for the individual physician practitioner to read and understand the provided notice and draft any additions in clear and understandable language and (for 80% of individual physician practitioners) a computer programmer one hour to post the information in the provider's website. HHS estimates that the one-time burden for individual physician practitioners to develop, prepare, print, post the notices, and make website updates will be approximately 481,426 total burden hours. This results in an equivalent cost of approximately $75,075,712.[276]

HHS assumes that each individual physician practitioner will incur a printing cost of $0.05 per page and materials for a total equivalent cost of $0.10. This results in an annual one-time equivalent cost of approximately $14,589 to all individual physician practitioners.

HHS estimates that the annual one-time burden for individual physician practitioners to develop, prepare, print, post the notices, and make website updates will be approximately 481,426 total burden hours with an associated equivalent cost of approximately $75,075,712, as shown in Table 39.

TABLE 39—ESTIMATED ONE-TIME COST AND HOUR BURDEN FOR INDIVIDUAL PHYSICIAN PRACTITIONERS TO DRAFT AND POST NOTICE OF GOOD FAITH ESTIMATE NOTICE [277]

Year	Estimated number of respondents	Estimated number of responses	Burden per response (hours)	Total annual burden (hours)	Printing and material costs	Total estimated cost
2021	145,887 (All Physicians)	145,887	2.5	364,717		$61,797,674
2021	116,709 * (Additional burden for Subset of Physicians with Websites).	* 116,709	1	116,709		13,278,038
Total			3.5	481,426		** 75,075,712

* This is calculated as the sum of $61,797,674 (cost for all individual physician practitioners to draft notice of right to GFE) + $13,278,038 (cost for computer programmers to post notice of right to GFE on 80% of practitioners' websites). Total estimated cost of $75,075,712 includes burden for all individual physician practitioners to draft the notice of right to GFE plus the additional burden for computer programmers to add the notice to the website for the subset (80 percent) of total physicians that have websites, (80 percent of 145,887 = 116,709).

Wholly-Physician-Owned Private Practices

HHS estimates that 120,525 wholly physician-owned private practices will incur burden and cost to comply with this provision.[278] For each practice, HHS estimates an average of 2 hours and 30 minutes for a general and operations manager to read and understand the provided notice and draft any additions in clear and understandable language and a computer programmer one hour to post the information in the provider's website. This results in an equivalent cost of approximately $50,650,005 to be incurred as a one-time cost in 2021.[279]

[274] Estimated cost includes the sum of Table 28 and 29. It also includes computer programming cost to update health care facility websites with uninsured (or self-pay) individuals' right to the good faith estimate. Total printing and material costs for all health care facilities of $24,534 to all non-hospital health care facilities and an overall one-time cost of approximately $25,752 for hospitals.

[275] In generating these estimates, HHS reviewed data from the American Medical Association (AMA) and Kaiser Family Foundation. See Kane C. Policy Research Perspectives Recent Changes in Physician Practice Arrangements: Private Practice Dropped to Less than 50 Percent of Physicians in 2020. Accessed July 15, 2021. *https://www.ama-assn.org/system/files/2021-05/2020-prp-physician-practice-arrangements.pdf;* Professionally Active Physicians. KFF. Published May 20, 2020. *https://www.kff.org/other/state-indicator/total-active-physicians/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22.*

[276] The burden is estimated as follows: 145,887 individual physician practitioners × 2.5 hours = 364,717 hours. A labor rate of $169.40 is used for a physician. The labor rate is applied to the following calculation: 145,887 individual physician practitioners × 2.5 hours × $169.40 = $61,783,085. HHS assumes that 80 percent of individual physician practitioners have a website resulting in 116,709 websites needed to be updated with good faith estimate notices. HHS assumes that the physician will pay a computer programmer to make the website update. The burden is estimated as follows: 116,709 websites needing updates × 1 hour = 116,709 hours. A labor rate of $113.77 is used for a computer programmer. The labor rate is applied to the following calculation: 116,709 websites needing updates × 1 hour × $113.77 = $13,278,038. Therefore, 364,717 hours + 116,709 hours = 481,426 total burden hours. The total annual respondent time cost is $61,783,085 + $13,276,038 = $75,061,124. Total printing and material costs are of $14,589. Therefore, $75,061,124 + $14,589 = $75,075,712.

[277] HHS estimates that 80 percent (116,709) of individual physician practitioners have a website. Therefore, estimated cost includes computer programming cost to update individual physician practitioners' websites with uninsured (or self-pay) individuals' right to good faith estimate. HHS assumes that each individual physician practitioner will incur a printing cost of $0.05 per page and materials for a total equivalent cost of $0.10. Total printing and material costs of $14,589 are included.

[278] In generating these estimates, HHS reviewed data from the American Medical Association (AMA) and Kaiser Family Foundation. See Kane C. Policy Research Perspectives Recent Changes in Physician Practice Arrangements: Private Practice Dropped to Less than 50 Percent of Physicians in 2020. Accessed July 15, 2021. *https://www.ama-assn.org/system/files/2021-05/2020-prp-physician-practice-arrangements.pdf;* Professionally Active Physicians. KFF. Published May 20, 2020. *https://www.kff.org/other/state-indicator/total-active-physicians/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22.*

[279] The burden is estimated as follows: 125,525 wholly physician-owned private practices × 2.5 hours = 301,312 hours. A labor rate of $122,55 is used for a general and operations manager. The labor rate is applied to the following calculation: 120,525 wholly physician-owned private practices

Continued

HHS assumes that each the wholly physician-owned private practice will incur a printing cost of $0.05 per page and materials for a total equivalent cost of $0.10. This results in a one-time equivalent cost of approximately $12,052 to all wholly physician-owned private practices.

HHS estimates that the annual one-time burden for wholly physician-owned private practices to develop, prepare, print, and post the notices, and make website updates will be approximately 421,837 total burden hours with an associated equivalent cost of approximately $50,650,005, as shown in Table 40.

TABLE 40—ESTIMATED ONE-TIME COST AND HOUR BURDEN FOR WHOLLY PHYSICIAN-OWNED PRIVATE PRACTICES TO DRAFT AND POST NOTICE OF GOOD FAITH ESTIMATE NOTICE *

Year	Estimated number of respondents	Estimated number of responses	Burden per response (hours)	Total annual burden (hours)	Material and printing costs	Total estimated cost
2021	120,525	120,525	3.5	421,837	$12,052	[280] $50,650,005

* Estimated cost includes computer programming cost to update wholly physician-owned private practice website with uninsured (or self-pay) individuals' right to a good faith estimate. HHS assumes that each the wholly physician-owned private practice will incur a printing cost of $0.05 per page and materials for a total equivalent cost of $0.10. Total printing and material costs of $12,052 are included.

Summary

HHS estimates that the one-time burden for health care providers (including providers associated with health care facilities, individual physician practitioners, and wholly physician-owned private practices) and health care facilities to provide notice of the right to a good faith estimate of expected charges to uninsured (self-pay) individuals will be approximately 2,743,283 total burden hours with an associated equivalent cost of approximately $320,250,169.

TABLE 41—ESTIMATED TOTAL ONE-TIME COST RELATED TO NOTICE OF RIGHT TO GOOD FAITH ESTIMATE *

Year	Estimated number of respondents	Estimated number of responses	Burden per response (hours) [281]	Total annual labor burden (hours)	Total printing and material costs	Total estimated cost
2021	511,748	511,748	15.5	2,743,283	$52,393	$320,250,169

* Tables 38 through 40 are combined to estimate total amounts. This table presents a cumulative 15.5 hours of burden per response for summary purposes.

7. ICRs Regarding Requirements for Provision of Good Faith Estimate of Expected Charges Upon Request of Uninsured (or Self-Pay) Individuals and for Scheduled Items and Services (45 CFR 149.610)

These interim final rules require a convening provider or facility to provide a good faith estimate of expected charges to uninsured (or self-pay) individuals for scheduled items and services and upon request (45 CFR 149.610) including those items or services furnished by a co-provider or co-facility in conjunction with the primary items or services. HHS estimates that approximately 3,498,942 uninsured (or self-pay) individuals will be impacted by this rule requirement.[282] A total of 511,748 providers associated with health care facilities, individual physician practitioners, and wholly physician-owned private practices will incur the burden and costs associated with generating a good faith estimate.[283] HHS welcomes comments on this estimate.

HHS estimates that it will take an average of 30 minutes for a business operations specialist to determine a patient's insurance status, orally inform the patient of their right to receive a good faith estimate of expected charges, and provide an oral good faith estimate, if no additional items and services are needed. HHS assumes 1,749,471 (50 percent) of uninsured (or self-pay) individuals fall in this category. Therefore, the annual equivalent cost estimate for provision of good faith estimates where no additional items and services are needed is of $88,628,201.[284]

HHS estimates that it will take an average of 30 minutes for a business operations specialist to generate a good faith estimate of expected charges furnished by a co-provider and co-facility for items and services to the convening provider. Given that 1,749,471 (50 percent) of uninsured (or

× 2.5 hours × $122.55 = $36,925,829. 120,525 wholly physician-owned private practices × 1 hour = 120,525 hours. A labor rate of $113.77 is used for a computer programmer. The labor rate is applied to the following calculation: 120,525 wholly physician-owned private practices × 1 hour × $113.77 = $13,712,123. Therefore, the total burden hours are 301,312 + 120,525 = 421,837 and the total equivalent costs are $36,925,829 + $13,712,123 = $50,637,952. The printing and material costs are $12,052. Therefore, $50,637,952 + $12,052 = $50,650,005.

[280] 301,312 + 120,525 = 421,837 and the total equivalent costs are $36,925,829 + $13,712,123 = $50,637,952. The printing and material costs are $12,052. Therefore, $50,637,952 + $12,052 = $50,650,005.

[281] This includes the time for providers associated with health care facilities to enter into agreements with health care facilities to provide good faith estimates on their behalf.

[282] The number is estimated as follows: 51,744,200 nonemergency elective procedures (surgical and non-surgical) performed annually × 9.2% uninsured rate = 4,760,466. HHS assumes that some uninsured populations will forego elective procedures because of costs. Therefore, a 30% decrease adjustment was included resulting in 3,332,326. HHS also assumes a 5% adjustment for good faith estimate inquires only resulting in a final value of 3,498,942. See Squitieri, Lee *et al.* ''Resuming Elective Surgery during Covid–19: Can Inpatient Hospitals Collaborate with Ambulatory Surgery Centers?.'' *Plastic and reconstructive surgery. Global open* vol. 9,2 e3442. 18 Feb. 2021, doi:10.1097/GOX.0000000000003442 (The study estimates 4,297,850 nonemergency elective procedures (surgical and non-surgical) are performed each month. This value was multiplied by 12 months = 51,574,200. HHS adjusted by approximately one-third of one percent to account annual increase in volume since study publication resulting in 51,744,200). See also KFF Health Insurance Coverage of the Total Population.

[283] These estimates include the total number of health care facilities and health care providers from the preceding ICR Regarding Notice of Right to Good Faith Estimate.

[284] The burden is estimated as follows: 1,749,471 uninsured (or self-pay) individuals in need of good faith estimates without items and services × 0.50 hours = 874,736 hours. A labor rate of $101.32 is used for a business operations specialist. The labor rate is applied in the following calculation: 1,749,471 claims × 0.50 hours × $101.32 = $88,628,201.

self-pay) individuals require additional items and services, same number (1,749,471) of claims will be generated by co-providers or co-facilities. Therefore, the annual equivalent cost estimate for good faith estimates sent to convening providers by co-providers or co-facilities is $88,628,201.[285] HHS assumes that all communication between convening provider and convening facility, and co-provider or co-facility will be done electronically. Thus, the cost to generate a good faith estimate for both cases where additional items and services are needed and where no additional items and services are needed is $354,512,803.[286]

HHS estimates that it will take an average of 1 hour for a business operations specialist to determine a patient's insurance status, inform uninsured (or self-pay) individuals of their right to receive a good faith estimate of expected charges, and provide a good faith estimate, if additional items and services are needed. HHS assumes 1,749,471 (50 percent) of uninsured (or self-pay) individuals fall in this category. Therefore, the annual equivalent cost estimate is $177,256,402.[287] Thus, a total of $265,884,603 is estimated for business operations specialists, when adding the cost if no additional items and services are needed ($88,628,201) to the cost if additional items and services are needed ($177,256,402).

HHS estimates that approximately 90 percent of uninsured (or self-pay) individuals will receive a good faith estimate of expected charges through the mail that is 2 pages in length.[288] The remaining 10 percent of uninsured (or self-pay) individuals will receive the good faith estimate via electronic correspondence; costs are therefore accounted for in the 2 preceding paragraphs. HHS assumes that each convening provider or facility will incur a printing cost of $0.05 per page and materials for a total equivalent cost of $0.10 per good faith estimate. Therefore, the annual equivalent cost estimate for printing good faith estimates is $314,905 for all health care providers and health care facilities.[289]

HHS assumes that 5% of uninsured (or self-pay) individuals (*i.e.,* 157,452 uninsured (or self-pay) individuals) will request a mailed copy of their written good faith estimate of expected charges to a preferred location.[290] HHS assumes that it will take an average of 15 minutes for a medical secretary and administrative assistant to print and mail the good faith estimate to the uninsured (or self-pay) individual. HHS estimates a postage cost of $0.55 per mailing. Therefore, the annual equivalent cost estimate is $1,900,057 to mail the good faith estimate for all health care providers and health care facilities.[291]

TABLE 42—ESTIMATED ANNUAL COST AND HOUR BURDEN PER RESPONSE PER HEALTH CARE PROVIDER AND HEALTH CARE FACILITY TO ACCEPT AND FULFILL REQUESTS FOR MAILED GOOD FAITH ESTIMATES OF EXPECTED CHARGES

[Mailing costs only]

Occupation	Burden hours per response	Labor cost per hour	Total mailing cost per response
Medical Secretary and Administrative Assistant	0.25	$46.07	[292] $3.71
Total per Response	0.25		3.71

TABLE 43—ESTIMATED ANNUAL COST AND HOUR BURDEN FOR ALL HEALTH CARE PROVIDER AND HEALTH CARE FACILITY TO ACCEPT AND FULFILL REQUESTS FOR MAILED GOOD FAITH ESTIMATES OF EXPECTED CHARGES

Number of respondents	Number of responses	Burden hours per respondent	Total burden hours	Total labor costs of reporting	Mailing cost	Total annual cost
511,748	157,452	0.25	39,363	$1,813,458	$86,599	[293] $1,900,057

Summary

HHS estimates the annual cost to a convening provider or facility to provide a good faith estimate of expected charges to uninsured (or self-pay) individuals for scheduled items and services and upon requests between 2022–2024 to be $356,727,765 (inclusive of printing, materials, mailing costs) and total burden hours of 3,538,305, as shown in Table 44.

HHS estimates the annual cost for printing and materials to provide written good faith estimates to uninsured (or self-pay) individuals to be $314,905. The mailing costs of good faith estimates to uninsured (or self-pay)

[285] The burden is estimated as follows: 1,749,471 uninsured individuals in need of good faith estimates with additional items and services × 0.50 hours = 874,736 hours. A labor rate of $101.32 is used for a business operations specialist. The labor rate is applied in the following calculation: 1,749,471 claims × 0.50 hours × $101.32 = $88,628,201.

[286] The burden is estimated as follows: $88,628,201 + $177,256,402 + $88,628,201 = $354,512,803.

[287] The burden is estimated as follows: 1,749,471 claims × 1 hour = 1,749,471 hours. A labor rate of $101.32 is used for a business operations specialist. The labor rate is applied in the following calculation: 1,749,471 claims × 1 hour × $101.32 = $177,256,402.

[288] HHS assumes that the good faith estimate will be printed in 8.5'' x 11'' letter sized paper.

[289] The estimate is calculated as follows: $0.05 cost per page × 2 pages × 3,149,048 uninsured (or self-pay) individuals who receive a written good faith estimate = $314,905.

[290] An estimated 3,149,048 uninsured (or self-pay) individuals who receive a written good faith estimate × 5% = 157,452 uninsured (or self-pay) individuals who request a mailed good faith estimate of expected charges.

[291] The burden is estimated as follows: 157,452 good faith estimates × 0.25 hours = 39,363 hours. A labor rate of $46.07 is used for a medical secretary and administrative assistant. The labor rate is applied in the following calculation: 157,452 good faith estimates × 0.25 hours × $46.07 = $1,813,458. Therefore, 157,452 mailed good faith estimates × $0.55 postage cost = $86,599 in mailing costs + $1,813,458 in annual respondent time cost = $1,900,057.

[292] The cost per respondent is calculated as: $1,900,057 in medical secretary and administrative assistant annual respondent time cost to mail good faith estimate and mailing costs (printing costs are already accounted for in preceding section) divided by 511,748 health care providers and health care facilities = $3.71 cost per respondent.

[293] Therefore, 157,452 mailed good faith estimates × $0.55 postage cost = $86,599 in mailing costs + $1,813,458 in annual respondent time cost = $1,900,057.

individuals is $86,599 with an annual total burden hour estimate of 39,363 hours and a total annual respondent time cost of $1,813,458. This estimate is included in the total cost of $356,727,765. HHS invites comment on the assumptions and calculations made in this ICR.

TABLE 44—ANNUAL BURDEN AND TOTAL COST RELATED TO PROVISION OF GOOD FAITH ESTIMATES FOR UNINSURED (OR-SELF-PAY) INDIVIDUALS (LABOR, PRINTING, AND MAILING)

Estimated number of respondents	Estimated number of responses	Burden per response (hours)	Total annual burden (hours)	Total annual respondent time cost	Printing and mailing costs (labor cost included) *	Total estimated cost
3,498,942	3,498,942	2.0	3,538,305	$354,512,803	$2,214,961	** $356,727,765

* This is calculated as following: $314,905 in printing costs + $86,599 in mailing costs + $1,813,458 in estimated annual respondent time cost to mail good faith estimate = $2,214,961. The Department assumes that it will take an average of fifteen minutes for a medical secretary and administrative assistant to print and mail the good faith estimate to the uninsured (or self-pay) individual. The annual burden hours associated with printing and mailing a good faith estimate of expected charges is 39,363 hours.

** The total estimated cost burden is the sum $88,628,201 (the GFE costs without co-providers or co-facilities) + $177,256,402 (the GFE costs with co-providers or co-facilities) + 88, 628, 201 (the GFE costs to convening providers) + $2,214,961 (printing and mailing costs, including labor).

8. ICRs Regarding Patient-Provider Dispute Resolution Process (45 CFR 149.620)

These interim final rules enable uninsured (or self-pay) individuals to initiate a patient-provider dispute resolution process if their final billed charges are in excess of the expected charges by at least $400 more than the amount listed in the good faith estimate supplied by the provider or facility. HHS does not have data on how many claims will be likely to result in patient-provider dispute resolution. For the estimates in this section, HHS relied on the experience of New York State. In 2015–2018 New York State had 1,486 disputes involving surprise bills submitted to IDR, 31% of these disputes (457 in all) were found ineligible for IDR for various reasons including 8% (approximately 36 cases) due to enrollment in self-insured plans.[294] For purposes of this analysis, HHS assumes that going forward, New York State will continue to see 40 IDR cases each year involving surprise bills for individuals enrolled with self-insured plans. Accordingly, the Departments estimate that there will be 26,659 claims that result in patient-provider dispute resolution each year.[295]

HHS estimates that it will take an average of 2 hours for an uninsured (or self-pay) individual or, if they use an authorized representative, 1 hour for their authorized representative to write, prepare, and send the notice to initiate the patient-provider dispute resolution to the Secretary of HHS. HHS assumes that uninsured (or self-pay) individuals will self-represent in 90% of the cases, while the remaining 10% will be represented by the uninsured (or self-pay) individual's authorized representative, as allowed by these interim final rules.

HHS assumes the authorized representative will be a lawyer. Additionally, HHS assumes that a small percentage of uninsured (or self-pay) individuals or their authorized representatives will be asked to resubmit or send additional materials to complete the initiation process. This results in an annual equivalent cost estimate of $3,789,694.[296] The patient-provider dispute resolution initiation notice must be submitted to the Secretary of HHS within 120 calendar days of receiving billed charges substantially in excess of the good faith estimate. HHS assumes for uninsured (or self-pay) individuals that 8,973 (34%) of initiation notices, including those that need to be resubmitted with additional materials, will be sent electronically and 17,419 (66%) of the initiation notices, including those that need to be resubmitted with additional materials will be mailed with an associated printing and materials and postage costs of $12,193.[297] [298] To facilitate communication between parties and compliance with this notice requirement, HHS is concurrently issuing a model notice that the parties may use to satisfy the patient-provider dispute resolution initiation notice requirement. HHS will consider timely use of the model notice in accordance with the accompanying instructions to satisfy the notice requirement.

These interim final rules require the SDR entity to attest to the Secretary of HHS whether a conflict of interest exists with the uninsured (or self-pay) individual, provider, or facility. HHS assumes that it will take an average of one hour for a general and operations manager and one hour for a lawyer to

[294] See *https://www.dfs.ny.gov/system/files/documents/2019/09/dfs_oon_idr.pdf.*

[295] The number is estimated as follows: 51,744,200 nonemergency elective procedures (surgical and non-surgical) performed annually × 9.2% uninsured rate = 4,760,466. HHS assumes that some uninsured (or self-pay) individuals will forego elective procedures because of costs. Therefore, a 30% decrease adjustment was included resulting in 3,332,326. HHS assumes that 10% of uninsured (or self-pay) individuals who undergo a nonemergency elective procedure will receive a billed charge that is $400 or greater more than the total expected charges listed in the good faith estimate, therefore 3,332,326 × 10% = 333,233. HHS assumes that 8% will engage the provider-patient dispute resolution process, therefore 333,233 × 8% = 26,659.

[296] The burden is estimated as follows: 26,659 × 90% = 23,993 uninsured (or self-pay) individuals will self-represent. 23,993 × 2 hours = 47,986 hours. A labor rate of $64.32 is used for uninsured (or self-pay) individuals (all occupations). The labor rate is applied in the following calculation: 23,993 claims × 2 hours × $64.32 = $3,086,427. HHS assumes that uninsured (or self-pay) individual will appoint an authorized representative in 10% of cases. .26,659 × 10% = 2,666 claims represented by an authorized representative. HHS assumes approximately 15% of uninsured (or self-pay) individuals will need to resubmit or submit additional materials to initiate IDR, either themselves or through their authorized representative. Therefore, the burden estimate is calculated as follows: 23,993 claims × 10% = 2,399 resubmitted claims by individual × 2 hours × $64.32 (labor rate) = $129,899. 2,666 claims × 5% = 133 resubmitted claims by authorized representative × 1 hour × $140.96 (labor rate) = $18,789. The total annual respondent time cost estimates are added as follows: $3,086,472 + $375,785 + $308,647 + $18,789 = $3,789,694. The total burden hours are 55,584.

[297] HHS assumes that the average initiation notice sent via mail by uninsured (or self-pay) individuals will be three pages in length and printed on 8.5'' x 11'' sized paper. HHS assumes a $0.05 cost in printing and materials cost per page and $0.55 in postage cost. Therefore, $0.05 cost per page × 3 pages × 17,419 mailed initiation notices (inclusive of notices that needed to be resubmitted) = $2,613 in printing and material costs. The postage costs are calculated as $0.55 cost per postage × 17,419 mailed initiation notices = $9,580 in postage cost. The total printing and materials and postage costs are therefore $2,613 + $9,580 = $12,193.

[298] According to data from the National Telecommunications and Information Agency, 34% 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.*

determine whether a conflict of interest exists. HHS assumes all communication will be done electronically. This results in annual equivalent cost estimate of $7,024,811, as shown in Table 45.[299]

TABLE 45—ESTIMATED ANNUAL COST AND HOUR BURDEN RELATED TO ATTESTATION OF CONFLICT OF INTEREST WITH A PATIENT-PROVIDER DISPUTE RESOLUTION INITIATION NOTICE

Estimated number of respondents	Estimated number of responses	Burden per response (hours)	Total annual burden (hours)	Total estimated cost
26,659	26,659	2	53,317	$7,024,811

These interim final rules also require the selected SDR entity to review eligibility and completeness of the initiation notice and notify uninsured (or self-pay) individuals, providers or facilities of the SDR entity's selection to conduct dispute resolution. Providers and facilities are thereafter required to furnish additional information to the SDR entity within 10 business days after receiving notification of SDR entity selection. This information must include: (1) A copy of the good faith estimate provided to the uninsured (or self-pay) individual for the items or services under dispute; (2) a copy of the bill provided to the uninsured (or self-pay) individual for items or services under dispute; and (3) documentation providing evidence to demonstrate the difference between the billed charge and the expected charges in the good faith estimate reflects a medically necessary item or service and is based on unforeseen circumstances that could not have reasonably been anticipated by the provider or facility when the good faith estimate was provided. HHS estimates that it will take an average of 1 hour for a general and operations manager to address these requirements and send to the SDR entity. This results in an annual equivalent cost estimate of $3,267,013.[300]

These interim final rules require the SDR entity to assess the information provided by the provider or facility according to the standards described in 45 CFR 149.620(f) and discussed in section VI.B.7 of the preamble. The SDR entity must respond within 30 days after receipt information from the provider or facility to make determinations on charges to the paid by the uninsured (or self-pay) individual. HHS estimates that it will take an average of 2 hours for a general and operations manager and 2 hours for a lawyer to assess the merits of the submitted information and determine a prevailing party. This results in an annual equivalent cost estimate of $14,049,622.[301]

TABLE 46—ESTIMATED ANNUAL BURDEN TO ASSESS THE SUBMITTED INFORMATION AND DETERMINE A PREVAILING PARTY

Estimated number of respondents	Estimated number of responses	Burden per response (hours)	Total annual burden (hours)	Total estimated cost
26,659	26,659	4	106,634	$14,049,622

HHS estimates that it will take an average of 30 minutes for an SDR entity's general and operations manager to notify parties of the IDR determination. This results in an annual equivalent cost estimate of $1,633,506.[302]

The SDR entity must also submit the administrative fee to the Secretary of HHS on behalf of uninsured (or self-pay) individuals. This burden includes time to review instructions, search existing data resources, gather data needed, and complete and review information collection. HHS estimates that the time required to complete and submit this information collection is estimated to average a clerical worker 1.5 hours per month (or 18 hours annually), with a total annual cost of $2,982.42, as shown in Table 47.[303] HHS estimates the total annual ongoing costs associated with the implementation and administration of the patient-provider dispute resolution program, including system maintenance, and program support, is estimated to be 12.6 million this cost will be offset by the collection of the $25 administrative fee, resulting in a total anticipated collection of $655,475 and a total annual cost to the Federal Government of $12 million.

[299] The burden is estimated as follows: 26,659 claims × 1 hour = 26,659 hours. A labor rate of $122.55 is used for a general and operations manager. The labor rate is applied in the following calculation: 26,659 claims × 1 hour × $122.55 = $3,267,013. The burden for legal review is estimated as follows: 26,659 claims × 1 hour = 26,659 hours. A labor rate of $140.96 is used for a lawyer. The labor rates are applied in the following calculation: 26,659 claims × 1 hour × $140.96 = $3,757,798. The total annual response time cost estimates are added as follows: $3,267,013 + $3,757,798 = $7,024,811. The total burden hours are 53,317.

[300] The burden is estimated as follows: 26,659 claims × 1 hour = 26,659 hours. A labor rate of $101.32 is used for a general and operations manager. The labor rate is applied in the following calculation: 26,659 claims × 1 hour × $122.55 = $3,267,013. Total burden hours are 26,659 hours.

[301] The burden is estimated as follows: 26,659 claims × 2 hours = 53,317 hours. A labor rate of $122.55 is used for a general and operations manager. The labor rate is applied in the following calculation: 26,659 claims × 2 hours × $122.55 = $6,534,026. The burden for legal review is estimated as follows: 26,659 claims × 2 hours = 53,317 hours. A labor rate of $140.96 is used for a lawyer. The labor rates are applied in the following calculation: 53,317 × 2 hours × $140.96 = $7,515,596. The total annual respond time cost estimates are calculated as follows: $6,534,026 + $7,515,596 = $14,049,622. The total annual burden hours are 106,634 hours.

[302] The burden is estimated as follows: 26,659 claims × 0.50 hours = 13,329 hours. A labor rate of $122.55 is used for a general and operations manager. The labor rate is applied in the following calculation: 26,659 claims × 0.50 hours × $122.55 = $1,633,506.

[303] The burden is estimated as follows: A labor rate of $55.23 is used for a clerical worker. The labor rate is applied in the following calculation: 3 annual responses × 18 hours × $55.23 = $2,982.42.

TABLE 47—ESTIMATED ANNUAL BURDEN AND COST RELATED TO SDR SUBMISSION OF THE ADMINISTRATIVE FEE TO HHS

Estimated number of responses	Total annual burden (1.5 hours × 12 months)	Annual cost per IDR entity	Annual cost for all responses
3	18	994.14	$2,982.42

Summary

The total annual burden associated with the patient-provider dispute resolution process for uninsured (or self-pay) individuals and providers and facilities is 255,524 hours with an equivalent cost of $29,764,646, as shown in Table 48.[304] HHS invites comment on the assumptions and calculations made in this ICR.

TABLE 48—ANNUAL BURDEN AND COST RELATED TO PATIENT-PROVIDER DISPUTE RESOLUTION PROCESS FOR UNINSURED (SELF-PAY) INDIVIDUALS AND PROVIDERS AND FACILITIES

Estimated number of respondents	Estimated number of responses	Burden per response (hours)	Total annual burden (hours)	Total estimated cost
26,659	26,659	13.50	255,524	$29,764,646

9. ICRs Regarding Patient-Provider Dispute Resolution Entity Certification (45 CR 149.620)

An SDR entity contracted by HHS must be certified under standards and procedures set forth in 45 CFR 149.620(d). HHS estimates that there will be between 1 and 3 entities that HHS contracts with to be an SDR entity.

To be an SDR entity, the entity will need to establish the processes and complete the corresponding paperwork. HHS estimates that on average it will take a general and operations manager 5 hours and medical secretary and administrative assistant 15 minutes to satisfy the requirement. As shown in Table 49, this result in an equivalent cost burden of $1,554 in the first year.[305]

TABLE 49—ESTIMATED FIRST YEAR ONE-TIME COST ANNUAL BURDEN AND COST RELATED TO PATIENT-PROVIDER SDR ENTITY CERTIFICATION PROCESS COST RELATED TO PATIENT-PROVIDER DISPUTE RESOLUTION PROCESS

Estimated number of respondents	Estimated number of responses	Burden per response (hours)	Total annual burden (hours)	Total estimated cost
3	3	5.25	15.75	$1,873

HHS estimates that on average one-third of SDR entities (*i.e.,* one of the three contracted organizations) will need to be recertified or reapproved, through the contracting process, each year and that on average it will take a general and operations manager 2 hours and medical secretary and administrative assistant 15 minutes to satisfy the requirement. This results in an equivalent cost burden of $257.[306]

The total annual burden associated with the SDR entity certification is 16 hours with an equivalent cost of $1,873. In subsequent years, the total hour burden associated with the SDR entity certification or recertification is 2.25 hours with an equivalent cost of $257. HHS will assess whether the SDR entity's meets the certification standards as discussed in section VI.B.5. of this preamble as part of contracting per the contract period. HHS invites comment on the assumptions and calculations made in this ICR.

[304] The total estimated cost burden is the sum of $3,789,694 (the cost for uninsured or self-pay individuals and authorized representatives to write, prepare and send the initiation notice for the patient-provider dispute resolution to the Secretary of HHS, including resubmission costs) + $7,024,811 (the cost for SDR entities to attest whether a Conflict of Interest exists with the uninsured or self-pay individual, provider or facility) + $3,267,013 (the cost for uninsured or self-pay individuals and providers or facilities to furnish additional information to selected SDR entities) + $14,049,622 (the cost for the SDR entity to carry out the dispute outcome analysis for uninsured or self-pay individuals and providers and facilities) + 1,633,506 (the cost for the SDR entity to notify the parties of the SDR entity's determination) = $29,764,646. These costs represent 13.5 burden hours.

[305] The burden is estimated as follows: (3 SDR entities × 5 hours) + (3 SDR entities × 0.25 hours) = 15.75 hours. A labor rate of $101.32 is used for a general and operations manager and a labor rate of $46.07 is used for a medical secretary and administrative assistant. The labor rates are applied in the following calculation: (3 SDR entities × 5 hours × $101.32) + (3 SDR entities × 0.25 hours × $46.07) = $1,554.

[306] The burden is estimated as follows: (1 SDR entities × 2 hours) + (1 SDR entities × 0.25 hours) = 2.25 hours. A labor rate of $122.55 is used for a general and operations manager and a labor rate of $46.07 is used for medical secretary and administrative assistant. The labor rates are applied in the following calculation: (1 SDR entities × 2 hours × $122.55) + (1 SDR entities × 0.25 hours × $46.07) = $257.

TABLE 50—ANNUAL BURDEN AND COST RELATED TO SDR ENTITY RE-CERTIFICATION PROCESS

Year	Estimated number of respondents	Estimated number of responses	Burden per response (hours)	Total annual burden (hours)	Total estimated cost
2023	1	1	2.25	2.25	$257

10. Summary

The total hour burden in the first six months associated with the Federal IDR process is 3,400,460 hours with an equivalent cost burden of $366,082,073. The total annual hour burden associated with the Federal IDR process is 4,972,056 hours with an equivalent cost burden of $518,688,160.

The Departments assume that half of the burden associated with the required notices will be allocated to plans, issuers, and FEHB carriers and the other half of the burden will be allocated to providers, facilities, and providers of air ambulance services. The burden of the plans, issuers, and FEHB carriers will be allocated toward the hour burden of DOL, the Department of the Treasury, and OPM, and the burden of the providers will be allocated toward the hour burden of HHS. The burden of IDR entities will be fully allocated toward the cost burden.

The total annual hour burden in the first six months associated with the Federal IDR process associated with HHS requirements is estimated to be 3,327,917 hours with an equivalent cost burden of $358,970,847. The total annual hour burden is 4,826,970 hours with an equivalent cost burden of $504,465,709.

The total annual hour burden in the first six months associated with the Federal IDR process associated with DOL requirements is estimated to be estimated to be 32,974 hours with an equivalent cost of $3,232,375. The total annual hour burden is 65,948 hours with an equivalent cost burden of $6,464,751.

The total annual hour burden in the first six months associated with the Federal IDR process for the Department of the Treasury is estimated to be 32,974 hours with an equivalent cost of $3,232,375. The total annual hour burden is estimated to be 65,948 hours with an equivalent cost burden of $6,464,751.

The total annual hour burden in the first six months associated with the Federal IDR process for OPM is estimated to be 6,595 hours with an equivalent cost of $646,475. The total annual hour burden is estimated to be 13,190 hours with an equivalent cost burden of $1,292,950.

In terms of the cost burden, the total cost burden in the first six months associated with the Federal IDR process is $610,675. The first year associated with the Federal IDR process is $1,206,242. In subsequent years, the total cost burden associated with the Federal IDR process is $1,143,314. Thus, the 3-year average cost burden is $1,164,290.

The Departments classify the burden born by IDR entities and certified IDR entities as a cost burden. For certification, re-certification, and monthly reporting requirements, 45 percent of the burden will be allocated toward the cost burden of HHS, while DOL and the Department of the Treasury will each be allocated 25 percent of the burden, and OPM will be allocated 5 percent of the burden. As shown in Table 51, for HHS requirements, the total cost burden associated with the Federal IDR process in the first six months is $392,214. The total cost burden in the first year is estimated to be $784,429 and in subsequent years, the total cost burden associated with the Federal IDR process is estimated to be $735,318. Thus, the 3-year average cost burden associated with HHS requirements is $751,688.

As shown in Table 52, for DOL requirements, the total cost burden associated with the Federal IDR process in the first six months is $99,300. The total cost burden in the first year is estimated to be $191,734 and in subsequent years, the total cost burden associated with the Federal IDR process is estimated to be $185,452. Thus, the 3-year average cost burden associated with DOL requirements is $187,546.

As shown in Table 52, for the Department of the Treasury requirements, the total cost burden associated with the Federal IDR process in the first six months is $99,300. The total cost burden in the first year is estimated to be $191,734 and in subsequent years, the total cost burden associated with the Federal IDR process is estimated to be $185,452. Thus, the 3-year average cost burden associated with the Department of the Treasury requirements is $187,546.

As shown in Table 53, for OPM requirements, the total cost burden associated with the Federal IDR process in the first six months is $19,860. The total cost burden in the first year is estimated to $38,347 and in subsequent years, the total cost burden associated with the Federal IDR process is estimated to be $37,090. Thus, the 3-year average cost burden associated with OPM requirements is $37,509.

TABLE 51—HHS SUMMARY TABLE

Year	Estimated number of respondents	Estimated number of responses	Burden per response (hours)	Total annual burden (hours)	Total estimated labor cost	Total estimated cost
2022	4,059,610	4,103,368	1.1763434	4,826,970	$504,465,709	$784,429
2023	4,059,610	4,103,368	1.1763434	4,826,970	504,465,709	735,318
2024	4,059,610	4,103,368	1.1763434	4,826,970	504,465,709	735,318
3 Year Average	4,059,610	4,103,368	1.1763434	4,826,970	504,465,709	751,688

TABLE 52—DOL'S AND DEPARTMENT OF THE TREASURY'S SUMMARY TABLE

Year	Estimated number of respondents	Estimated number of responses	Burden per response (hours)	Total annual burden (hours)	Total estimated labor cost	Total estimated cost
2022	22,257	36,675	1.7981697	65,948	$6,464,751	$191,734

TABLE 52—DOL'S AND DEPARTMENT OF THE TREASURY'S SUMMARY TABLE—Continued

Year	Estimated number of respondents	Estimated number of responses	Burden per response (hours)	Total annual burden (hours)	Total estimated labor cost	Total estimated cost
2023	22,257	36,675	1.7981697	65,948	6,464,751	185,452
2024	22,257	36,675	1.7981697	65,948	6,464,751	185,452
3 Year Average	22,257	36,675	1.7981697	65,948	6,464,751	187,546

TABLE 53—OPM'S SUMMARY TABLE

Year	Estimated number of respondents	Estimated number of responses	Burden per response (hours)	Total annual burden (hours)	Total estimated labor cost	Total estimated cost
2022	22,257	5,986	2.2034535	13,190	$1,292,950	$38,347
2023	22,257	5,986	2.2034535	13,190	1,292,950	37,090
2024	22,257	5,986	2.2034535	13,190	1,292,950	37,090
3 Year Average	22,257	5,986	2.2034535	13,190	1,292,950	37,509

These paperwork burden estimates are summarized as follows:

Agency: Centers for Medicare & Medicaid Services, Department of Health and Human Services.

Type of Review: New collection.

Title: Surprise Medical Billing: Independent Dispute Resolution.

OMB Control Number: 0938–NEW.

Affected Public: Businesses or other for-profits; not-for-profit institutions.

Estimated Number of Respondents: 4,059,610.

Estimated Number of Annual Responses: 4,103,368.

Frequency of Response: Occasionally.

Estimated Total Annual Burden Hours: 4,826,970 (3,327,917 during the first six months).

Estimated Total Annual Burden Cost: $751,688 ($392,214 during the first six months).

Agency: Employee Benefits Security Administration, Department of Labor.

Type of Review: New collection.

Title: Surprise Medical Billing: Independent Dispute Resolution.

OMB Control Number: 1210–New.

Affected Public: Businesses or other for-profits; not-for-profit institutions.

Estimated Number of Respondents: 22,257.

Estimated Number of Annual Responses: 36,675.

Frequency of Response: Occasionally.

Estimated Total Annual Burden Hours: 65,948 (32,974 during the first six months).

Estimated Total Annual Burden Cost: $187,546 ($99,300 during the first six months).

Agency: Internal Revenue Service, Department of the Treasury.

Type of Review: New collection.

Title: Surprise Medical Billing: Independent Dispute Resolution.

OMB Control Number: 1545–New.

Affected Public: Businesses or other for-profits; not-for-profit institutions.

Estimated Number of Respondents: 22,257

Estimated Number of Annual Responses: 36,675.

Frequency of Response: Occasionally.

Estimated Total Annual Burden Hours: 65,948 (32,974 during the first six months).

Estimated Total Annual Burden Cost: $187,546 ($99,300 during the first six months).

Agency: Office of Personnel Management.

Type of Review: New collection.

Title: Surprise Medical Billing: Independent Dispute Resolution.

OMB Control Number: NEW.

Affected Public: Businesses or other for-profits; not-for-profit institutions.

Estimated Number of Respondents: 22,257.

Estimated Number of Annual Responses: 5,986.

Frequency of Response: Occasionally.

Estimated Total Annual Burden Hours: 13,190 (6,595 during the first six months).

Estimated Total Annual Burden Cost: $37,509 ($19,860 during the first six months).

11. ICRs Regarding Internal Claims and Appeals and External Review Requirements for Non- Grandfathered Plans and Grandfathered Plans—Applicability (26 CFR 54.9815–2719, 29 CFR 2590.715–2719, and 45 CFR 147.136)

The No Surprises Act extends the protections related to external reviews to grandfathered plans. Grandfathered plans must comply either with a state external review process or a Federal review process. The disclosure requirements of the Federal external review process require: (1) A preliminary review by plans of requests for external review; (2) IROs to notify claimants of eligibility and acceptance for external review; (3) the plan or issuer to provide IROs with documentation and other information considered in making adverse benefit determination; (4) the IRO to forward to the plan or issuer any information submitted by the claimant; (5) plans to notify the claimant and IRO if it reverses its decision; (6) the IRO to provide notice of the final external review decision to the claimant and plan; and (7) the IRO to maintain records for six years.

The Departments already have an existing information collection on the claim, appeals, and external review requirements for non-grandfathered plans (1210–0144). Due to these interim final rules, the Departments have added the burden associated with the external review requirements for grandfathered plans and non-grandfathered plans in the information collection. The burden associated with the additional standards that non-grandfathered and grandfathered ERISA-covered plans must meet is shared equally between the Department of Labor and the Department of the Treasury. The burden associated with the additional standards that non-grandfathered and grandfathered non-Federal governmental plans and individual market policies must meet is assigned to the Department of Health and Human Services.

The Departments estimate that there are approximately 84.4 million participants in self-insured ERISA-covered plans. Prior to the interim final rules, the Departments estimate that there are approximately 8.1 million participants in ERISA-covered plans in

the states which have no external review laws or whose laws do not meet the Federal minimum requirements.[307] These estimates lead to a total of 92.5 million participants. Among the 92.5 million participants, 80.5 million participants in non-grandfathered plans and 12 million participants in grandfathered plans will be required to be covered by the external review requirement.

The Departments estimate that there are approximately 1.3 external reviews for every 10,000 participants [308] and that there will be approximately 12,275 external reviews annually. Experience from North Carolina indicates that about 75 percent of requests for external reviews are actually eligible to proceed to an external review,[309] therefore it is expected that there will be about 16,261 (12,275/0.7549) requests for external review. In addition, a 2 percent increase in the number of out-of-networks claims was incorporated in the estimate to capture the increase in burden on non-grandfathered plans resulting from the surprise billing and cost sharing protections of the external review.

As shown in Table 54, the hour burden related to the preliminary review by grandfathered and non-grandfathered plans subject to ERISA of the request for external review is estimated to be 4,0655 hours (16,261 * 0.25 hours) with an equivalent cost of $373,303 (4,065 hours * $91.83). The Departments assume that plans have a human resources specialist with a labor rate of $91.83. The human resource specialist will spend an average of 15 minutes for each of the requests, for a plan to make an eligibility determination. Plans will already have conducted internal reviews for eligible claimants; therefore, the required information for plans to make this determination should be readily available. Additionally, plans will incur material costs of $0.05 for paper and printing and $0.55 for postage for each request for external review, resulting in a cost of $9,756 (16,261 * $0.60).

TABLE 54—ANNUAL BURDEN AND COST FOR PLANS TO CONDUCT A PRELIMINARY REVIEW OF THE REQUEST FOR THE EXTERNAL REVIEW STARTING IN 2022

Year	Estimated number of responses	Total annual burden (hours)	Total estimated labor cost	Other costs	Total estimated cost
2022	16,261	4,065	$373,303	$9,756	$383,060

Once an eligibility determination is made, plans must provide the IRO with all documentation and other information considered in making an adverse benefit determination. The Departments assume that plans have clerical staff with a labor rate of $55.23. The clerical staff will spend an average of 5 minutes for each of the requests for a plan to send documentation to the IRO. As shown in Table 55, for the 12,275 verified requests for external review the hour burden for grandfathered and non-grandfathered plans is estimated as 1,023 hours (12,275 * 5 minutes), with an equivalent cost of $56,494 (1,023 * $55.23). Additionally, plans will incur material costs of $0.05 for each sheet of paper. The Departments assume that each set of documentation will be 20 pages. Plans will also incur a cost of $0.55 for postage for each set of documentation, resulting in a cost burden of $19,026 ($12,275 \times \$0.05 \times 20 + 12,275 * \$0.55$). The Departments estimate that this will cost, on average, $1.55 per claimant.

TABLE 55—ANNUAL BURDEN AND COST FOR PLANS TO PROVIDE THE IRO WITH DOCUMENTATION STARTING IN 2022

Year	Estimated number of responses	Total annual burden (hours)	Total estimated labor cost	Other costs	Total estimated cost
2022	12,275	1,023	$56,494	$19,026	$75,519

IROs must also send each eligible claimant a notice of eligibility and acceptance. The Departments assume that the IRO has clerical staff with a labor rate of $55.23 that will spend, on average 5 minutes per claimant preparing the notice, and that IROs incur an average cost of $0.60 to print and mail the notice. As shown in Table 56, for the 12,275 verified requests for external review, the cost burden for the clerical worker to send the notice of eligibility and acceptance is estimated to be $56,493 ($12,275 \times 5$ minutes $\times$ $55.23). Additionally, IROs will incur material costs of $0.05 for each sheet of paper. The Departments assume that each notice of eligibility and acceptance will be 1 page. Plans will also incur a cost of $0.55 for postage for each set of documentation, resulting in a cost of $7,365 ($12,275 \times \$0.05 + 12,275 * \$0.55$). Thus, the total cost burden relating to the notice of eligibility and acceptance is $63,858.

[307] These states are Alabama, Florida, Georgia, Pennsylvania, Texas, and Wisconsin. See Affordable Care Act: Working with States to Protect Consumers, available at *https://www.cms.gov/CCIIO/Resources/Files/external_appeals.html.*

[308] AHIP Center for Policy and Research, ''An Update on State External Review Programs, 2006,'' July 2008.

[309] North Carolina Department of Insurance. ''Health Insurance Smart NC: Annual Report on External Review Activity 2013.'' *https://digital.ncdcr.gov/digital/collection/p249901coll22/id/730531.*

TABLE 56—ANNUAL BURDEN AND COST FOR IROS TO SEND NOTICES OF ELIGIBILITY AND ACCEPTANCE STARTING IN 2022

Year	Estimated number of responses	Total annual burden (hours)	Total estimated labor cost	Other costs	Total estimated cost
2022	12,275	0	$0	$63,858	$63,858

IROs are required to send to plans all documents that claimants submit. The Departments do not know what fraction of claimants will submit additional documentation, but for purposes of this burden analysis assume that half of claimants (6,137) do. The Departments assume that the IRO has clerical staff with a labor rate of $55.23 that will spend, on average 5 minutes per claimant preparing and forwarding the required documents, and that IROs incur an average cost of $1.05 to print and mail the documents. As shown in Table 57, for the 6,137 verified requests for external review, the cost burden for the clerical worker to send the claimants' documentation to the plans is estimated to be $28,247 (6,137 × 5 minutes × $55.23). Additionally, IROs will incur material costs of $0.05 for each sheet of paper. The Departments assume that such documentation will be 10 pages. Plans will also incur a cost of $0.55 for postage for each set of documentation, resulting in a cost of $6,444 (6,137 × $0.05 × 10 + 12,275 * $0.55). Thus, the total cost burden relating to preparing and forwarding the required documents is $34,691.

TABLE 57—ANNUAL BURDEN AND COST FOR IROS TO SEND PLANS ALL DOCUMENTS THAT CLAIMANTS SUBMIT STARTING IN 2022

Year	Estimated number of responses	Total annual burden (hours)	Total estimated labor cost	Other costs	Total estimated cost
2022	6,137	0	$0	$34,691	$34,691

IROs are required to provide the notice of the final external review decision to the claimant and plan. The Departments estimate that preparing and sending the notices for each of the 12,275 external reviews will take IRO clerical staff, with a labor rate of $55.23, on average 5 minutes per claimant, and that IROs will incur an average cost of $1.05 to mail the documents. As shown in Table 58, for the 12,275 verified requests for external review, the cost burden for the clerical worker to send the notice is estimated to be $56,494 (12,275 × 5 minutes × $55.23). Additionally, IROs will incur material costs of $0.05 for each sheet of paper. The Departments assume that such documentation will be 10 pages. Plans will also incur a cost of $0.55 for postage for each set of documentation, resulting in a cost of $12,888 (12,275 × $0.05 × 10 + 12,275 * $0.55). Thus, the total cost burden relating to notifying the claimant and plan of the final external review decision is $69,382.

TABLE 58—ANNUAL BURDEN AND COST FOR IROS TO NOTIFY THE CLAIMANT AND PLAN OF THE RESULT OF THE FINAL EXTERNAL REVIEW DECISION STARTING IN 2022

Year	Estimated number of responses	Total annual burden (hours)	Total estimated labor cost	Other costs	Total estimated cost
2022	12,275	0	$0	$69,382	$69,382

IROs also are required to maintain records of all claims and notices associated with the external review process for six years. The Departments are of the view that these documents would be retained as a customary part of business, but estimate that clerical staff will spend on average an additional 5 minutes per claimant ensuring all files are complete. As shown in Table 59, for the 12,275 verified requests for external review, the cost burden for the clerical worker to maintain records is estimated to be $56,494 (12,275 × 5 minutes × $55.23).

TABLE 59—ANNUAL BURDEN AND COST FOR IROS TO MAINTAIN RECORD OF ALL CLAIMS AND NOTICES STARTING IN 2022

Year	Estimated number of responses	Total annual burden (hours)	Total estimated labor cost	Other costs	Total estimated cost
2022	12,275	0	$0	$56,494	$56,494

The Departments estimate that the Federal external review process will result in an hour burden of 5,088 hours with an equivalent cost of $429,797 related to external reviews. The cost burden of approximately $253,207 annually. The cost burden results from the cost associated with preparing and

mailing required notices and documents.

The Departments are not able to estimate the number of reversals and the associated notices to claimants and IROs that plans would send due to reversing prior decisions, but the Departments are of the view that the number would be small.

The existing information collection had an estimated hour burden of 1,394 hours with an equivalent cost of $97,616 and an estimated cost burden by $3,002,150.

In summary, the total burden associated the information collection for DOL and the Department of the Treasury, including the existing collection, is approximately 6,482 hours at an equivalent cost of $527,413 annually. The cost burden is approximately $3,255,357 annually. Because the burden is shared equally between the DOL and the Department of the Treasury, the DOL's share is 3,241 hours at an equivalent cost of $263,706 annually. The DOL's share of the cost burden is $1,627,679 annually. The summary of burden for DOL and the Department of the Treasury's information collection has also been provided below.

TABLE 60—DOL AND DEPARTMENT OF THE TREASURY'S SUMMARY TABLE

Year	Estimated number of responses	Total annual burden (hours)	Total estimated labor cost	Other costs	Total estimated cost
2022	381,826	3,241	$263,706	$1,627,679	$1,891,385
2023	381,826	3,241	263,706	1,627,679	1,891,385
2024	381,826	3,241	263,706	1,627,679	1,891,385
3 Year Average	381,826	3,241	263,706	1,627,679	1,891,385

HHS estimates that there are approximately 13.5 million individual market enrollees and 19.3 million non-Federal governmental plans enrollees.[310] These estimates lead to a total of 32.8 million total enrollees in individual market and non-Federal Government plans. Among the 32.8 million participants, 2.6 million are in grandfathered plans and 30.1 million are in non-grandfathered plans. HHS also added a two percent increase in the number of out-of-networks claims to capture the increase in burden on non-grandfathered plans resulting from the surprise billing and cost sharing protections of the external review resulting in an adjusted total of 30.7 million for non-grandfathered plans and an adjusted total of 33.3 million for all individual market and non-Federal Government plans.

HHS also estimates there are an estimated 1.3 external reviews for every 10,000 participants and that there will be approximately 4,337 total external reviews annually for individual market and non-Federal Government plans. This amount includes 3,994 reviews for non-grandfathered plans and 343 for grandfathered plans. Experience from North Carolina indicates that about 75 percent of requests for external reviews are actually eligible to proceed to an external review, therefore it is expected that there will be about 5,783 requests for external review. This amount includes 5,326 requests for non-grandfathered plans and 457 requests for grandfathered plans.

HHS estimated the burden for the disclosure requirements of the Federal external review process to align with the methodologies used to calculate the amounts in Tables 54 through 59. As shown in Table 61, HHS estimates that the disclosure requirements will require 3,066 burden hours that result in $222,224 in estimated labor costs and $19,625 in other costs for printing and mailing. The total estimated updated burden for Federal external review to individual market and non-Federal Government plans is $241,850. This amount includes $222,729 in costs for non-grandfathered plans and $19,121 for grandfathered plans. The existing collection for HHS for Federal external review is $128,876.

TABLE 61—HHS' SUMMARY TABLE NEW COLLECTION BURDEN FOR FEDERAL EXTERNAL REVIEW

Year	Estimated number of responses	Total annual burden (hours)	Total estimated labor cost	Other costs	Total estimated cost
2022	5,783	3,066	$222,224	$19,625	$241,850
2023	5,783	3,066	222,224	19,625	241,850
2024	5,783	3,066	222,224	19,625	241,850
3 Year Average	5,783	3,066	222,224	19,625	241,850

Summary of Burden

Type of Review: Revised Collection.

Agency: DOL–EBSA.

Title: Affordable Care Act Internal Claims and Appeals and External Review Procedures for Plans.

OMB Numbers: 1210–0144.

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

Estimated Number of Respondents: 2,524,241.

Estimated Number of Annual Responses: 381,826.

Frequency of Response: Occasionally.

Estimated Total Annual Burden Hours: 3,241.

Estimated Total Annual Burden Cost: $1,627,679.

Type of Review: Revised Collection.

Agency: Treasury—IRS.

Title: Affordable Care Act Internal Claims and Appeals and External Review Procedures for Plans.

OMB Numbers: 1545–2182.

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

Estimated Number of Respondents: 2,524,241.

[310] Individual market data is based on data from MLR annual report for the 2019 MLR reporting year, available at *https://www.cms.gov/CCIIO/Resources/Data-Resources/mlr.* Non-federal government plans data from Agency for Healthcare Research and Quality, Center for Financing, Access and Cost Trends. 2019 Medical Expenditure Panel Survey-Insurance Component.

Estimated Number of Annual Responses: 381,826.
Frequency of Response: Occasionally.
Estimated Total Annual Burden Hours: 3,241.
Estimated Total Annual Burden Cost: $1,627,679.
Type of Review: Revised Collection.
Agency: Centers for Medicare & Medicaid Services, Department of Health and Human Services.
Title: Affordable Care Act Internal Claims and Appeals and External Review Procedures for Plans.
OMB Numbers: 0938–1099.
Affected Public: Businesses or other for-profits, Not-for-profit institutions.
Estimated Number of Respondents: 5,783.
Estimated Number of Annual Responses: 5,783.
Frequency of Response: Occasionally.
Estimated Total Annual Burden Hours: 3,066.
Estimated Total Annual Burden Cost: $241,850.

D. Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) (RFA) imposes certain requirements with respect to Federal rules that are (1) required to be published as a notice of proposed rulemaking subject to the notice and comment requirements of the Administrative Procedure Act (5 U.S.C. 553(b)) and (2) likely to have a significant economic impact on a substantial number of small entities. The RFA generally defines a ''small entity'' as (1) a proprietary firm meeting the size standards of the Small Business Administration (SBA), (2) a not-for-profit organization that is not dominant in its field, or (3) a small government jurisdiction with a population of less than 50,000. States and individuals are not included in the definition of ''small entity.'' The Departments use 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.

These interim final rules are exempt from the RFA because the Departments were not required to publish a notice of proposed rulemaking. Therefore, the RFA does not apply and the Departments are not required to either certify that the interim final rules will not have a significant economic impact on a substantial number of small entities or conduct a regulatory flexibility analysis. Nevertheless, the Departments carefully considered the likely impact of the interim final rules on small entities in connection with its assessment of the interim final rules' cost and benefits under Executive Order 12866.

Table 58 summarizes the estimated costs on small issuers, physicians, and providers of air ambulance services. The original analysis was based on a cost per IDR payment determination basis. To break down the cost to a per-entity basis, the Departments assume that the distribution of per-entity costs is proportional to annual receipts. The affected entities are estimated based on the SBA's size standards. The size standards applied for issuers is North American Industry Classification System (NAICS) 524114, for which a business with less than $41.5 million in receipts is considered to be small. The size standard applied for physicians is NAICS 62111, for which a business with less than $12.0 million in receipts is considered to be small.[311]

TABLE 62—SUMMARY OF ESTIMATES COSTS ON SMALL ENTITIES

Affected entity	Affected small entities [312]	Aggregate annual cost for small entities [313]	Annual cost per entity [314]
Issuer	132	$714,065	$5,410
Physicians [315]	61,890	136,976,819	2,213

The Departments do not have the same level of data used in the table above the air ambulance sub-sector and are of the view that this sub-sector is likely to differ from the ambulance services industry as a whole. In 2020, the total revenue of providers of air ambulance services is estimated to be $4.2 billion with 1,073 businesses in the industry.[316] This results in an industry average of $3.9 million per business. Accordingly, the Departments are of the view that most providers of air ambulance services are likely to be small entities.

Additionally, this analysis also excludes certified IDR entities and their respective costs, as the Departments do not have information on how many certified IDR entities are likely to be small entities.

Consistent with the policy of the RFA, the Departments seek comment regarding the impact of these interim final rules on small entities.

E. Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) requires each Federal agency to prepare a written statement assessing the effects of any Federal mandate in a proposed agency rule, or a finalization of such a proposal, that may result in an expenditure of $100 million or more (adjusted annually

[311] U.S. Small Business Administration. ''Table of Size Standards.'' (August 2019). *https://www.sba.gov/document/support--table-size-standards.*

[312] For issuers, it is assumed that the size distribution across establishments is the same for issuers as their respective industry. For physicians, it is assumed that the size distribution across employment is the same for physicians as the respective industry. For more information, refer to the Affected Entities section in the Regulatory Impact Analysis.

[313] To estimate the proportion of the total costs that would fall onto small entities, the Departments assume that the proportion of costs is proportional to the industry receipts. The Departments are of the view that this assumption is reasonable, as the number of IDR payment determinations an entity is involved in is likely to be proportional to the amount of business in which the entity is involved. Applying data from the Census bureau of receipts by size for each industry, the Departments estimate that small issuers will incur 0.2 percent of the total costs incurred by all issuers, that physicians in small offices will incur 36.8 percent of total costs incurred by all physicians, and small providers of air ambulance services will incur 31.0 percent of total costs incurred by all providers of air ambulance services. (*See* Census Bureau. ''2017 SUSB Annual Data Tables by Establishment Industry, Data by Enterprise Receipt Size.'' (May 2021). *https://www.census.gov/data/tables/2017/econ/susb/2017-susb-annual.html.*)

[314] The Annual Cost per Entity is calculated by dividing the estimated Aggregate Annual Cost for Small Entities by the Estimated Affected Small Entities.

[315] The costs for physicians refers to the cost associated with each physician. The Departments estimate that 140,270 physicians, on average, bill on an out-of-network basis and will be affected by these interim final rules, but the Departments do not have data on how many of the affected physicians are employed in small offices. This analysis is based on the number physicians affected, not the number of physician offices.

[316] IBIS World. ''Air Ambulance Service Industry in the US—Market Research Report.'' (December 2020). *https://www.ibisworld.com/united-states/market-research-reports/air-ambulance-services-industry/.*

for inflation with the base year 1995) in any one year by state, local, and tribal governments, in the aggregate, or by the private sector.[317] However, Section 202 of UMRA does not apply to interim final rules or non-notice rules issued under the 'good cause' exemption in 5 U.S.C. 553(b)(B).[318] For purposes of the UMRA, this rule does not include any Federal mandate that the Departments expect to result in such expenditures by state, local, or tribal governments.

F. Federalism Statement

Executive Order 13132 outlines fundamental principles of Federalism and requires Federal agencies to adhere to specific criteria when 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 Federalism implications must consult with state and local officials and describe the extent of their consultation and the nature of the concerns of state and local officials in the preamble to the final rule.

In the Departments' view, these interim final rules have Federalism implications because they have direct effects on the states, the relationship between the national government and the states, or the distribution of power and responsibilities among various levels of government. State and local government health plans may be subject to the Federal IDR process, where a specified state law does not apply. Additionally, the No Surprises Act authorizes states to enforce the new requirements, 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 otherwise not enforcing, or HHS has made a determination that a state has failed to substantially enforce the requirements. However, in the Departments' view, the Federalism implications of these interim final rules are substantially mitigated because the Departments expect that some states will have their own process for determining the total amount payable under such a plan or coverage for emergency services and to out-of-network providers at in-network facilities. Where a state has such a specified state law, the state law, rather than the Federal IDR process, will apply. The Departments anticipate that some states with their own IDR process may want to change their laws or adopt new laws in response to these interim final rules. The Departments anticipate that these states will incur a small incremental cost when making changes to their laws.

In general, ERISA section 514 supersedes state laws to the extent that they relate to any covered employee benefit plan, including covered group health plans, and preserves state laws that regulate insurance, banking, or securities. While ERISA prohibits states from regulating a plan as an insurance or investment company or bank, the preemption provisions of ERISA section 731 and PHS Act section 2724 (implemented in 29 CFR 2590.731(a) and 45 CFR 146.143(a)) apply so that requirements of Part 7 of ERISA and title XXVII of the PHS Act (including those of the Affordable Care Act) are not to be ''construed to supersede any provision of state law which establishes, implements, or continues in effect any standard or requirement solely relating to health insurance issuers in connection with 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 HIPAA indicates that this is intended to be the ''narrowest'' preemption of state laws.[319] Additionally, the No Surprises Act requires that when a state law determines the total amount payable under such a plan, coverage, or issuer for emergency services or to out-of-network providers at in-network facilities, such state law will apply, rather than the Federal IDR process specified in these regulations.

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 as detailed in the July 2021 interim final rule.

While developing these interim final rules, the Departments and OPM 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 and OPM complied with the requirements of Executive Order 13132. The Departments welcome input from affected states regarding this assessment.

G. Congressional Review Act

These interim final rules are determined to be major and 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.

Laurie Bodenheimer,

Associate Director Healthcare and Insurance Office of Personnel Management

Douglas W. O'Donnell,

Deputy Commissioner for Services and Enforcement, Internal Revenue Service.

Lily L. Batchelder,

Assistant Secretary of the Treasury (Tax Policy).

Ali Khawar,

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

Xavier Becerra,

Secretary, Department of Health and Human Services.

Office of Personnel Management

5 CFR Chapter I

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

[317] 2 U.S.C. 1501 *et seq.* (1995).

[318] See OMB, Memorandum for the Heads of Executive Departments and Agencies, M–95–09, ''Guidance for Implementing Title II of S.1,'' 1995, available at *https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/memoranda/1995-1998/m95-09.pdf*.

[319] *See* House Conf. Rep. No. 104–736, at 205, reprinted in 1996 U.S. Code Cong. & Admin. News 2018.

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. Amend § 890.114 by revising paragraph (a) and adding paragraph (d) to read as follows:

§ 890.114 Surprise billing.

(a) A carrier must comply with requirements described in 26 CFR 54.9816–3T through 54.9816–8T, 54.9817–1T, 54.9817–2T and 54.9822–1T; 29 CFR 2590.716–3 through 2590.716–8, 2590.717–1, 2590.717–2 and 2590.722; and 45 CFR 149.30, 149.110 through 149.140, 149.310, 149.510, and 149.520, 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.

* * * * *

(d)(1) In addition to notification to the Department per 26 CFR 54.9816–8T(b)(2)(iii), 29 CFR 2590.716–8(b)(2)(iii), and 45 CFR 149.510(b)(2)(iii), a carrier must notify the Director of its intent to initiate the Federal IDR process, or its receipt of written notice that a provider, facility, or provider of air ambulance services has initiated the Federal IDR process, upon sending or receiving such notice.

(2) The Director will coordinate with the Departments in resolving matters under 26 CFR 54.9816–8T(c)(4)(vi)(A)(*1*), 29 CFR 2590.716–8(c)(4)(vi)(A)(*1*), or 45 CFR 149.510(c)(4)(vi)(A)(*1*) where fraud or misrepresentation are presented, and matters involving 26 CFR 54.9816–8T(c)(4)(vii)(A)(*2*), 29 CFR 2590.716–8(c)(4)(vii)(A)(*2*), and 45 CFR 149.510(c)(4)(vii)(A)(*2*). The Director will coordinate with the Departments in oversight of reports submitted by certified IDR entities with respect to carriers pursuant to 26 CFR 54.9816–8T(f), 29 CFR 2590.716–8(f), or 45 CFR 149.510(f).

Department of the Treasury

Internal Revenue Service

26 CFR Chapter I

Accordingly, 26 CFR part 54 is amended as follows:

PART 54—PENSION EXCISE TAXES

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

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

* * * * *

■ 4. Section 54.9815–2719T is added to read as follows:

§ 54.9815–2719T Internal claims and appeals and external review processes (temporary).

(a) *Scope and definitions*—(1) *Scope*—(i) *In general.* This section sets forth requirements with respect to internal claims and appeals and external review processes for group health plans and health insurance issuers. Paragraph (b) of this section provides requirements for internal claims and appeals processes. Paragraph (c) of this section sets forth rules governing the applicability of State external review processes. Paragraph (d) of this section sets forth a Federal external review process for plans and issuers not subject to an applicable State external review process. Paragraph (e) of this section prescribes requirements for ensuring that notices required to be provided under this section are provided in a culturally and linguistically appropriate manner. Paragraph (f) of this section describes the authority of the Secretary to deem certain external review processes in existence on March 23, 2010, as in compliance with paragraph (c) or (d) of this section.

(ii) *Application to grandfathered health plans and health insurance coverage.* The provisions of this section generally do not apply to coverage offered by health insurance issuers and group health plans that are grandfathered health plans, as defined under § 54.9815–1251. However, the external review process requirements under paragraphs (c) and (d) of this section, and related notice requirements under paragraph (e) of this section, apply to grandfathered health plans or coverage with respect to adverse benefit determinations involving items and services within the scope of the requirements for out-of-network emergency services, nonemergency services performed by nonparticipating providers at participating facilities, and air ambulance services furnished by nonparticipating providers of air ambulance services under sections 9816 and 9817 and §§ 54.9816–4T through 54.9816–5T and 54.9817–1T.

(2) *Definitions.* For purposes of this section, the following definitions apply—

(i) *Adverse benefit determination.* An *adverse benefit determination* means an adverse benefit determination as defined in 29 CFR 2560.503–1, as well as any rescission of coverage, as described in § 54.9815–2712(a)(2) (whether or not, in connection with the rescission, there is an adverse effect on any particular benefit at that time).

(ii) *Appeal (or internal appeal).* An *appeal* or *internal appeal* means review by a plan or issuer of an adverse benefit determination, as required in paragraph (b) of this section.

(iii) *Claimant. Claimant* means an individual who makes a claim under this section. For purposes of this section, references to claimant include a claimant's authorized representative.

(iv) *External review. External review* means a review of an adverse benefit determination (including a final internal adverse benefit determination) conducted pursuant to an applicable State external review process described in paragraph (c) of this section or the Federal external review process of paragraph (d) of this section.

(v) *Final internal adverse benefit determination.* A *final internal adverse benefit determination* means an adverse benefit determination that has been upheld by a plan or issuer at the completion of the internal appeals process applicable under paragraph (b) of this section (or an adverse benefit determination with respect to which the internal appeals process has been exhausted under the deemed exhaustion rules of paragraph (b)(2)(ii)(F) of this section).

(vi) *Final external review decision.* A *final external review decision* means a determination by an independent review organization at the conclusion of an external review.

(vii) *Independent review organization (or IRO).* An *independent review organization* (or *IRO*) means an entity that conducts independent external reviews of adverse benefit determinations and final internal adverse benefit determinations pursuant to paragraph (c) or (d) of this section.

(viii) *NAIC Uniform Model Act.* The *NAIC Uniform Model Act* means the Uniform Health Carrier External Review Model Act promulgated by the National Association of Insurance Commissioners in place on July 23, 2010.

(b) *Internal claims and appeals process*—(1) *In general.* A group health plan and a health insurance issuer offering group health insurance

coverage must implement an effective internal claims and appeals process, as described in this paragraph (b).

(2) *Requirements for group health plans and group health insurance issuers.* A group health plan and a health insurance issuer offering group health insurance coverage must comply with all the requirements of this paragraph (b)(2). In the case of health insurance coverage offered in connection with a group health plan, if either the plan or the issuer complies with the internal claims and appeals process of this paragraph (b)(2), then the obligation to comply with this paragraph (b)(2) is satisfied for both the plan and the issuer with respect to the health insurance coverage.

(i) *Minimum internal claims and appeals standards.* A group health plan and a health insurance issuer offering group health insurance coverage must comply with all the requirements applicable to group health plans under 29 CFR 2560.503–1, except to the extent those requirements are modified by paragraph (b)(2)(ii) of this section. Accordingly, under this paragraph (b), with respect to health insurance coverage offered in connection with a group health plan, the group health insurance issuer is subject to the requirements in 29 CFR 2560.503–1 to the same extent as the group health plan.

(ii) *Additional standards.* In addition to the requirements in paragraph (b)(2)(i) of this section, the internal claims and appeals processes of a group health plan and a health insurance issuer offering group health insurance coverage must meet the requirements of this paragraph (b)(2)(ii).

(A) *Clarification of meaning of adverse benefit determination.* For purposes of this paragraph (b)(2), an ''adverse benefit determination'' includes an adverse benefit determination as defined in paragraph (a)(2)(i) of this section. Accordingly, in complying with 29 CFR 2560.503–1, as well as the other provisions of this paragraph (b)(2), a plan or issuer must treat a rescission of coverage (whether or not the rescission has an adverse effect on any particular benefit at that time) as an adverse benefit determination. (Rescissions of coverage are subject to the requirements of § 54.9815–2712.)

(B) *Expedited notification of benefit determinations involving urgent care.* The requirements of 29 CFR 2560.503–1(f)(2)(i) (which generally provide, among other things, in the case of urgent care claims for notification of the plan's benefit determination (whether adverse or not) as soon as possible, taking into account the medical exigencies, but not later than 72 hours after the receipt of the claim) continue to apply to the plan and issuer. For purposes of this paragraph (b)(2)(ii)(B), a claim involving urgent care has the meaning given in 29 CFR 2560.503–1(m)(1), as determined by the attending provider, and the plan or issuer shall defer to such determination of the attending provider.

(C) *Full and fair review.* A plan and issuer must allow a claimant to review the claim file and to present evidence and testimony as part of the internal claims and appeals process. Specifically, in addition to complying with the requirements of 29 CFR 2560.503–1(h)(2)—

(*1*) The plan or issuer must provide the claimant, free of charge, with any new or additional evidence considered, relied upon, or generated by the plan or issuer (or at the direction of the plan or issuer) in connection with the claim; such evidence must be provided as soon as possible and sufficiently in advance of the date on which the notice of final internal adverse benefit determination is required to be provided under 29 CFR 2560.503–1(i) to give the claimant a reasonable opportunity to respond prior to that date; and

(*2*) Before the plan or issuer can issue a final internal adverse benefit determination based on a new or additional rationale, the claimant must be provided, free of charge, with the rationale; the rationale must be provided as soon as possible and sufficiently in advance of the date on which the notice of final internal adverse benefit determination is required to be provided under 29 CFR 2560.503–1(i) to give the claimant a reasonable opportunity to respond prior to that date. Notwithstanding the rules of 29 CFR 2560.503–1(i), if the new or additional evidence is received so late that it would be impossible to provide it to the claimant in time for the claimant to have a reasonable opportunity to respond, the period for providing a notice of final internal adverse benefit determination is tolled until such time as the claimant has a reasonable opportunity to respond. After the claimant responds, or has a reasonable opportunity to respond but fails to do so, the plan administrator shall notify the claimant of the plan's benefit determination as soon as a plan acting in a reasonable and prompt fashion can provide the notice, taking into account the medical exigencies.

(D) *Avoiding conflicts of interest.* In addition to the requirements of 29 CFR 2560.503–1(b) and (h) regarding full and fair review, the plan and issuer must ensure that all claims and appeals are adjudicated in a manner designed to ensure the independence and impartiality of the persons involved in making the decision. Accordingly, decisions regarding hiring, compensation, termination, promotion, or other similar matters with respect to any individual (such as a claims adjudicator or medical expert) must not be made based upon the likelihood that the individual will support the denial of benefits.

(E) *Notice.* A plan and issuer must provide notice to individuals, in a culturally and linguistically appropriate manner (as described in paragraph (e) of this section) that complies with the requirements of 29 CFR 2560.503–1(g) and (j). The plan and issuer must also comply with the additional requirements of this paragraph (b)(2)(ii)(E).

(*1*) The plan and issuer must ensure that any notice of adverse benefit determination or final internal adverse benefit determination includes information sufficient to identify the claim involved (including the date of service, the health care provider, the claim amount (if applicable), and a statement describing the availability, upon request, of the diagnosis code and its corresponding meaning, and the treatment code and its corresponding meaning).

(*2*) The plan and issuer must provide to participants and beneficiaries, as soon as practicable, upon request, the diagnosis code and its corresponding meaning, and the treatment code and its corresponding meaning, associated with any adverse benefit determination or final internal adverse benefit determination. The plan or issuer must not consider a request for such diagnosis and treatment information, in itself, to be a request for an internal appeal under this paragraph (b) or an external review under paragraphs (c) and (d) of this section.

(*3*) The plan and issuer must ensure that the reason or reasons for the adverse benefit determination or final internal adverse benefit determination includes the denial code and its corresponding meaning, as well as a description of the plan's or issuer's standard, if any, that was used in denying the claim. In the case of a notice of final internal adverse benefit determination, this description must include a discussion of the decision.

(*4*) The plan and issuer must provide a description of available internal appeals and external review processes, including information regarding how to initiate an appeal.

(*5*) The plan and issuer must disclose the availability of, and contact

information for, any applicable office of health insurance consumer assistance or ombudsman established under PHS Act section 2793 to assist individuals with the internal claims and appeals and external review processes.

(F) *Deemed exhaustion of internal claims and appeals processes.* (*1*) In the case of a plan or issuer that fails to strictly adhere to all the requirements of this paragraph (b)(2) with respect to a claim, the claimant is deemed to have exhausted the internal claims and appeals process of this paragraph (b), except as provided in paragraph (b)(2)(ii)(F)(*2*) of this section. Accordingly the claimant may initiate an external review under paragraph (c) or (d) of this section, as applicable. The claimant is also entitled to pursue any available remedies under section 502(a) of ERISA or under State law, as applicable, on the basis that the plan or issuer has failed to provide a reasonable internal claims and appeals process that would yield a decision on the merits of the claim. If a claimant chooses to pursue remedies under section 502(a) of ERISA under such circumstances, the claim or appeal is deemed denied on review without the exercise of discretion by an appropriate fiduciary.

(*2*) Notwithstanding paragraph (b)(2)(ii)(F)(*1*) of this section, the internal claims and appeals process of this paragraph (b) will not be deemed exhausted based on de minimis violations that do not cause, and are not likely to cause, prejudice or harm to the claimant so long as the plan or issuer demonstrates that the violation was for good cause or due to matters beyond the control of the plan or issuer and that the violation occurred in the context of an ongoing, good faith exchange of information between the plan and the claimant. This exception is not available if the violation is part of a pattern or practice of violations by the plan or issuer. The claimant may request a written explanation of the violation from the plan or issuer, and the plan or issuer must provide such explanation within 10 days, including a specific description of its bases, if any, for asserting that the violation should not cause the internal claims and appeals process of this paragraph (b) to be deemed exhausted. If an external reviewer or a court rejects the claimant's request for immediate review under paragraph (b)(2)(ii)(F)(*1*) of this section on the basis that the plan met the standards for the exception under this paragraph (b)(2)(ii)(F)(*2*), the claimant has the right to resubmit and pursue the internal appeal of the claim. In such a case, within a reasonable time after the external reviewer or court rejects the claim for immediate review (not to exceed 10 days), the plan shall provide the claimant with notice of the opportunity to resubmit and pursue the internal appeal of the claim. Time periods for re-filing the claim shall begin to run upon claimant's receipt of such notice.

(iii) *Requirement to provide continued coverage pending the outcome of an appeal.* A plan and issuer subject to the requirements of this paragraph (b)(2) are required to provide continued coverage pending the outcome of an appeal. For this purpose, the plan and issuer must comply with the requirements of 29 CFR 2560.503–1(f)(2)(ii), which generally provides that benefits for an ongoing course of treatment cannot be reduced or terminated without providing advance notice and an opportunity for advance review.

(c) *State standards for external review*—(1) *In general.* (i) If a State external review process that applies to and is binding on a health insurance issuer offering group health insurance coverage includes at a minimum the consumer protections in the NAIC Uniform Model Act, then the issuer must comply with the applicable State external review process and is not required to comply with the Federal external review process of paragraph (d) of this section. In such a case, to the extent that benefits under a group health plan are provided through health insurance coverage, the group health plan is not required to comply with either this paragraph (c) or the Federal external review process of paragraph (d) of this section.

(ii) To the extent that a group health plan provides benefits other than through health insurance coverage (that is, the plan is self-insured) and is subject to a State external review process that applies to and is binding on the plan (for example, is not preempted by ERISA) and the State external review process includes at a minimum the consumer protections in the NAIC Uniform Model Act, then the plan must comply with the applicable State external review process and is not required to comply with the Federal external review process of paragraph (d) of this section. Where a self-insured plan is not subject to an applicable State external review process, but the State has chosen to expand access to its process for plans that are not subject to the applicable State laws, the plan may choose to comply with either the applicable State external review process or the Federal external review process of paragraph (d) of this section.

(iii) If a plan or issuer is not required under paragraph (c)(1)(i) or (ii) of this section to comply with the requirements of this paragraph (c), then the plan or issuer must comply with the Federal external review process of paragraph (d) of this section, except to the extent, in the case of a plan, the plan is not required under paragraph (c)(1)(i) of this section to comply with paragraph (d) of this section.

(2) *Minimum standards for State external review processes.* An applicable State external review process must meet all the minimum consumer protections in this paragraph (c)(2). The Department of Health and Human Services will determine whether State external review processes meet these requirements.

(i) The State process must provide for the external review of adverse benefit determinations (including final internal adverse benefit determinations) by issuers (or, if applicable, plans) that are based on the issuer's (or plan's) requirements for medical necessity, appropriateness, health care setting, level of care, or effectiveness of a covered benefit, as well as a consideration of whether a plan or issuer is complying with the surprise billing and cost-sharing protections under sections 9816 and 9817 and §§ 54.9816–1T through 54.9816–6T and 54.9817–1T.

(ii) The State process must require issuers (or, if applicable, plans) to provide effective written notice to claimants of their rights in connection with an external review for an adverse benefit determination.

(iii) To the extent the State process requires exhaustion of an internal claims and appeals process, exhaustion must be unnecessary where the issuer (or, if applicable, the plan) has waived the requirement; the issuer (or the plan) is considered to have exhausted the internal claims and appeals process under applicable law (including by failing to comply with any of the requirements for the internal appeal process, as outlined in paragraph (b)(2) of this section), or the claimant has applied for expedited external review at the same time as applying for an expedited internal appeal.

(iv) The State process provides that the issuer (or, if applicable, the plan) against which a request for external review is filed must pay the cost of the IRO for conducting the external review. Notwithstanding this requirement, a State external review process that expressly authorizes, as of November 18, 2015, a nominal filing fee may continue to permit such fees. For this purpose, to be considered nominal, a filing fee must not exceed $25; it must be refunded to the claimant if the adverse benefit determination (or final

internal adverse benefit determination) is reversed through external review; it must be waived if payment of the fee would impose an undue financial hardship; and the annual limit on filing fees for any claimant within a single plan year must not exceed $75.

(v) The State process may not impose a restriction on the minimum dollar amount of a claim for it to be eligible for external review. Thus, the process may not impose, for example, a $500 minimum claims threshold.

(vi) The State process must allow at least four months after the receipt of a notice of an adverse benefit determination or final internal adverse benefit determination for a request for an external review to be filed.

(vii) The State process must provide that IROs will be assigned on a random basis or another method of assignment that assures the independence and impartiality of the assignment process (such as rotational assignment) by a State or independent entity, and in no event selected by the issuer, plan, or the individual.

(viii) The State process must provide for maintenance of a list of approved IROs qualified to conduct the external review based on the nature of the health care service that is the subject of the review. The State process must provide for approval only of IROs that are accredited by a nationally recognized private accrediting organization.

(ix) The State process must provide that any approved IRO has no conflicts of interest that will influence its independence. Thus, the IRO may not own or control, or be owned or controlled by a health insurance issuer, a group health plan, the sponsor of a group health plan, a trade association of plans or issuers, or a trade association of health care providers. The State process must further provide that the IRO and the clinical reviewer assigned to conduct an external review may not have a material professional, familial, or financial conflict of interest with the issuer or plan that is the subject of the external review; the claimant (and any related parties to the claimant) whose treatment is the subject of the external review; any officer, director, or management employee of the issuer; the plan administrator, plan fiduciaries, or plan employees; the health care provider, the health care provider's group, or practice association recommending the treatment that is subject to the external review; the facility at which the recommended treatment would be provided; or the developer or manufacturer of the principal drug, device, procedure, or other therapy being recommended.

(x) The State process allows the claimant at least five business days to submit to the IRO in writing additional information that the IRO must consider when conducting the external review, and it requires that the claimant is notified of the right to do so. The process must also require that any additional information submitted by the claimant to the IRO must be forwarded to the issuer (or, if applicable, the plan) within one business day of receipt by the IRO.

(xi) The State process must provide that the decision is binding on the plan or issuer, as well as the claimant except to the extent the other remedies are available under State or Federal law, and except that the requirement that the decision be binding shall not preclude the plan or issuer from making payment on the claim or otherwise providing benefits at any time, including after a final external review decision that denies the claim or otherwise fails to require such payment or benefits. For this purpose, the plan or issuer must provide benefits (including by making payment on the claim) pursuant to the final external review decision without delay, regardless of whether the plan or issuer intends to seek judicial review of the external review decision and unless or until there is a judicial decision otherwise.

(xii) The State process must require, for standard external review, that the IRO provide written notice to the issuer (or, if applicable, the plan) and the claimant of its decision to uphold or reverse the adverse benefit determination (or final internal adverse benefit determination) within no more than 45 days after the receipt of the request for external review by the IRO.

(xiii) The State process must provide for an expedited external review if the adverse benefit determination (or final internal adverse benefit determination) concerns an admission, availability of care, continued stay, or health care service for which the claimant received emergency services, but has not been discharged from a facility; or involves a medical condition for which the standard external review time frame would seriously jeopardize the life or health of the claimant or jeopardize the claimant's ability to regain maximum function. As expeditiously as possible but within no more than 72 hours after the receipt of the request for expedited external review by the IRO, the IRO must make its decision to uphold or reverse the adverse benefit determination (or final internal adverse benefit determination) and notify the claimant and the issuer (or, if applicable, the plan) of the determination. If the notice is not in writing, the IRO must provide written confirmation of the decision within 48 hours after the date of the notice of the decision.

(xiv) The State process must require that issuers (or, if applicable, plans) include a description of the external review process in or attached to the summary plan description, policy, certificate, membership booklet, outline of coverage, or other evidence of coverage it provides to participants, beneficiaries, or enrollees, substantially similar to what is set forth in section 17 of the NAIC Uniform Model Act.

(xv) The State process must require that IROs maintain written records and make them available upon request to the State, substantially similar to what is set forth in section 15 of the NAIC Uniform Model Act.

(xvi) The State process follows procedures for external review of adverse benefit determinations (or final internal adverse benefit determinations) involving experimental or investigational treatment, substantially similar to what is set forth in section 10 of the NAIC Uniform Model Act.

(3) *Transition period for external review processes.* (i) Through December 31, 2017, an applicable State external review process applicable to a health insurance issuer or group health plan is considered to meet the requirements of PHS Act section 2719(b). Accordingly, through December 31, 2017, an applicable State external review process will be considered binding on the issuer or plan (in lieu of the requirements of the Federal external review process). If there is no applicable State external review process, the issuer or plan is required to comply with the requirements of the Federal external review process in paragraph (d) of this section.

(ii) An applicable State external review process must apply for final internal adverse benefit determinations (or, in the case of simultaneous internal appeal and external review, adverse benefit determinations) provided on or after January 1, 2018. The Federal external review process will apply to such internal adverse benefit determinations unless the Department of Health and Human Services determines that a State law meets all the minimum standards of paragraph (c)(2) of this section. Through December 31, 2017, a State external review process applicable to a health insurance issuer or group health plan may be considered to meet the minimum standards of paragraph (c)(2), if it meets the temporary standards established by the

Secretary in guidance for a process similar to the NAIC Uniform Model Act.

(d) *Federal external review process.* A plan or issuer not subject to an applicable State external review process under paragraph (c) of this section must provide an effective Federal external review process in accordance with this paragraph (d) (except to the extent, in the case of a plan, the plan is described in paragraph (c)(1)(i) of this section as not having to comply with this paragraph (d)). In the case of health insurance coverage offered in connection with a group health plan, if either the plan or the issuer complies with the Federal external review process of this paragraph (d), then the obligation to comply with this paragraph (d) is satisfied for both the plan and the issuer with respect to the health insurance coverage. A Multi State Plan or MSP, as defined by 45 CFR 800.20, must provide an effective Federal external review process in accordance with this paragraph (d). In such circumstances, the requirement to provide external review under this paragraph (d) is satisfied when a Multi State Plan or MSP complies with standards established by the Office of Personnel Management.

(1) *Scope.*—(i) *In general.* The Federal external review process established pursuant to this paragraph (d) applies to the following:

(A) An adverse benefit determination (including a final internal adverse benefit determination) by a plan or issuer that involves medical judgment (including, but not limited to, those based on the plan's or issuer's requirements for medical necessity, appropriateness, health care setting, level of care, or effectiveness of a covered benefit; its determination that a treatment is experimental or investigational; its determination whether a participant or beneficiary is entitled to a reasonable alternative standard for a reward under a wellness program; its determination whether a plan or issuer is complying with the nonquantitative treatment limitation provisions of Code section 9812 and § 54.9812–1, which generally require, among other things, parity in the application of medical management techniques), as determined by the external reviewer. (A denial, reduction, termination, or a failure to provide payment for a benefit based on a determination that a participant or beneficiary fails to meet the requirements for eligibility under the terms of a group health plan or health insurance coverage is not eligible for the Federal external review process under this paragraph (d));

(B) An adverse benefit determination that involves consideration of whether a plan or issuer is complying with the surprise billing and cost-sharing protections set forth in sections 9816 and 9817 and §§ 54.9816–4T through 54.9816–5T and 54.9817–1T; and

(C) A rescission of coverage (whether or not the rescission has any effect on any particular benefit at that time).

(ii) *Examples.* The rules of paragraph (d)(1)(i) of this section are illustrated by the following examples:

(A) *Example 1*—(*1*) *Facts.* A group health plan provides coverage for 30 physical therapy visits generally. After the 30th visit, coverage is provided only if the service is preauthorized pursuant to an approved treatment plan that takes into account medical necessity using the plan's definition of the term. Individual *A* seeks coverage for a 31st physical therapy visit. *A*'s health care provider submits a treatment plan for approval, but it is not approved by the plan, so coverage for the 31st visit is not preauthorized. With respect to the 31st visit, *A* receives a notice of final internal adverse benefit determination stating that the maximum visit limit is exceeded.

(*2*) *Conclusion.* In this Example 1, the plan's denial of benefits is based on medical necessity and involves medical judgment. Accordingly, the claim is eligible for external review under paragraph (d)(1)(i) of this section. Moreover, the plan's notification of final internal adverse benefit determination is inadequate under paragraphs (b)(2)(i) and (b)(2)(ii)(E)(3) of this section because it fails to make clear that the plan will pay for more than 30 visits if the service is preauthorized pursuant to an approved treatment plan that takes into account medical necessity using the plan's definition of the term. Accordingly, the notice of final internal adverse benefit determination should refer to the plan provision governing the 31st visit and should describe the plan's standard for medical necessity, as well as how the treatment fails to meet the plan's standard.

(B) *Example 2*—(*1*) *Facts.* A group health plan does not provide coverage for services provided out of network, unless the service cannot effectively be provided in network. Individual *B* seeks coverage for a specialized medical procedure from an out-of-network provider because *B* believes that the procedure cannot be effectively provided in network. *B* receives a notice of final internal adverse benefit determination stating that the claim is denied because the provider is out-of-network.

(*2*) *Conclusion.* In this Example 2, the plan's denial of benefits is based on whether a service can effectively be provided in network and, therefore, involves medical judgment. Accordingly, the claim is eligible for external review under paragraph (d)(1)(i) of this section. Moreover, the plan's notice of final internal adverse benefit determination is inadequate under paragraphs (b)(2)(i) and (b)(2)(ii)(E)(*3*) of this section because the plan does provide benefits for services on an out-of-network basis if the services cannot effectively be provided in network. Accordingly, the notice of final internal adverse benefit determination is required to refer to the exception to the out-of-network exclusion and should describe the plan's standards for determining effectiveness of services, as well as how services available to the claimant within the plan's network meet the plan's standard for effectiveness of services.

(C) *Example 3*—(*1*) *Facts.* A group health plan generally provides benefits for services in an emergency department of a hospital or independent freestanding emergency department. Individual *C* receives pre-stabilization emergency treatment in an out-of-network emergency department of a hospital. The group health plan determines that protections for emergency services under § 54.9816–4T do not apply because the treatment did not involve ''emergency services'' within the meaning of § 54.9816–4T(c)(2)(i). *C* receives an adverse benefit determination, and the plan imposes cost-sharing requirements that are greater than the requirements that would apply if the same services were provided in an in-network emergency department.

(*2*) *Conclusion.* In this *Example 3,* the plan's determination that treatment received by *C* did not include emergency services involves medical judgment and consideration of whether the plan complied with § 54.9816–4T. Accordingly, the claim is eligible for external review under paragraph (d)(1)(i) of this section.

(D) *Example 4*—(*1*) *Facts.* A group health plan generally provides benefits for anesthesiology services. Individual *D* undergoes a surgery at an in-network health care facility and during the course of the surgery, receives anesthesiology services from an out-of-network provider. The plan decides the claim for these services without regard to the protections related to items and services furnished by out-of-network providers at in-network facilities under § 54.9816–5T. As a result, *D* receives an adverse benefit determination for the

services and is subject to cost-sharing liability that is greater than it would be if cost sharing had been calculated in a manner consistent with the requirements of § 54.9816–5T.

(*2*) *Conclusion.* In this *Example 4,* whether the plan was required to decide the claim in a manner consistent with the requirements of § 54.9816–5T involves considering whether the plan complied with § 54.9816–5T, as well as medical judgment, because it requires consideration of the health care setting and level of care. Accordingly, the claim is eligible for external review under paragraph (d)(1)(i) of this section.

(E) *Example 5*—(*1*) *Facts.* A group health plan generally provides benefits for services in an emergency department of a hospital or independent freestanding emergency department. Individual *E* receives emergency services in an out-of-network emergency department of a hospital, including certain post-stabilization services. The plan processes the claim for the post-stabilization services as not being for emergency services under § 54.9816–4T(c)(2)(ii) based on representations made by the treating provider that *E* was in a condition to receive notice from the provider about cost-sharing and surprise billing protections for these services, and subsequently gave informed consent to waive those protections. *E* receives an adverse benefit determination and is subject to cost-sharing requirements that are greater than the cost-sharing requirements that would apply if the services were processed in a manner consistent with § 54.9816–4T.

(*2*) *Conclusion.* In this *Example 5,* whether *E* was in a condition to receive notice about the availability of cost-sharing and surprise billing protections and give informed consent to waive those protections involves medical judgment and consideration of whether the plan complied with the requirements under § 54.9816–4T(c)(2)(ii). Accordingly, the claim is eligible for external review under paragraph (d)(1)(i) of this section.

(F) *Example 6*—(*1*) *Facts.* Individual *F* gives birth to a baby at an in-network hospital. The baby is born prematurely and receives certain neonatology services from a nonparticipating provider during the same visit as the birth. *F* was given notice about cost-sharing and surprise billing protections for these services, and subsequently gave informed consent to waive those protections. The claim for the neonatology services is coded as a claim for routine post-natal services and the plan decides the claim without regard to the requirements under § 54.9816–5T(a) and the fact that those protections may not be waived for neonatology services under § 54.9816–5T(b).

(*2*) *Conclusion.* In this *Example 6,* medical judgment is necessary to determine whether the correct code was used and compliance with § 54.9816–5T(a) and (b) must also be considered. Accordingly, the claim is eligible for external review under paragraph (d)(1)(i) of this section. The Departments also note that, to the extent the nonparticipating provider balance bills Individual *F* for the outstanding amounts not paid by the plan for the neonatology services, such provider would be in violation of PHS Act section 2799B–2 and its implementing regulations at 45 CFR 149.420(a).

(G) *Example 7*—(*1*) *Facts.* A group health plan generally provides benefits to cover knee replacement surgery. Individual *G* receives a knee replacement surgery at an in-network facility and, after receiving proper notice about the availability of cost-sharing and surprise billing protections, provides informed consent to waive those protections. However, during the surgery, certain anesthesiology services are provided by an out-of-network nurse anesthetist. The claim for these anesthesiology services is decided by the plan without regard to the requirements under § 54.9816–5T(a) or to the fact that those protections may not be waived for ancillary services such as anesthesiology services provided by an out-of-network provider at an in-network facility under § 54.9816–5T(b). *G* receives an adverse benefit determination and is subject to cost-sharing requirements that are greater than the cost-sharing requirements that would apply if the services were provided in a manner consistent with § 54.9816–5T(a) and (b).

(*2*) *Conclusion.* In this *Example 7,* consideration of whether the plan complied with the requirements in § 54.9816–5T(a) and (b) is necessary to determine whether cost-sharing requirements were applied appropriately. Accordingly, the claim is eligible for external review under paragraph (d)(1)(i) of this section.

(2) *External review process standards.* The Federal external review process established pursuant to this paragraph (d) is considered similar to the process set forth in the NAIC Uniform Model Act and, therefore satisfies the requirements of paragraph (d)(2) if such process provides the following.

(i) *Request for external review.* A group health plan or health insurance issuer must allow a claimant to file a request for an external review with the plan or issuer if the request is filed within four months after the date of receipt of a notice of an adverse benefit determination or final internal adverse benefit determination. If there is no corresponding date four months after the date of receipt of such a notice, then the request must be filed by the first day of the fifth month following the receipt of the notice. For example, if the date of receipt of the notice is October 30, because there is no February 30, the request must be filed by March 1. If the last filing date would fall on a Saturday, Sunday, or Federal holiday, the last filing date is extended to the next day that is not a Saturday, Sunday, or Federal holiday.

(ii) *Preliminary review*—(A) *In general.* Within five business days following the date of receipt of the external review request, the group health plan or health insurance issuer must complete a preliminary review of the request to determine whether:

(*1*) The claimant is or was covered under the plan or coverage at the time the health care item or service was requested or, in the case of a retrospective review, was covered under the plan or coverage at the time the health care item or service was provided;

(*2*) The adverse benefit determination or the final adverse benefit determination does not relate to the claimant's failure to meet the requirements for eligibility under the terms of the group health plan or health insurance coverage (*e.g.,* worker classification or similar determination);

(*3*) The claimant has exhausted the plan's or issuer's internal appeal process unless the claimant is not required to exhaust the internal appeals process under paragraph (b)(1) of this section; and

(*4*) The claimant has provided all the information and forms required to process an external review.

(B) Within one business day after completion of the preliminary review, the plan or issuer must issue a notification in writing to the claimant. If the request is complete but not eligible for external review, such notification must include the reasons for its ineligibility and current contact information, including the phone number, for the Employee Benefits Security Administration. If the request is not complete, such notification must describe the information or materials needed to make the request complete, and the plan or issuer must allow a claimant to perfect the request for external review within the four-month filing period or within the 48 hour period following the receipt of the notification, whichever is later.

(iii) *Referral to Independent Review Organization*—(A) *In general.* The group health plan or health insurance issuer must assign an IRO that is accredited by URAC or by similar nationally-recognized accrediting organization to conduct the external review. The IRO referral process must provide for the following:

(*1*) The plan or issuer must ensure that the IRO process is not biased and ensures independence;

(*2*) The plan or issuer must contract with at least three (3) IROs for assignments under the plan or coverage and rotate claims assignments among them (or incorporate other independent, unbiased methods for selection of IROs, such as random selection); and

(*3*) The IRO may not be eligible for any financial incentives based on the likelihood that the IRO will support the denial of benefits.

(*4*) The IRO process may not impose any costs, including filing fees, on the claimant requesting the external review.

(B) *IRO contracts.* A group health plan or health insurance issuer must include the following standards in the contract between the plan or issuer and the IRO:

(*1*) The assigned IRO will utilize legal experts where appropriate to make coverage determinations under the plan or coverage.

(*2*) The assigned IRO will timely notify a claimant in writing whether the request is eligible for external review. This notice will include a statement that the claimant may submit in writing to the assigned IRO, within ten business days following the date of receipt of the notice, additional information. This additional information must be considered by the IRO when conducting the external review. The IRO is not required to, but may, accept and consider additional information submitted after ten business days.

(*3*) Within five business days after the date of assignment of the IRO, the plan or issuer must provide to the assigned IRO the documents and any information considered in making the adverse benefit determination or final internal adverse benefit determination. Failure by the plan or issuer to timely provide the documents and information must not delay the conduct of the external review. If the plan or issuer fails to timely provide the documents and information, the assigned IRO may terminate the external review and make a decision to reverse the adverse benefit determination or final internal adverse benefit determination. Within one business day after making the decision, the IRO must notify the claimant and the plan.

(*4*) Upon receipt of any information submitted by the claimant, the assigned IRO must within one business day forward the information to the plan or issuer. Upon receipt of any such information, the plan or issuer may reconsider its adverse benefit determination or final internal adverse benefit determination that is the subject of the external review. Reconsideration by the plan or issuer must not delay the external review. The external review may be terminated as a result of the reconsideration only if the plan decides, upon completion of its reconsideration, to reverse its adverse benefit determination or final internal adverse benefit determination and provide coverage or payment. Within one business day after making such a decision, the plan must provide written notice of its decision to the claimant and the assigned IRO. The assigned IRO must terminate the external review upon receipt of the notice from the plan or issuer.

(*5*) The IRO will review all of the information and documents timely received. In reaching a decision, the assigned IRO will review the claim de novo and not be bound by any decisions or conclusions reached during the plan's or issuer's internal claims and appeals process applicable under paragraph (b) of this section. In addition to the documents and information provided, the assigned IRO, to the extent the information or documents are available and the IRO considers them appropriate, will consider the following in reaching a decision:

(*i*) The claimant's medical records;

(*ii*) The attending health care professional's recommendation;

(*iii*) Reports from appropriate health care professionals and other documents submitted by the plan or issuer, claimant, or the claimant's treating provider;

(*iv*) The terms of the claimant's plan or coverage to ensure that the IRO's decision is not contrary to the terms of the plan or coverage, unless the terms are inconsistent with applicable law;

(*v*) Appropriate practice guidelines, which must include applicable evidence-based standards and may include any other practice guidelines developed by the Federal Government, national or professional medical societies, boards, and associations;

(*vi*) Any applicable clinical review criteria developed and used by the plan or issuer, unless the criteria are inconsistent with the terms of the plan or coverage or with applicable law; and

(*vii*) To the extent the final IRO decision maker is different from the IRO's clinical reviewer, the opinion of such clinical reviewer, after considering information described in this notice, to the extent the information or documents are available and the clinical reviewer or reviewers consider such information or documents appropriate.

(*6*) The assigned IRO must provide written notice of the final external review decision within 45 days after the IRO receives the request for the external review. The IRO must deliver the notice of the final external review decision to the claimant and the plan or issuer.

(*7*) The assigned IRO's written notice of the final external review decision must contain the following:

(*i*) A general description of the reason for the request for external review, including information sufficient to identify the claim (including the date or dates of service, the health care provider, the claim amount (if applicable), and a statement describing the availability, upon request, of the diagnosis code and its corresponding meaning, the treatment code and its corresponding meaning, and the reason for the plan's or issuer's denial);

(*ii*) The date the IRO received the assignment to conduct the external review and the date of the IRO decision;

(*iii*) References to the evidence or documentation, including the specific coverage provisions and evidence-based standards, considered in reaching its decision;

(*iv*) A discussion of the principal reason or reasons for its decision, including the rationale for its decision and any evidence-based standards that were relied on in making its decision;

(*v*) A statement that the IRO's determination is binding except to the extent that other remedies may be available under State or Federal law to either the group health plan or health insurance issuer or to the claimant, or to the extent the health plan or health insurance issuer voluntarily makes payment on the claim or otherwise provides benefits at any time, including after a final external review decision that denies the claim or otherwise fails to require such payment or benefits;

(*vi*) A statement that judicial review may be available to the claimant; and

(*vii*) Current contact information, including phone number, for any applicable office of health insurance consumer assistance or ombudsman established under PHS Act section 2793.

(*viii*) After a final external review decision, the IRO must maintain records of all claims and notices associated with the external review process for six years. An IRO must make such records available for examination by the claimant, plan, issuer, or State or Federal oversight agency upon request,

except where such disclosure would violate State or Federal privacy laws.

(*iv*) *Reversal of plan's or issuer's decision.* Upon receipt of a notice of a final external review decision reversing the adverse benefit determination or final adverse benefit determination, the plan or issuer immediately must provide coverage or payment (including immediately authorizing care or immediately paying benefits) for the claim.

(3) *Expedited external review.* A group health plan or health insurance issuer must comply with the following standards with respect to an expedited external review:

(i) *Request for external review.* A group health plan or health insurance issuer must allow a claimant to make a request for an expedited external review with the plan or issuer at the time the claimant receives:

(A) An adverse benefit determination if the adverse benefit determination involves a medical condition of the claimant for which the timeframe for completion of an expedited internal appeal under paragraph (b) of this section would seriously jeopardize the life or health of the claimant or would jeopardize the claimant's ability to regain maximum function and the claimant has filed a request for an expedited internal appeal; or

(B) A final internal adverse benefit determination, if the claimant has a medical condition where the timeframe for completion of a standard external review would seriously jeopardize the life or health of the claimant or would jeopardize the claimant's ability to regain maximum function, or if the final internal adverse benefit determination concerns an admission, availability of care, continued stay, or health care item or service for which the claimant received emergency services, but has not been discharged from the facility.

(ii) *Preliminary review.* Immediately upon receipt of the request for expedited external review, the plan or issuer must determine whether the request meets the reviewability requirements set forth in paragraph (d)(2)(ii) of this section for standard external review. The plan or issuer must immediately send a notice that meets the requirements set forth in paragraph (d)(2)(ii)(B) for standard review to the claimant of its eligibility determination.

(iii) *Referral to independent review organization.* (A) Upon a determination that a request is eligible for expedited external review following the preliminary review, the plan or issuer will assign an IRO pursuant to the requirements set forth in paragraph (d)(2)(iii) of this section for standard review. The plan or issuer must provide or transmit all necessary documents and information considered in making the adverse benefit determination or final internal adverse benefit determination to the assigned IRO electronically or by telephone or facsimile or any other available expeditious method.

(B) The assigned IRO, to the extent the information or documents are available and the IRO considers them appropriate, must consider the information or documents described above under the procedures for standard review. In reaching a decision, the assigned IRO must review the claim de novo and is not bound by any decisions or conclusions reached during the plan's or issuer's internal claims and appeals process.

(iv) *Notice of final external review decision.* The plan's or issuer's contract with the assigned IRO must require the IRO to provide notice of the final external review decision, in accordance with the requirements set forth in paragraph (d)(2)(iii)(B) of this section, as expeditiously as the claimant's medical condition or circumstances require, but in no event more than 72 hours after the IRO receives the request for an expedited external review. If the notice is not in writing, within 48 hours after the date of providing that notice, the assigned IRO must provide written confirmation of the decision to the claimant and the plan or issuer.

(4) *Alternative, federally-administered external review process.* Insured coverage not subject to an applicable State external review process under paragraph (c) of this section may elect to use either the Federal external review process, as set forth under paragraph (d) of this section or the federally-administered external review process, as set forth by HHS in guidance. In such circumstances, the requirement to provide external review under this paragraph (d) is satisfied.

(e) *Form and manner of notice*—(1) *In general.* For purposes of this section, a group health plan and a health insurance issuer offering group health insurance coverage are considered to provide relevant notices in a culturally and linguistically appropriate manner if the plan or issuer meets all the requirements of paragraph (e)(2) of this section with respect to the applicable non-English languages described in paragraph (e)(3) of this section.

(2) *Requirements.* (i) The plan or issuer must provide oral language services (such as a telephone customer assistance hotline) that includes answering questions in any applicable non-English language and providing assistance with filing claims and appeals (including external review) in any applicable non-English language;

(ii) The plan or issuer must provide, upon request, a notice in any applicable non-English language; and

(iii) The plan or issuer must include in the English versions of all notices, a statement prominently displayed in any applicable non-English language clearly indicating how to access the language services provided by the plan or issuer.

(3) *Applicable non-English language.* With respect to an address in any United States county to which a notice is sent, a non-English language is an applicable non-English language if ten percent or more of the population residing in the county is literate only in the same non-English language, as determined in guidance published by the Secretary.

(f) *Secretarial authority.* The Secretary may determine that the external review process of a group health plan or health insurance issuer, in operation as of March 23, 2010, is considered in compliance with the applicable process established under paragraph (c) or (d) of this section if it substantially meets the requirements of paragraph (c) or (d) of this section, as applicable.

(g) *Applicability date.* The provisions of this section generally are applicable to group health plans and health insurance issuers for plan years beginning on or after January 1, 2017. The external review scope provision at paragraph (d)(1)(i)(B) of this section is applicable for plan years beginning on or after January 1, 2022. The external review provisions described in paragraphs (c) and (d) of this section are applicable to grandfathered health plans, with respect to the types of claims specified under paragraph (a)(1)(ii) of this section, for plan years beginning on or after January 1, 2022.

■ 5. Section 54.9816–1T is revised to read as follows:

§ 54.9816–1T Basis and scope (temporary).

(a) *Basis.* This section and §§ 54.9816–2T through 54.9816–8T, 54.9817–1T, 54.9817–2T, 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. This part also establishes an independent dispute resolution process and standards for certifying independent dispute resolution entities.

■ 6. Section 54.9816–2T is amended by revising paragraph (a) and paragraph (b) introductory text to read as follows:

§ 54.9816–2T Applicability (temporary).

(a) *In general.* (1) 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 § 54.9815–1251), except as specified in paragraph (b) of this section.

(2) The requirements in §§ 54.9816–8T and 54.9817–2T apply to certified IDR entities and group health plans (including grandfathered health plans as defined in § 54.9815–1251) except as specified in paragraph (b) of this section.

(b) *Exceptions.* The requirements in §§ 54.9816–4T through 54.9816–8T, 54.9817–1T, 54.9817–2T, and 54.9822–1T do not apply to the following:

* * * * *

■ 7. Section 54.9816–8T is added to read as follows:

§ 54.9816–8T Independent dispute resolution process (temporary).

(a) *Scope and definitions*—(1) *Scope.* This section sets forth requirements with respect to the independent dispute resolution (IDR) process (referred to in this section as the Federal IDR process) under which a nonparticipating provider, nonparticipating emergency facility, or nonparticipating provider of air ambulance services (as applicable); and a group health plan complete a requisite open negotiation period, and at least one party submits a notification under paragraph (b) of this section to initiate the Federal IDR process under paragraph (c) of this section, and under which an IDR entity (as certified under paragraph (e) of this section) determines the amount of payment under the plan for an item or service furnished by the provider or facility.

(2) *Definitions.* Unless otherwise stated, the definitions in § 54.9816–3T apply to this section. Additionally, for purposes of this section, the following definitions apply:

(i) *Batched items and services* means multiple qualified IDR items or services that are considered jointly as part of one payment determination by a certified IDR entity for purposes of the Federal IDR process. In order for a qualified IDR item or service to be included in a batched item or service, the qualified IDR item or service must meet the criteria set forth in paragraph (c)(3) of this section.

(ii) *Breach* means the acquisition, access, use, or disclosure of individually identifiable health information (IIHI) in a manner not permitted under paragraph (e)(2)(v) of this section that compromises the security or privacy of the IIHI.

(A) Breach excludes:

(*1*) Any unintentional acquisition, access, or use of IIHI by personnel, a contractor, or a subcontractor of a certified IDR entity that is acting under the authority of that certified IDR entity, if the acquisition, access, or use was made in good faith and within the scope of that authority and that does not result in further use or disclosure in a manner not permitted under paragraph (e)(2)(v) of this section.

(*2*) Any inadvertent disclosure by a person who is authorized to access IIHI at a certified IDR entity to another person authorized to access IIHI at the same certified IDR entity, and the information received as a result of the disclosure is not further used or disclosed in a manner not permitted under paragraph (e)(2)(v) of this section.

(*3*) A disclosure of IIHI in which a certified IDR entity has a good faith belief that an unauthorized person to whom the disclosure was made would not reasonably have been able to retain such information.

(B) Except as provided in paragraph (a)(2)(ii)(A) of this section, access, use, or disclosure of IIHI in a manner not permitted under paragraph (e)(2)(v) of this section is presumed to be a breach unless the certified IDR entity demonstrates that there is a low probability that the security or privacy of the IIHI has been compromised based on a risk assessment encompassing at least the following factors:

(*1*) The nature and extent of the IIHI involved, including the types of identifiers and the likelihood of re-identification;

(*2*) The unauthorized person who used the IIHI or to whom the disclosure was made;

(*3*) Whether the IIHI was actually acquired or viewed; and

(*4*) The extent to which the risk to the IIHI has been mitigated.

(iii) *Certified IDR entity* means an entity responsible for conducting determinations under paragraph (c) of this section that meets the certification criteria specified in paragraph (e) of this section and that has been certified by the Secretary, jointly with the Secretaries of Health and Human Services and Labor.

(iv) *Conflict of interest* means, with respect to a party to a payment determination or certified IDR entity, a material relationship, status, or condition of the party or certified IDR entity that impacts the ability of the certified IDR entity to make an unbiased and impartial payment determination. For purposes of this section, a conflict of interest exists when a certified IDR entity is:

(A) A group health plan; a health insurance issuer offering group health insurance coverage, individual health insurance coverage, or short-term, limited-duration insurance; a carrier offering a health benefits plan under 5 U.S.C. 8902; or a provider, a facility or a provider of air ambulance services;

(B) An affiliate or a subsidiary of a group health plan; a health insurance issuer offering group health insurance coverage, individual health insurance coverage, or short-term, limited-duration insurance; a carrier offering a health benefits plan under 5 U.S.C. 8902; or a provider, a facility, or a provider of air ambulance services;

(C) An affiliate or subsidiary of a professional or trade association representing group health plans; health insurance issuers offering group health insurance coverage, individual health insurance coverage, or short-term, limited-duration insurance; carriers offering a health benefits plan under 5 U.S.C. 8902; or providers, facilities, or providers of air ambulance services.

(D) A certified IDR entity that has, or that has any personnel, contractors, or subcontractors assigned to a determination who have, a material familial, financial, or professional relationship with a party to the payment determination being disputed, or with any officer, director, or management employee of the plan, issuer, or carrier offering a health benefits plan under 5 U.S.C. 8902; the plan administrator, plan fiduciaries, or plan, issuer, or carrier employees; the health care provider, the health care provider's group or practice association; the provider of air ambulance services, the provider of air ambulance services' group or practice association, or the facility that is a party to the dispute.

(v) *Credible information* means information that upon critical analysis is worthy of belief and is trustworthy.

(vi) *IDR entity* means an entity that may apply or has applied for certification to conduct determinations under paragraph (c) of this section, and that currently is not certified by the Secretary, jointly with the Secretaries of Health and Human Services and Labor, pursuant to paragraph (e) of this section.

(vii) *Individually identifiable health information (IIHI)* means any information, including demographic data, that relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or

future payment for the provision of health care to an individual; and

(A) That identifies the individual; or

(B) With respect to which there is a reasonable basis to believe the information can be used to identify the individual.

(viii) *Material difference* means a substantial likelihood that a reasonable person with the training and qualifications of a certified IDR entity making a payment determination would consider the submitted information significant in determining the out of network rate and would view the information as showing that the qualifying payment amount is not the appropriate out-of-network rate.

(ix) *Material familial relationship* means any relationship as a spouse, domestic partner, child, parent, sibling, spouse's or domestic partner's parent, spouse's or domestic partner's sibling, spouse's or domestic partner's child, child's parent, child's spouse or domestic partner, or sibling's spouse or domestic partner.

(x) *Material financial relationship* means any financial interest of more than five percent of total annual revenue or total annual income of a certified IDR entity, or an officer, director, or manager thereof, or of a reviewer or reviewing physician employed or engaged by a certified IDR entity to conduct or participate in any review in the Federal IDR process. The terms annual revenue and annual income do not include mediation fees received by mediators who are also arbitrators, provided that the mediator acts in the capacity of a mediator and does not represent a party in the mediation.

(xi) *Material professional relationship* means any physician-patient relationship, any partnership or employment relationship, any shareholder or similar ownership interest in a professional corporation, partnership, or other similar entity; or any independent contractor arrangement that constitutes a material financial relationship with any expert used by the certified IDR entity or any officer or director of the certified IDR entity.

(xii) *Qualified IDR item or service* means an item or service:

(A) That is an emergency service furnished by a nonparticipating provider or nonparticipating facility subject to the protections of § 54.9816–4T, 29 CFR 2590.716–4, or 45 CFR 149.110, as applicable, for which the conditions of 45 CFR 149.410(b) are not met, or an item or service furnished by a nonparticipating provider at a participating health care facility, subject to the requirements of § 54.9816–5T, 29 CFR 2590.716–5, or 45 CFR 149.120, as applicable, for which the conditions of 45 CFR 149.420(c) through (i) are not met, or air ambulance services furnished by a nonparticipating provider of air ambulance services subject to the protections of § 54.9817–1T, 29 CFR 2590.717–1, or 45 CFR 149.130, as applicable, and for which the out-of-network rate is not determined by reference to an All-Payer Model Agreement under section 1115A of the Social Security Act or a specified State law as defined in § 54.9816–3T;

(B) With respect to which a provider or facility (as applicable) or group health plan submits a notification under paragraph (b)(2) of this section;

(C) That is not an item or service that is the subject of an open negotiation under paragraph (b)(1) of this section; and

(D) That is not an item or service for which a notification under paragraph (b)(2) of this section is submitted during the 90-calendar-day period under paragraph (c)(4)(vi)(B) of this section, but that may include such an item or service if the notification is submitted during the subsequent 30-business-day period under paragraph (c)(4)(vi)(C) of this section.

(xiii) *Unsecured IIHI* means IIHI that is not rendered unusable, unreadable, or indecipherable to unauthorized persons through the use of a technology or methodology specified by the Secretary, jointly with the Secretary of Health and Human Services and the Secretary of Labor.

(b) *Determination of payment amount through open negotiation and initiation of the Federal IDR process*—(1) *Determination of payment amount through open negotiation*—(i) *In general.* With respect to an item or service that meets the requirements of paragraph (a)(2)(xii)(A) of this section, the provider, facility, or provider of air ambulance services or the group health plan may, during the 30-business-day period beginning on the day the provider, facility, or provider of air ambulance services receives an initial payment or notice of denial of payment regarding the item or service, initiate an open negotiation period for purposes of determining the out-of-network rate for such item or service. To initiate the open negotiation period, a party must send a notice to the other party (open negotiation notice) in accordance with paragraph (b)(1)(ii) of this section.

(ii) *Open negotiation notice*—(A) *Content.* The open negotiation notice must include information sufficient to identify the item(s) and service(s) (including the date(s) the item(s) or service(s) were furnished, the service code, and initial payment amount, if applicable), an offer of an out-of-network rate, and contact information for the party sending the open negotiation notice.

(B) *Manner.* The open negotiation notice must be provided, using the standard form developed by the Secretary, in writing within 30 business days beginning on the day the provider, facility, or provider of air ambulance services receives an initial payment or a notice of denial of payment from the plan regarding the item or service. The day on which the open negotiation notice is first sent by a party is the date the 30-business-day open negotiation period begins. This notice may be provided to the other party electronically (such as by email) if the following two conditions are satisfied:

(*1*) The party sending the open negotiation notice has a good faith belief that the electronic method is readily accessible by the other party; and

(*2*) The notice is provided in paper form free of charge upon request.

(2) *Initiating the Federal IDR process*—(i) *In general.* With respect to an item or service for which the parties do not agree upon an out-of-network rate by the last day of the open negotiation period under paragraph (b)(1) of this section, either party may initiate the Federal IDR process. To initiate the Federal IDR process, a party must submit a written notice of IDR initiation to the other party and to the Secretary, using the standard form developed by the Secretary, during the 4-business-day period beginning on the 31st business day after the start of the open negotiation period.

(ii) *Exception for items and services provided by certain nonparticipating providers and facilities.* A party may not initiate the Federal IDR process with respect to an item or service if, with respect to that item or service, the party knows (or reasonably should have known) that the provider or facility provided notice and received consent under 45 CFR 149.410(b) or 149.420(c) through (i).

(iii) *Notice of IDR initiation*—(A) *Content.* The notice of IDR initiation must include:

(*1*) Information sufficient to identify the qualified IDR items or services under dispute (and whether the qualified IDR items or services are designated as batched items and services as described in paragraph (c)(3) of this section), including the date(s) and location the item or service was furnished, the type of item or service (such as whether the qualified IDR item or service is an emergency service as defined in § 54.9816–4T(c)(2)(i), 29 CFR

2590.716–4(c)(2)(i), or 45 CFR 149.110(c)(2)(i), as applicable, an emergency service as defined in § 54.9816–4T(c)(2)(ii), 29 CFR 2590.716–4(c)(2)(ii), or 45 CFR 149.110(c)(2)(ii), as applicable, or a nonemergency service; and whether any service is a professional service or facility-based service), corresponding service codes, place of service code, the amount of cost sharing allowed, and the amount of the initial payment made for the qualified IDR item or service, if applicable;

(*2*) Names of the parties involved and contact information, including name, email address, phone number, and mailing address;

(*3*) State where the qualified IDR item or service was furnished;

(*4*) Commencement date of the open negotiation period under paragraph (b)(1) of this section;

(*5*) Preferred certified IDR entity;

(*6*) An attestation that the items and services under dispute are qualified IDR items or services;

(*7*) Qualifying payment amount;

(*8*) Information about the qualifying payment amount as described in § 54.9816–6T(d); and

(*9*) General information describing the Federal IDR process as specified by the Secretary.

(B) *Manner.* The initiating party must provide written notice of IDR initiation to the other party. The initiating party may satisfy this requirement by furnishing the notice of IDR initiation to the other party electronically (such as by email) if the following two conditions are satisfied—

(*1*) The initiating party has a good faith belief that the electronic method is readily accessible by the other party; and

(*2*) The notice is provided in paper form free of charge upon request.

(C) *Notice to the Secretary.* The initiating party must also furnish the notice of IDR initiation to the Secretary by submitting the notice through the Federal IDR portal. The initiation date of the Federal IDR process will be the date of receipt by the Secretary.

(c) *Federal IDR process following initiation*—(1) *Selection of certified IDR entity*—(i) *In general.* The plan or the provider, facility, or provider of air ambulance services receiving the notice of IDR initiation under paragraph (b)(2) of this section may agree or object to the preferred certified IDR entity identified in the notice of IDR initiation. If the party in receipt of the notice of IDR initiation fails to object within 3 business days, the preferred certified IDR entity identified in the notice of IDR initiation will be selected and will be treated as jointly agreed to by the parties, provided that the certified IDR entity does not have a conflict of interest. If the party in receipt of the notice of IDR initiation objects, that party must notify the initiating party of the objection and propose an alternative certified IDR entity. The initiating party must then agree or object to the alternative certified IDR entity; if the initiating party fails to agree or object to the alternative certified IDR entity, the alternative certified IDR entity will be selected and will be treated as jointly agreed to by the parties. In order to select a preferred certified IDR entity, the plan and the provider, facility, or provider of air ambulance services, must jointly agree on a certified IDR entity not later than 3 business days after the initiation date of the Federal IDR process. If the plan and the provider, facility, or provider of air ambulance services fail to agree upon a certified IDR entity within that time, the Secretary shall select a certified IDR entity in accordance with paragraph (c)(1)(iv) of this section.

(ii) *Requirements for selected certified IDR entity.* The certified IDR entity selected must be an IDR entity certified under paragraph (e) of this section, that:

(A) Does not have a conflict of interest as defined in paragraph (a)(2) of this section;

(B) Ensures that assignment of personnel to a payment determination and decisions regarding hiring, compensation, termination, promotion, or other similar matters related to personnel assigned to the dispute are not made based upon the likelihood that the assigned personnel will support a particular party to the determination being disputed other than as outlined under paragraph (c)(4)(iii) of this section; and

(C) Ensures that any personnel assigned to a payment determination do not have any conflicts of interests as defined in paragraph (a)(2) of this section regarding any party to the dispute within the 1 year immediately preceding an assignment of dispute determination, similar to the requirements laid out in 18 U.S.C. 207(b).

(iii) *Notice of certified IDR entity selection.* Upon the selection of a certified IDR entity, in accordance with paragraph (c)(1)(i) of this section, the plan or the provider or emergency facility that submitted the notice of IDR initiation under paragraph (b)(2) of this section must notify the Secretary of the selection as soon as reasonably practicable, but no later than 1 business day after such selection, through the Federal IDR portal. In addition, if the non-initiating party believes that the Federal IDR process is not applicable, the non-initiating party must also provide information regarding the Federal IDR process's inapplicability through the Federal IDR portal by the same date that the notice of certified IDR entity selection must be submitted.

(A) *Content.* If the parties have agreed on the selection of a certified IDR entity or the party in receipt of the notice of IDR initiation has not objected to the other party's selection, the notice of the certified IDR entity selection must include the following information:

(*1*) Name of the certified IDR entity;

(*2*) The certified IDR entity number; and

(*3*) Attestation by both parties, or by the initiating party if the non-initiating party fails to object to the selection of the certified IDR entity, that the selected certified IDR entity meets the requirements of paragraph (c)(1)(ii) of this section.

(B) [Reserved]

(iv) *Failure to select a certified IDR entity.* If the plan and the provider, facility, or provider of air ambulance services fail to select a certified IDR entity in accordance with paragraph (c)(1)(i) of this section, the initiating party must notify the Secretary of the failure no later than 1 business day after the date of such failure (or in other words, 4 business days after initiation of the Federal IDR process) by electronically submitting the notice as described in paragraph (c)(1)(iii) of this section but indicating that the parties have failed to select a certified IDR entity. In addition, if the non-initiating party believes that the Federal IDR process is not applicable, the non-initiating party must also provide information regarding the Federal IDR process's inapplicability through the Federal IDR portal by the same date that the notice of failure to select must be submitted. Upon notification of the failure of the parties to select a certified IDR entity, the Secretary will select a certified IDR entity that charges a fee within the allowed range of certified IDR entity fees through a random selection method not later than 6 business days after the date of initiation of the Federal IDR process and will notify the plan and the provider or facility of the selection. If there are insufficient certified IDR entities that charge a fee within the allowed range of certified IDR entity fees available to arbitrate the dispute, the Secretary, jointly with the Secretary of Health and Human Services and Secretary of Labor, will select a certified IDR entity that has received approval, as described in paragraph (e)(2)(vi)(B) of this section, to

charge a fee outside of the allowed range of certified IDR entity fees.

(v) *Review by certified IDR entity.* After selection by the parties (including when the initiating party selects a certified IDR entity and the other party does not object), or by the Secretary under paragraph (c)(1)(iv) of this section, the certified IDR entity must review the selection and attest that it meets the requirements of paragraph (c)(1)(ii) of this section. If the certified IDR entity is unable to attest that it meets the requirements of paragraph (c)(1)(ii) within 3 business days of selection, the parties, upon notification, must select another certified IDR entity under paragraph (c)(1) of this section, treating the date of notification of the failure to attest to the requirements of (c)(1)(ii) of this section as the date of initiation of the Federal IDR process for purposes of the time periods in paragraphs (c)(1)(i) and (iv) of this section. Additionally, the certified IDR entity selected must review the information submitted in the notice of IDR initiation to determine whether the Federal IDR process applies. If the Federal IDR process does not apply, the certified IDR entity must notify the Secretary and the parties within 3 business days of making that determination.

(2) *Authority to continue negotiations*—(i) *In general.* If the parties to the Federal IDR process agree on an out-of-network rate for a qualified IDR item or service after providing the notice of IDR initiation to the Secretary consistent with paragraph (b)(2) of this section, but before the certified IDR entity has made its payment determination, the amount agreed to by the parties for the qualified IDR item or service will be treated as the out-of-network rate for the qualified IDR item or service. To the extent the amount exceeds the initial payment amount (or initial denial of payment) and any cost sharing paid or required to be paid by the participant or beneficiary, payment must be made directly by the plan to the nonparticipating provider, facility, or nonparticipating provider of air ambulance services not later than 30 business days after the agreement is reached. In no instance may either party seek additional payment from the participant or beneficiary, including in instances in which the out-of-network rate exceeds the qualifying payment amount. The initiating party must send a notification to the Secretary and to the certified IDR entity (if selected) electronically through the Federal IDR portal, as soon as possible, but no later than 3 business days after the date of the agreement. The notification must include the out-of-network rate for the qualified IDR item or service and signatures from authorized signatories for both parties.

(ii) *Method of allocation of the certified IDR entity fee.* In the case of an agreement described in paragraph (c)(2)(i) of this section, the certified IDR entity is required to return half of each parties' certified IDR entity fee, unless directed otherwise by both parties. The administrative fee under paragraph (d)(2) of this section will not be returned to the parties.

(3) *Treatment of batched items and services*—(i) *In general.* Batched items and services may be submitted and considered jointly as part of one payment determination by a certified IDR entity only if the batched items and services meet the requirements of this paragraph (c)(3). Batched items and services submitted and considered jointly as part of one payment determination under this paragraph (c)(3)(i) are treated as a batched determination and subject to the fee for batched determinations under this section.

(A) The qualified IDR items and services are billed by the same provider or group of providers, the same facility, or the same provider of air ambulance services. Items and services are billed by the same provider or group of providers, the same facility, or the same provider of air ambulance services if the items or services are billed with the same National Provider Identifier or Tax Identification Number;

(B) Payment for the qualified IDR items and services would be made by the same plan;

(C) The qualified IDR items and services are the same or similar items and services. The qualified IDR items and services are considered to be the same or similar items or services if each is billed under the same service code, or a comparable code under a different procedural code system, such as Current Procedural Terminology (CPT) codes with modifiers, if applicable, Healthcare Common Procedure Coding System (HCPCS) with modifiers, if applicable, or Diagnosis-Related Group (DRG) codes with modifiers, if applicable; and

(D) All the qualified IDR items and services were furnished within the same 30-business-day period, or the same 90-calendar-day period under paragraph (c)(4)(vi)(B) of this section, as applicable.

(ii) *Treatment of bundled payment arrangements.* In the case of qualified IDR items and services billed by a provider, facility, or provider of air ambulance services as part of a bundled payment arrangement, or where a plan makes or denies an initial payment as a bundled payment, the qualified IDR items and services may be submitted as part of one payment determination. Bundled payment arrangements submitted under this paragraph (c)(3)(ii) are subject to the rules for batched determinations set forth in paragraph (c)(3)(i) of this section and the certified IDR entity fee for single determinations as set forth in paragraph (e)(2)(vii) of this section.

(4) *Payment determination for a qualified IDR item or service*—(i) *Submission of offers.* Not later than 10 business days after the selection of the certified IDR entity, the plan and the provider, facility, or provider of air ambulance services:

(A) Must each submit to the certified IDR entity:

(*1*) An offer of an out-of-network rate expressed as both a dollar amount and the corresponding percentage of the qualifying payment amount represented by that dollar amount;

(*2*) Information requested by the certified IDR entity relating to the offer.

(*3*) The following additional information, as applicable—

(*i*) For providers and facilities, information on the size of the provider's practice or of the facility (if applicable). Specifically, a group of providers must specify whether the providers' practice has fewer than 20 employees, 20 to 50 employees, 51 to 100 employees, 101 to 500 employees, or more than 500 employees. For facilities, the facility must specify whether the facility has 50 or fewer employees, 51 to 100 employees, 101 to 500 employees, or more than 500 employees;

(*ii*) For providers and facilities, information on the practice specialty or type, respectively (if applicable);

(*iii*) For plans, information on the coverage area of the plan, the relevant geographic region for purposes of the qualifying payment amount, whether the coverage is fully-insured or partially or fully self-insured; and

(*iv*) The qualifying payment amount for the applicable year for the same or similar item or service as the qualified IDR item or service.

(B) May each submit to the certified IDR entity any information relating to the offer that was submitted by either party, except that the information may not include information on factors described in paragraph (c)(4)(v) of this section.

(ii) *Payment determination and notification.* Not later than 30 business days after the selection of the certified IDR entity, the certified IDR entity must:

(A) Select as the out-of-network rate for the qualified IDR item or service one

of the offers submitted under paragraph (c)(4)(i) of this section, taking into account the considerations specified in paragraph (c)(4)(iii) of this section (as applied to the information provided by the parties pursuant to paragraph (c)(4)(i) of this section). The certified IDR entity must select the offer closest to the qualifying payment amount unless the certified IDR entity determines that credible information submitted by either party under paragraph (c)(4)(i) clearly demonstrates that the qualifying payment amount is materially different from the appropriate out-of-network rate, or if the offers are equally distant from the qualifying payment amount but in opposing directions. In these cases, the certified IDR entity must select the offer as the out-of-network rate that the certified IDR entity determines best represents the value of the qualified IDR item or services, which could be either offer.

(B) Notify the plan and the provider or facility, as applicable, of the selection of the offer under paragraph (c)(4)(ii)(A) of this section, and provide the written decision required under (c)(4)(vi) of this section.

(iii) *Considerations in determination.* In determining which offer to select, the certified IDR entity must consider:

(A) The qualifying payment amount(s) for the applicable year for the same or similar item or service.

(B) Information requested by the certified IDR entity under paragraph (c)(4)(i)(A)(*2*) of this section relating to the offer, to the extent a party provides credible information.

(C) Additional information submitted by a party, provided the information is credible and relates to the circumstances described in paragraphs (c)(4)(iii)(C)(*1*) through (*5*) of this section, with respect to a qualified IDR item or service of a nonparticipating provider, facility, or group health plan that is the subject of a payment determination. This information must also clearly demonstrate that the qualifying payment amount is materially different from the appropriate out-of-network rate.

(*1*) The level of training, experience, and quality and outcomes measurements of the provider or facility that furnished the qualified IDR item or service (such as those endorsed by the consensus-based entity authorized in section 1890 of the Social Security Act).

(*2*) The market share held by the provider or facility or that of the plan in the geographic region in which the qualified IDR item or service was provided.

(*3*) The acuity of the participant, or beneficiary, receiving the qualified IDR item or service, or the complexity of furnishing the qualified IDR item or service to the participant or beneficiary.

(*4*) The teaching status, case mix, and scope of services of the facility that furnished the qualified IDR item or service, if applicable.

(*5*) Demonstration of good faith efforts (or lack thereof) made by the provider or facility or the plan to enter into network agreements with each other, and, if applicable, contracted rates between the provider or facility, as applicable, and the plan during the previous 4 plan years.

(D) Additional information submitted by a party, provided the information is credible and relates to the offer submitted by either party and does not include information on factors described in paragraph (c)(4)(v) of this section.

(iv) *Examples.* The rules of paragraph (c)(4)(iii) of this section are illustrated by the following examples:

(A) *Example 1*—(*1*) *Facts.* A nonparticipating provider and a group health plan are parties to a payment determination in the Federal IDR process. The nonparticipating provider submits an offer and additional written information asserting that the provider has made good faith efforts to enter into network agreements with the plan. The nonparticipating provider fails to provide any documentation of these efforts, such as correspondence or records of conversations with representatives of the plan.

(*2*) *Conclusion.* In this *Example 1,* the nonparticipating provider has submitted additional information. However, this information is not credible, as the nonparticipating provider has failed to provide any documentation in support of the provider's assertions of good faith efforts to enter into network agreements with the plan. Therefore, the certified IDR entity cannot consider the information.

(B) *Example 2*—(*1*) *Facts.* A nonparticipating provider and a group health plan are parties to a payment determination in the Federal IDR process. The nonparticipating provider submits credible information relating to the provider's level of training, experience, and quality and outcome measurements from 2019. The provider also submits credible information that clearly demonstrates that the provider's level of training and expertise was necessary for providing the service that is the subject of the payment determination to the particular patient. Further, the provider submits credible information that clearly demonstrates that the qualifying payment amount generally presumes the service would be delivered by a provider with a lower level of training, experience, and quality and outcome measurements. This information, taken together, demonstrates that the qualifying payment amount is not an appropriate payment amount, and the provider submits an offer that is higher than the qualifying payment amount and commensurate with the provider's level of training, experience, and quality and outcome measurements with respect to the service provided. The plan submits the qualifying payment amount as its offer with no additional information.

(*2*) *Conclusion.* In this *Example 2,* the nonparticipating provider has submitted information that is credible. Moreover, the credible information clearly demonstrates that the qualifying payment amount does not adequately take into account the provider's level of training, experience, and quality and outcome measurements with respect to the service provided, and that the appropriate out-of-network rate should therefore be higher than the qualifying payment amount. Accordingly, the certified IDR entity must select the provider's offer, as that offer best represents the value of the service that is the subject of the payment determination.

(C) *Example 3*—(*1*) *Facts.* A nonparticipating provider and a group health plan are parties to a payment determination in the Federal IDR process. The nonparticipating provider submits credible information to the certified IDR entity relating to the acuity of the patient that received the service, and the complexity of furnishing the service to the patient, by providing details of the service at issue and the training required to furnish the complex service. The provider contends that this information demonstrates that the qualifying payment amount is not an appropriate payment amount, and the provider submits an offer that is higher than the qualifying payment amount and equal to what the provider believes is commensurate with the acuity of the patient and the complexity of the service that is the subject of the payment determination. However, the evidence submitted by the provider does not clearly demonstrate that the qualifying payment amount fails to encompass the acuity and complexity of the service. The plan submits the qualifying payment amount as its offer, along with credible information that demonstrates how the qualifying payment amount was calculated for this particular service, taking into consideration the acuity of the patient and the complexity of the service.

(*2*) *Conclusion.* The information submitted by the provider to the certified IDR entity is credible with respect to the acuity of the patient and complexity of the service. However, in this example, the provider has not clearly demonstrated that the qualifying payment amount is materially different from the appropriate out-of-network rate, based on the acuity of the patient and the complexity of the service that is the subject of the payment determination. Accordingly, the certified IDR entity must select the offer closest to the qualifying payment amount, which is the plan's offer.

(D) *Example 4*—(*1*) *Facts.* A nonparticipating provider and a group health plan are parties to a payment determination in the Federal IDR process. The plan submits credible information demonstrating that the patent for the item that is the subject of the payment determination has expired, including written documentation that demonstrates how much the cost of the item was at the time the provider rendered service and how the qualifying payment amount exceeds that cost. The plan submits an offer that is lower than the qualifying payment amount and commensurate with the cost of the item at the time service was rendered. The nonparticipating provider submits the qualifying payment amount as its offer and also submits credible information demonstrating the provider's level of training, experience, and quality and outcome measurements from 2019, but the provider does not explain how this additional information is relevant to the cost of the item.

(*2*) *Conclusion.* In this *Example 4,* both the nonparticipating provider and plan submitted information that is credible and that may be considered by the certified IDR entity. However, only the plan provided credible information that was relevant to the service that is the subject of the payment determination. Moreover, the plan has clearly demonstrated that the qualifying payment amount does not adequately take into account the complexity of the item furnished—in this case that the item is no longer patent protected. While the provider submitted credible information, the provider failed to show how the information was relevant to the item that is the subject of the payment determination. Accordingly, the certified IDR entity must select the offer that best represents the value of the item, which is the plan's offer in this example.

(v) *Prohibition on consideration of certain factors.* In determining which offer to select, the certified IDR entity must not consider:

(A) Usual and customary charges (including payment or reimbursement rates expressed as a proportion of usual and customary charges);

(B) The amount that would have been billed by the provider or facility with respect to the qualified IDR item or service had the provisions of 45 CFR 149.410 and 149.420 (as applicable) not applied; or

(C) The payment or reimbursement rate for items and services furnished by the provider or facility payable by a public payor, including under the Medicare program under title XVIII of the Social Security Act; the Medicaid program under title XIX of the Social Security Act; the Children's Health Insurance Program under title XXI of the Social Security Act; the TRICARE program under chapter 55 of title 10, United States Code; chapter 17 of title 38, United States Code; or demonstration projects under section 1115 of the Social Security Act.

(vi) *Written decision.* (A) The certified IDR entity must explain its determination in a written decision submitted to the parties and the Secretary, in a form and manner specified by the Secretary;

(B) If the certified IDR entity does not choose the offer closest to the qualifying payment amount, the certified IDR entity's written decision must include an explanation of the credible information that the certified IDR entity determined demonstrated that the qualifying payment amount was materially different from the appropriate out-of-network rate, based on the considerations allowed under paragraphs (c)(4)(iii)(B) through (D) of this section, with respect to the qualified IDR item or service.

(vii) *Effects of determination*—(A) *Binding.* A determination made by a certified IDR entity under paragraph (c)(4)(ii) of this section:

(*1*) Is binding upon the parties, in the absence of fraud or evidence of intentional misrepresentation of material facts presented to the certified IDR entity regarding the claim; and

(*2*) Is not subject to judicial review, except in a case described in any of paragraphs (1) through (4) of section 10(a) of title 9, United States Code.

(B) *Suspension of certain subsequent IDR requests.* In the case of a determination made by a certified IDR entity under paragraph (c)(4)(ii) of this section, the party that submitted the initial notification under paragraph (b)(2) of this section may not submit a subsequent notification involving the same other party with respect to a claim for the same or similar item or service that was the subject of the initial notification during the 90-calendar-day period following the determination.

(C) *Subsequent submission of requests permitted.* If the end of the open negotiation period specified in paragraph (b)(1) of this section occurs during the 90-calendar-day suspension period regarding claims for the same or similar item or service that were the subject of the initial notice of IDR determination as described in paragraph (c)(4)(vi) of this section, either party may initiate the Federal IDR process for those claims by submitting a notification as specified in paragraph (b)(2) of this section during the 30-business-day period beginning on the day after the last day of the 90-calendar-day suspension period.

(viii) *Recordkeeping requirements.* The certified IDR entity must maintain records of all claims and notices associated with the Federal IDR process with respect to any determination for 6 years. The certified IDR entity must make these records available for examination by the plan, provider, facility, provider of air ambulance services, or a State or Federal oversight agency upon request, except to the extent the disclosure would violate either State or Federal privacy law.

(ix) *Payment.* If applicable, the amount of the offer selected by the certified IDR entity (less the sum of the initial payment and any cost sharing paid or owed by the participant or beneficiary) must be paid directly to the provider, facility, or provider of air ambulance services not later than 30 calendar days after the determination by the certified IDR entity. If the offer selected by the certified IDR entity is less than the sum of the initial payment and any cost sharing paid by the participant or beneficiary, the provider, facility, or provider of air ambulance services will be liable to the plan for the difference. The provider, facility, or provider of air ambulance services must pay the difference directly to the plan not later than 30 calendar days after the determination by the certified IDR entity.

(d) *Costs of IDR process*—(1) *Certified IDR entity fee.* (i) With respect to the Federal IDR process described in paragraph (c) of this section, the party whose offer submitted to the certified IDR entity under paragraph (c)(4)(ii)(A) of this section is not selected is responsible for the payment to the certified IDR entity of the predetermined fee charged by the certified IDR entity.

(ii) Each party to a determination for which a certified IDR entity is selected under paragraph (c)(1) of this section must pay the predetermined certified

IDR entity fee charged by the certified IDR entity to the certified IDR entity at the time the parties submit their offers under (c)(4)(i) of this section. The certified IDR entity fee paid by the prevailing party whose offer is selected by the certified IDR entity will be returned to that party within 30 business days following the date of the certified IDR entity's determination.

(2) *Administrative fee.* (i) Each party to a determination for which a certified IDR entity is selected under paragraph (c)(1) of this section must, at the time the certified IDR entity is selected under paragraph (c)(1), pay to the certified IDR entity a non-refundable administrative fee due to the Secretary for participating in the Federal IDR process described in this section.

(ii) The administrative fee amount will be established in guidance published annually by the Secretary in a manner such that the total fees paid for a year are estimated to be equal to the projected amount of expenditures by the Departments of the Treasury, Labor, and Health and Human Services for the year in carrying out the Federal IDR process.

(e) *Certification of IDR entity*—(1) *In general.* In order to be selected under paragraph (c)(1) of this section—

(i) An IDR entity must meet the standards described in this paragraph (e) and be certified by the Secretary, jointly with the Secretaries of Health and Human Services and Labor, as set forth in this paragraph (e) and guidance promulgated by the Secretary. Once certified, the IDR entity will be provided with a certified IDR entity number.

(ii) An IDR entity must provide written documentation to the Secretary regarding general company information (such as contact information, Taxpayer Identification Number, and website), as well as the applicable service area in which the IDR entity intends to conduct payment determinations under the Federal IDR process. IDR entities may choose to submit their application for all States or self-limit to a particular subset of States.

(iii) An IDR entity that the Secretary, jointly with the Secretary of Labor and the Secretary of Health and Human Services, certifies must enter into an agreement as a condition of certification. The agreement shall include specified provisions encompassed by this section, including, but not limited to, the requirements applicable to certified IDR entities when making payment determinations, as well as the requirements regarding certification and revocation (such as specifications for wind-down activities and reallocation of certified IDR entity fees, where warranted).

(2) *Requirements.* An IDR entity must provide written documentation to the Secretary through the Federal IDR portal that demonstrates that the IDR entity satisfies the following standards to be a certified IDR entity under this paragraph (e):

(i) Possess (directly or through contracts or other arrangements) sufficient arbitration and claims administration of health care services, managed care, billing and coding, medical and legal expertise to make the payment determinations described in paragraph (c) of this section within the time prescribed in paragraph (c)(4)(ii) of this section.

(ii) Employ (directly or through contracts or other arrangements) a sufficient number of personnel to make the determinations described in paragraph (c) of this section within the time prescribed by (c)(4)(ii) of this section. To satisfy this standard, the written documentation must include a description of the IDR entity's organizational structure and capabilities, including an organizational chart and the credentials, responsibilities, and number of personnel employed to make determinations described in paragraph (c) of this section.

(iii) Maintain a current accreditation from a nationally recognized and relevant accrediting organization, such as URAC, or ensure that it otherwise possesses the requisite training to conduct payment determinations (for example, providing documentation that personnel employed by the IDR entity have completed arbitration training by the American Arbitration Association, the American Health Law Association, or a similar organization);

(iv) Have a process to ensure that no conflict of interest, as defined in paragraph (a)(2) of this section, exists between the parties and the personnel the certified IDR entity assigns to a payment determination to avoid violating paragraph (c)(1)(ii) of this section, including policies and procedures for conducting ongoing audits for conflicts of interest, to ensure that should any conflicts of interest arise, the certified IDR entity has procedures in place to inform the Secretary, jointly with the Secretary of Health and Human Services and the Secretary of Labor, of the conflict of interest and to mitigate the risk by reassigning the dispute to other personnel in the event that any personnel previously assigned have a conflict of interest.

(v) Have a process to maintain the confidentiality of IIHI obtained in the course of conducting determinations. A certified IDR entity's responsibility to comply with these confidentiality requirements shall survive revocation of the IDR entity's certification for any reason, and IDR entities must comply with the record retention and disposal requirements described in this section. Under this process, once certified, the certified IDR entity must comply with the following requirements:

(A) *Privacy.* The certified IDR entity may create, collect, handle, disclose, transmit, access, maintain, store, and/or use IIHI, only to perform:

(*1*) The certified IDR entity's required duties described in this section; and

(*2*) Functions related to carrying out additional obligations as may be required under applicable Federal or State laws or regulations.

(B) *Security.* (*1*) The certified IDR entity must ensure the confidentiality of all IIHI it creates, obtains, maintains, stores, and transmits;

(*2*) The certified IDR entity must protect against any reasonably anticipated threats or hazards to the security of this information;

(*3*) The certified IDR entity must ensure that IIHI is securely destroyed or disposed of in an appropriate and reasonable manner 6 years from either the date of its creation or the first date on which the certified IDR entity had access to it, whichever is earlier;

(*4*) The certified IDR entity must implement policies and procedures to prevent, detect, contain, and correct security violations in the event of a breach of IIHI;

(C) *Breach notification.* The certified IDR entity must, following the discovery of a breach of unsecured IIHI, notify of the breach the provider, facility, or provider of air ambulance services; the plan; the Secretary, jointly with the Secretary of Health and Human Services and the Secretary of Labor; and each individual whose unsecured IIHI has been, or is reasonably believed to have been, subject to the breach, to the extent possible.

(*1*) *Breaches treated as discovered.* For purposes of this paragraph (e)(2)(v)(C), a breach shall be treated as discovered by a certified IDR entity as of the first day on which the breach is known to the certified IDR entity or, by exercising reasonable diligence, would have been known to the certified IDR entity. A certified IDR entity shall be deemed to have knowledge of a breach if the breach is known, or by exercising reasonable diligence would have been known, to any person, other than the person committing the breach, who is

an employee, officer, or other agent of the certified IDR entity;

(*2*) *Timing of notification.* A certified IDR entity must provide the notification required by this paragraph (e)(2)(v)(C) without unreasonable delay and in no case later than 60 calendar days after discovery of a breach.

(*3*) *Content of notification.* The notification required by this paragraph (e)(2)(v)(C) must include, to the extent possible:

(*i*) The identification of each individual whose unsecured IIHI has been, or is reasonably believed by the certified IDR entity to have been, subject to the breach;

(*ii*) A brief description of what happened, including the date of the breach and the date of the discovery of the breach, to the extent known;

(*iii*) A description of the types of unsecured IIHI that were involved in the breach (for example whether full name, social security number, date of birth, home address, account number, diagnosis, disability code, or other types of information were involved);

(*iv*) A brief description of what the certified IDR entity involved is doing to investigate the breach, to mitigate harm to the affected parties, and to protect against any further breaches; and

(*v*) Contact procedures for individuals to ask questions or learn additional information, which must include a toll-free telephone number, email address, website, or postal address.

(*4*) *Method for providing notification.* A certified IDR entity must submit the notification required by this paragraph (e)(2)(v)(C) in written form (in clear and understandable language) either on paper or electronically through the Federal IDR portal or electronic mail.

(D) *Application to contractor and subcontractors.* The certified IDR entity must ensure compliance with this paragraph (e)(2)(v) of this section by any contractor or subcontractor with access to IIHI performing any duties related to the Federal IDR process.

(vi) Meet appropriate indicators of fiscal integrity and stability by demonstrating that the certified IDR entity has a system of safeguards and controls in place to prevent and detect improper financial activities by its employees and agents to assure fiscal integrity and accountability for all certified IDR entity fees and administrative fees received, held, and disbursed and by submitting 3 years of financial statements or, if not available, other information to demonstrate fiscal stability of the IDR entity;

(vii) Provide a fixed fee for single determinations and a separate fixed fee for batched determinations within the upper and lower limits for each, as set forth in guidance issued by the Secretary. The certified IDR entity may not charge a fee that is not within the approved limits as set forth in guidance unless the certified IDR entity or IDR entity seeking certification receives written approval from the Secretary to charge a flat rate beyond the upper or lower limits approved by the Secretary for fees. The certified IDR entity or IDR entity seeking certification may update its fees and seek approval from the Secretary to charge a flat fee beyond the upper or lower limits for fees annually as provided in guidance. In order for the certified IDR entity to receive the Secretary's written approval to charge a flat fee beyond the upper or lower limits for fees as set forth in guidance, it must satisfy both conditions in paragraphs (e)(2)(vii)(A) and (B) of this section as follows:

(A) Submit, in writing, a proposal to the Secretary that includes:

(*1*) The alternative flat fee the certified IDR entity or IDR entity seeking certification believes is appropriate for the certified IDR entity or IDR entity seeking certification to charge;

(*2*) A description of the circumstances that require the alternative fee; and

(*3*) A description of how the alternative flat rate will be used to mitigate the effects of these circumstances; and

(B) Receive from the Secretary, jointly with the Secretary of Health and Human Services and the Secretary of Labor, written approval to charge the fee documented in the certified IDR entity's or the IDR entity seeking certification's written proposal.

(viii) Have a procedure in place to retain the certified IDR entity fees described in paragraph (d)(1) of this section paid by both parties in a trust or escrow account and to return the certified IDR entity fee paid by the prevailing party of an IDR payment determination, or half of each party's certified IDR entity fee in the case of an agreement described in paragraph (c)(2)(i) of this section, within 30 business days following the date of the determination;

(ix) Have a procedure in place to retain the administrative fees described in paragraph (d)(2) of this section and to remit the administrative fees to the Secretary in accordance with the timeframe and procedures set forth in guidance published by the Secretary;

(x) Discharge its responsibilities in accordance with paragraph (c) of this section, including not making any determination with respect to which the certified IDR entity would not be eligible for selection pursuant to paragraph (c)(1) of this section; and

(xi) Collect the information required to be reported to the Secretary under paragraph (f) of this section and report the information on a timely basis in the form and manner provided in guidance published by the Secretary.

(3) *Conflict-of-interest standards.* In addition to the general standards set forth in paragraph (e)(2)(iv) of this section, an IDR entity must provide written documentation that the IDR entity satisfies the standards to be a certified IDR entity under this paragraph (e)(3).

(i) The IDR entity must provide an attestation indicating that it does not have a conflict of interest as defined in paragraph (a)(2) of this section;

(ii) The IDR entity must have procedures in place to ensure that personnel assigned to a determination do not have any conflicts of interest regarding any party to the dispute within the 1 year immediately preceding an assignment of dispute determination, similar to the requirements laid out in 18 U.S.C. 207(b). In order to satisfy this requirement, if certified, the IDR entity must ensure that any personnel assigned to a determination do not have any conflicts of interest as defined in paragraph (a)(2) of this section.

(iii) Following certification under this paragraph (e), if a certified IDR entity acquires control of, becomes controlled by, or comes under common control with any entity described in paragraph (e)(3)(i) of this section, the certified IDR entity must notify the Secretary in writing no later than 3 business days after the acquisition or exercise of control and shall be subject to revocation of certification under paragraph (e)(6)(ii) of this section.

(4) *Period of certification.* Subject to paragraphs (e)(5) and (6) of this section, each certification (including a recertification) of a certified IDR entity under the process described in paragraph (e)(1) of this section will be effective for a 5-year period.

(5) *Petition for denial or revocation*—(i) *In general.* An individual, provider, facility, provider of air ambulance services, plan, or issuer may petition for a denial of a certification for an IDR entity or a revocation of a certification for a certified IDR entity for failure to meet a requirement of this section using the standard form and manner set forth in guidance issued by the Secretary. The petition for denial of a certification must be submitted within the timeframe set forth in guidance issued by the Secretary.

(ii) *Content of petition.* The individual, provider, facility, provider of air ambulance services, plan, or issuer seeking denial or revocation of certification must submit a written petition using the standard form issued by the Secretary including the following information:

(A) The identity of the IDR entity seeking certification or certified IDR entity that is the subject of the petition;

(B) The reason(s) for the petition;

(C) Whether the petition seeks denial or revocation of a certification;

(D) Documentation to support the reasons outlined in the petition; and

(E) Other information as may be required by the Secretary.

(iii) *Process.* (A) The Secretary, jointly with the Secretary of Health and Human Services and the Secretary of Labor, will acknowledge receipt of the petition within 10 business days of receipt of the petition.

(B) If the Secretary finds that the petition adequately shows a failure of the IDR entity seeking certification or the certified IDR entity to follow the requirements of this paragraph (e), the Secretary, jointly with the Secretary of Health and Human Services and the Secretary of Labor, will notify the IDR entity seeking certification or the certified IDR entity by providing a de-identified copy of the petition. Following the notification, the IDR entity seeking certification or certified IDR entity will have 10 business days to provide a response. After the time period for providing the response has passed, the Secretary, jointly with the Secretary of Health and Human Services and the Secretary of Labor, will review the response (if any), determine whether a denial or revocation of a certification is warranted, and issue a notice of the decision to the IDR entity or certified IDR entity and to the petitioner. This decision will be subject to the appeal requirements of paragraph (e)(6)(v) of this section.

(C) Effect on certification under petition. Regarding a petition for revocation of a certified IDR entity's certification, if the Secretary, jointly with the Secretary of Health and Human Services and the Secretary of Labor, finds that the petition adequately shows a failure to comply with the requirements of this paragraph (e), following the Secretary's notification of the failure to the certified IDR entity under paragraph (e)(5)(iii)(B) of this section, the certified IDR entity may continue to work on previously assigned determinations but may not accept new determinations until the Secretary issues a notice of the decision to the certified IDR entity finding that a revocation of certification is not warranted.

(6) *Denial of IDR entity certification or revocation of certified IDR entity certification*—(i) *Denial of IDR entity certification.* The Secretary, jointly with the Secretary of Health and Human Services and the Secretary of Labor, may deny the certification of an IDR entity under paragraph (e)(1) of this section if, during the process of certification, including as a result of a petition described in paragraph (e)(5) of this section, the Secretary determines the following:

(A) The IDR entity fails to meet the applicable standards set forth under this paragraph (e);

(B) The IDR entity has committed or participated in fraudulent or abusive activities, including, during the certification process, submitting fraudulent data, or submitting information or data the IDR entity knows to be false to the Secretary, the Secretary of Health and Human Services, or the Secretary of Labor;

(C) The IDR entity has failed to comply with requests for information from the Secretary, the Secretary of Health and Human Services, or the Secretary of Labor as part of the certification process;

(D) In conducting payment determinations, including those outside the Federal IDR process, the IDR entity has failed to meet the standards that applied to those determinations or reviews, including standards of independence and impartiality; or

(E) The IDR entity is otherwise not fit or qualified to make determinations under the Federal IDR process.

(ii) *Revocation of certification of a certified IDR entity.* The Secretary, jointly with the Secretary of Health and Human Services and the Secretary of Labor, may revoke the certification of a certified IDR entity under paragraph (e)(1) of this section if, as a result of an audit, a petition described in paragraph (e)(5) of this section, or otherwise, the Secretary determines the following:

(A) The certified IDR entity has a pattern or practice of noncompliance with any requirements of this paragraph (e);

(B) The certified IDR entity is operating in a manner that hinders the efficient and effective administration of the Federal IDR process;

(C) The certified IDR entity no longer meets the applicable standards for certification set forth under this paragraph (e);

(D) The certified IDR entity has committed or participated in fraudulent or abusive activities, including submission of false or fraudulent data to the Secretary, the Secretary of Health and Human Services, or the Secretary of Labor;

(E) The certified IDR entity lacks the financial viability to provide arbitration under the Federal IDR process;

(F) The certified IDR entity has failed to comply with requests from the Secretary, the Secretary of Health and Human Services, or the Secretary of Labor made as part of an audit, including failing to submit all records of the certified IDR entity that pertain to its activities within the Federal IDR process; or

(G) The certified IDR entity is otherwise no longer fit or qualified to make determinations.

(iii) *Notice of denial or revocation.* The Secretary, jointly with the Secretary of Health and Human Services and the Secretary of Labor, will issue a written notice of denial to the IDR entity or revocation to the certified IDR entity within 10 business days of the Secretary's decision, including the effective date of denial or revocation, the reason(s) for denial or revocation, and the opportunity to request appeal of the denial or revocation.

(iv) *Request for appeal of denial or revocation.* To request an appeal, the IDR entity or certified IDR entity must submit a request for appeal to the Secretary within 30 business days of the date of the notice under paragraph (e)(6)(iii) of this section of denial or revocation and in the manner prescribed by the instructions to the notice. During this time period, the Secretary, jointly with the Secretary of Health and Human Services and the Secretary of Labor, will not issue a notice of final denial or revocation and a certified IDR entity may continue to work on previously assigned determinations but may not accept new determinations. If the IDR entity or certified IDR entity does not timely submit a request for appeal of the denial or revocation, the Secretary, jointly with the Secretary of Health and Human Services and the Secretary of Labor, will issue a notice of final denial or revocation to the IDR entity or certified IDR entity (if applicable) and the petitioner.

(v) *Denial or final revocation.* Upon notice of denial or final revocation, the IDR entity shall not be considered a certified IDR entity and therefore shall not be eligible to accept payment determinations under the Federal IDR process. Moreover, after a notice of final revocation, the IDR entity may not re-apply to be a certified IDR entity until on or after the 181st day after the date of the notice of denial or final revocation.

(f) *Reporting of information relating to the Federal IDR process*—(1) *Reporting of information.* Within 30 business days of the close of each month, for qualified IDR items and services furnished on or after January 1, 2022, each certified IDR entity must, in a form and manner specified by the Secretary, report:

(i) The number of notices of IDR initiation submitted under paragraph (b)(2) of this section to the certified IDR entity during the immediately preceding month;

(ii) The size of the provider practices and the size of the facilities submitting notices of IDR initiation under paragraph (b)(2) of this section during the immediately preceding month, as required to be provided to the certified IDR entity under paragraph (c)(4)(i)(A)(*2*) of this section;

(iii) The number of such notices of IDR initiation with respect to which a determination was made under paragraph (c)(4)(ii) of this section;

(iv) The number of times during the month that the out-of-network rate determined (or agreed to) under this section has exceeded the qualifying payment amount, specified by qualified IDR items and services;

(v) With respect to each notice of IDR initiation under paragraph (b)(2) of this section for which such a determination was made, the following information:

(A) A description of the qualified IDR items and services included with respect to the notification, including the relevant billing and service codes;

(B) The relevant geographic region for purposes of the qualifying payment amount for the qualified IDR items and services with respect to which the notification was provided;

(C) The amount of the offer submitted under paragraph (c)(4)(i) of this section by the plan and by the provider or facility (as applicable) expressed as a dollar amount and as a percentage of the qualifying payment amount;

(D) Whether the offer selected by the certified IDR entity under paragraph (c)(4) of this section was the offer submitted by the plan or by the provider or facility (as applicable);

(E) The amount of the selected offer expressed as a dollar amount and as a percentage of the qualifying payment amount;

(F) The rationale for the certified IDR entity's decision, including the extent to which the decision relied on the criteria in paragraph (c)(4)(iv) of this section;

(G) The practice specialty or type of each provider or facility, respectively, involved in furnishing each qualified IDR item or service;

(H) The identity for each plan, and provider or facility, with respect to the notification. Specifically, each certified IDR entity must provide each party's name and address, as applicable; and

(I) For each determination, the number of business days elapsed between selection of the certified IDR entity and the determination of the out-of-network rate by the certified IDR entity.

(vi) The total amount of certified IDR entity fees paid to the certified IDR entity under paragraph (d)(1) of this section during the month.

(g) *Extension of time periods for extenuating circumstances*—(1) *General.* The time periods specified in this section (other than the time for payment, if applicable, under paragraph (c)(4)(ix) of this section) may be extended in extenuating circumstances at the Secretary's discretion if:

(i) An extension is necessary to address delays due to matters beyond the control of the parties or for good cause; and

(ii) The parties attest that prompt action will be taken to ensure that the determination under this section is made as soon as administratively practicable under the circumstances.

(2) *Process to request an extension.* The parties may request an extension by submitting a request for extension due to extenuating circumstances through the Federal IDR portal if the extension is necessary to address delays due to matters beyond the control of the parties or for good cause.

(h) *Applicability date.* The provisions of this section are applicable with respect to plan years beginning on or after January 1, 2022, except that the provisions regarding IDR entity certification at paragraphs (a) and (e) of this section are applicable beginning on October 7, 2021.

■ 8. Section 54.9817–2T is added to read as follows:

§ 54.9817–2T Independent dispute resolution process for air ambulance services (temporary).

(a) *Definitions.* Unless otherwise stated, the definitions in § 54.9816–3T apply.

(b) *Determination of out-of-network rates to be paid by group health plans; independent dispute resolution process*—(1) *In general.* Except as provided in paragraphs (b)(2) and (3) of this section, in determining the out-of-network rate to be paid by group health plans for out-of-network air ambulance services, plans must comply with the requirements of § 54.9816–8T, except that references in § 54.9816–8T to the additional circumstances in § 54.9816–8T(c)(4)(iii)(C) shall be understood to refer to § 54.9817–2T(b)(2).

(2) *Additional information.* Additional information submitted by a party, provided the information is credible, relates to the circumstances described in paragraphs (b)(2)(i) through (vi) of this section, with respect to a qualified IDR service of a nonparticipating provider of air ambulance services or group health plan that is the subject of a payment determination. This information must also clearly demonstrate that the qualifying payment amount is materially different from the appropriate out-of-network rate.

(i) The quality and outcomes measurements of the provider that furnished the services.

(ii) The acuity of the condition of the participant or beneficiary receiving the service, or the complexity of furnishing the service to the participant or beneficiary.

(iii) The training, experience, and quality of the medical personnel that furnished the air ambulance services.

(iv) Ambulance vehicle type, including the clinical capability level of the vehicle.

(v) Population density of the point of pick-up (as defined in 42 CFR 414.605) for the air ambulance (such as urban, suburban, rural, or frontier).

(vi) Demonstrations of good faith efforts (or lack thereof) made by the nonparticipating provider of air ambulance services or the plan to enter into network agreements with each other and, if applicable, contracted rates between the provider of air ambulance services and the plan during the previous 4 plan years.

(3) *Reporting of information relating to the IDR process.* In applying the requirements of § 54.9816–8T(f), within 30 business days of the close of each month, for services furnished on or after January 1, 2022, the information the certified IDR entity must report, in a form and manner specified by the Secretary, with respect to the Federal IDR process involving air ambulance services is:

(i) The number of notices of IDR initiation submitted under the Federal IDR process to the certified IDR entity that pertain to air ambulance services during the immediately preceding month;

(ii) The number of such notices of IDR initiation with respect to which a final determination was made under § 54.9816–8T(c)(4)(ii) (as applied by paragraph (b)(1) of this section);

(iii) The number of times the payment amount determined (or agreed to) under this subsection has exceeded the qualifying payment amount, specified by services;

(iv) With respect to each notice of IDR initiation under § 54.9816–8T(b)(2) (as applied by paragraph (b)(1) of this section) for which a determination was made, the following information:

(A) A description of each air ambulance service included in such notification, including the relevant billing and service codes;

(B) The point of pick-up (as defined in 42 CFR 414.605) for the services included in such notification;

(C) The amount of the offers submitted under § 54.9816–8T(c)(4)(i) (as applied by paragraph (b)(1) of this section) by the group health plan and by the nonparticipating provider of air ambulance services, expressed as a dollar amount and as a percentage of the qualifying payment amount;

(D) Whether the offer selected by the certified IDR entity under § 54.9816–8T(c)(4)(ii) (as applied by paragraph (b)(1) of this section) to be the payment amount applied was the offer submitted by the plan or by the provider of air ambulance services;

(E) The amount of the selected offer expressed as a dollar amount and as a percentage of the qualifying payment amount;

(F) The rationale for the certified IDR entity's decision, including the extent to which the decision relied on the criteria in paragraph (b)(2) of this section;

(G) Air ambulance vehicle type, including the clinical capability level of such vehicle (to the extent this information has been provided to the certified IDR entity);

(H) The identity for each plan and provider of air ambulance services, with respect to the notification. Specifically, each certified IDR entity must provide each party's name and address, as applicable; and

(I) For each determination, the number of business days elapsed between selection of the certified IDR entity and the selection of the payment amount by the certified IDR entity.

(v) The total amount of certified IDR entity fees paid to the certified IDR entity under paragraph § 54.9816–8T(d)(1) (as applied by paragraph (b)(1) of this section) during the month for determinations involving air ambulance services.

(c) *Applicability date.* The provisions of this section are applicable with respect to plan years beginning on or after January 1, 2022.

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 continues to read as follows:

Authority: 29 U.S.C. 1027, 1059, 1135, 1161–1168, 1169, 1181–1183, 1181 note, 1185, 1185a–n, 1191, 1191a, 1191b, and 1191c; sec. 101(g), Pub. L. 104–191, 110 Stat. 1936; sec. 401(b), Pub. L. 105–200, 112 Stat. 645 (42 U.S.C. 651 note); sec. 512(d), Pub. L. 110–343, 122 Stat. 3881; sec. 1001, 1201, and 1562(e), Pub. L. 111–148, 124 Stat. 119, as amended by Pub. L. 111–152, 124 Stat. 1029; Division M, Pub. L. 113–235, 128 Stat. 2130; Secretary of Labor's Order 1–2011, 77 FR 1088 (Jan. 9, 2012).

Subpart C—Other Requirements

■ 10. Section 2590.715–2719 is amended by:

■ a. Revising paragraphs (a)(1), (c)(2)(i), and (d)(1)(i)(A) and (B);

■ b. Adding paragraph (d)(1)(i)(C);

■ c. Adding Examples 3 through 7 to paragraph (d)(1)(ii); and

■ d. Revising paragraph (g).

The revisions and additions read as follows:

§ 2590.715–2719 Internal claims and appeals and external review processes.

(a) *Scope and definitions*—(1) *Scope*—(i) *In general.* This section sets forth requirements with respect to internal claims and appeals and external review processes for group health plans and health insurance issuers. Paragraph (b) of this section provides requirements for internal claims and appeals processes. Paragraph (c) of this section sets forth rules governing the applicability of State external review processes. Paragraph (d) of this section sets forth a Federal external review process for plans and issuers not subject to an applicable State external review process. Paragraph (e) of this section prescribes requirements for ensuring that notices required to be provided under this section are provided in a culturally and linguistically appropriate manner. Paragraph (f) of this section describes the authority of the Secretary to deem certain external review processes in existence on March 23, 2010 as in compliance with paragraph (c) or (d) of this section.

(ii) *Application to grandfathered health plans and health insurance coverage.* The provisions of this section generally do not apply to coverage offered by health insurance issuers and group health plans that are grandfathered health plans, as defined under § 2590.715–1251. However, the external review process requirements under paragraphs (c) and (d) of this section, and related notice requirements under paragraph (e) of this section, apply to grandfathered health plans or coverage with respect to adverse benefit determinations involving items and services within the scope of the requirements for out-of-network emergency services, nonemergency services performed by nonparticipating providers at participating facilities, and air ambulance services furnished by nonparticipating providers of air ambulance services under ERISA sections 716 and 717 and §§ 2590.716–4 through 2590.716–5 and 2590.717–1.

* * * * *

(c) * * *

(2) * * *

(i) The State process must provide for the external review of adverse benefit determinations (including final internal adverse benefit determinations) by issuers (or, if applicable, plans) that are based on the issuer's (or plan's) requirements for medical necessity, appropriateness, health care setting, level of care, or effectiveness of a covered benefit, as well as a consideration of whether a plan or issuer is complying with the surprise billing and cost-sharing protections under ERISA sections 716 and 717 and §§ 2590.716–4 through 2590.716–5 and 2590.717–1.

* * * * *

(d) * * *

(1) * * *

(i) * * *

(A) An adverse benefit determination (including a final internal adverse benefit determination) by a plan or issuer that involves medical judgment (including, but not limited to, those based on the plan's or issuer's requirements for medical necessity, appropriateness, health care setting, level of care, or effectiveness of a covered benefit; its determination that a treatment is experimental or investigational; its determination whether a participant or beneficiary is entitled to a reasonable alternative standard for a reward under a wellness program; its determination whether a plan or issuer is complying with the nonquantitative treatment limitation provisions of ERISA section 712 and § 2590.712, which generally require, among other things, parity in the application of medical management techniques), as determined by the external reviewer. (A denial, reduction, termination, or a failure to provide payment for a benefit based on a determination that a participant or beneficiary fails to meet the

requirements for eligibility under the terms of a group health plan or health insurance coverage is not eligible for the Federal external review process under this paragraph (d));

(B) An adverse benefit determination that involves consideration of whether a plan or issuer is complying with the surprise billing and cost-sharing protections set forth in ERISA sections 716 and 717 and §§ 2590.716–4 through 2590.716–5 and 2590.717–1; and

(C) A rescission of coverage (whether or not the rescission has any effect on any particular benefit at that time).

(ii) * * *

Example 3. (i) *Facts.* A group health plan generally provides benefits for services in an emergency department of a hospital or independent freestanding emergency department. Individual *C* receives pre-stabilization emergency treatment in an out-of-network emergency department of a hospital. The group health plan determines that protections for emergency services under § 2590.716–4 do not apply because the treatment did not involve ''emergency services'' within the meaning of § 2590.716–4(c)(2)(i). *C* receives an adverse benefit determination and the plan imposes cost-sharing requirements that are greater than the requirements that would apply if the same services were provided in an in-network emergency department.

(ii) *Conclusion.* In this *Example 3,* the plan's determination that treatment received by *C* did not include emergency services involves medical judgment and consideration of whether the plan complied with § 2590.716–4. Accordingly, the claim is eligible for external review under paragraph (d)(1)(i) of this section.

* * * * *

Example 4. (i) *Facts.* A group health plan generally provides benefits for anesthesiology services. Individual *D* undergoes a surgery at an in-network health care facility and during the course of the surgery, receives anesthesiology services from an out-of-network provider. The plan decides the claim for these services without regard to the protections related to items and services furnished by out-of-network providers at in-network facilities under § 2590.716–5. As a result, *D* receives an adverse benefit determination for the services and is subject to cost-sharing liability that is greater than it would be if cost sharing had been calculated in a manner consistent with the requirements of § 2590.716–5.

(ii) *Conclusion.* In this *Example 4,* whether the plan was required to decide the claim in a manner consistent with the requirements of § 2590.716–5 involves considering whether the plan complied with § 2590.716–5, as well as medical judgment, because it requires consideration of the health care setting and level of care. Accordingly, the claim is eligible for external review under paragraph (d)(1)(i) of this section.

Example 5. (i) *Facts.* A group health plan generally provides benefits for services in an emergency department of a hospital or independent freestanding emergency department. Individual *E* receives emergency services in an out-of-network emergency department of a hospital, including certain post-stabilization services. The plan processes the claim for the post-stabilization services as not being for emergency services under § 2590.716–4(c)(2)(ii) based on representations made by the treating provider that *E* was in a condition to receive notice from the provider about cost-sharing and surprise billing protections for these services and subsequently gave informed consent to waive those protections. *E* receives an adverse benefit determination and is subject to cost-sharing requirements that are greater than the cost-sharing requirements that would apply if the services were processed in a manner consistent with § 2590.716–4.

(ii) *Conclusion.* In this *Example 5,* whether *E* was in a condition to receive notice about the availability of cost-sharing and surprise billing protections and give informed consent to waive those protections involves medical judgment and consideration of whether the plan complied with the requirements under § 2590.716–4(c)(2)(ii). Accordingly, the claim is eligible for external review under paragraph (d)(1)(i) of this section.

Example 6. (i) *Facts.* Individual *F* gives birth to a baby at an in-network hospital. The baby is born prematurely and receives certain neonatology services from a nonparticipating provider during the same visit as the birth. *F* was given notice about cost-sharing and surprise billing protections for these services, and subsequently gave informed consent to waive those protections. The claim for the neonatology services is coded as a claim for routine post-natal services and the plan decides the claim without regard to the requirements under § 2590.716–5(a) and the fact that those protections may not be waived for neonatology services under § 2590.716–5(b).

(ii) *Conclusion.* In this *Example 6,* medical judgment is necessary to determine whether the correct code was used and compliance with § 2590.716–5(a) and (b) must also be considered. Accordingly, the claim is eligible for external review under paragraph (d)(1)(i) of this section. The Departments also note that, to the extent the nonparticipating provider balance bills Individual *F* for the outstanding amounts not paid by the plan for the neonatology services, such provider would be in violation of PHS Act section 2799B–2 and its implementing regulations at 45 CFR 149.420(a).

Example 7. (i) *Facts.* A group health plan generally provides benefits to cover knee replacement surgery. Individual *G* receives a knee replacement surgery at an in-network facility and, after receiving proper notice about the availability of cost-sharing and surprise billing protections, provides informed consent to waive those protections. However, during the surgery, certain anesthesiology services are provided by an out-of-network nurse anesthetist. The claim for these anesthesiology services is decided by the plan without regard to the requirements under § 2590.716–5(a) or to the fact that those protections may not be waived for ancillary services such as anesthesiology services provided by an out-of-network provider at an in-network facility under § 2590.716–5(b). *G* receives an adverse benefit determination and is subject to cost-sharing requirements that are greater than the cost-sharing requirements that would apply if the services were provided in a manner consistent with § 2590.716–5(a) and (b).

(ii) *Conclusion.* In this *Example 7,* consideration of whether the plan complied with the requirements in § 2590.716–5(a) and (b) is necessary to determine whether cost-sharing requirements were applied appropriately. Accordingly, the claim is eligible for external review under paragraph (d)(1)(i) of this section.

* * * * *

(g) *Applicability date.* The provisions of this section generally are applicable to group health plans and health insurance issuers for plan years beginning on or after January 1, 2017. The external review scope provision at paragraph (d)(1)(i)(B) of this section is applicable for plan years beginning on or after January 1, 2022. The external review provisions described in paragraphs (c) and (d) of this section are applicable to grandfathered health plans, with respect to the types of claims specified under paragraph (a)(1)(ii) of this section, for plan years beginning on or after January 1, 2022.

■ 11. Section 2590.716–1 is amended by revising paragraph (b) to read as follows:

§ 716–1 Basis and scope.

* * * * *

(b) *Scope.* This part establishes standards for group health plans, and health insurance issuers offering group or individual health insurance coverage with respect to surprise medical bills, transparency in health care coverage, and additional patient protections. This part also establishes an independent dispute resolution process, and standards for certifying independent dispute resolution entities.

■ 12. Section 2590.716–2 is amended by revising paragraph (a) and paragraph (b) introductory text to read as follows:

§ 2590.716–2 Applicability.

(a) *In general.* (1) 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.

(2) The requirements in §§ 54.9816–8T and 54.9817–2T apply to certified IDR entities and 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 2590.716–8, 2590.717–1, 2590.717–2 and 2590.722 do not apply to the following:

* * * * *

■ 13. Section 2590.716–8 is added to read as follows:

§ 2590.716—8 Independent dispute resolution process.

(a) *Scope and definitions*–(1) *Scope.* This section sets forth requirements with respect to the independent dispute resolution (IDR) process (referred to in this section as the Federal IDR process) under which a nonparticipating provider, nonparticipating emergency facility, or nonparticipating provider of air ambulance services (as applicable), and a group health plan or health insurance issuer offering group health insurance coverage completes a requisite open negotiation period and at least one party submits a notification under paragraph (b) of this section to initiate the Federal IDR process under paragraph (c) of this section, and under which an IDR entity (as certified under paragraph (e) of this section) determines the amount of payment under the plan or coverage for an item or service furnished by the provider or facility.

(2) *Definitions.* Unless otherwise stated, the definitions in § 2590.716–3 of this part apply to this section. Additionally, for purposes of this section, the following definitions apply:

(i) *Batched items and services* means multiple qualified IDR items or services that are considered jointly as part of one payment determination by a certified IDR entity for purposes of the Federal IDR process. In order for a qualified IDR item or service to be included in a batched item or service, the qualified IDR item or service must meet the criteria set forth in paragraph (c)(3) of this section.

(ii) *Breach* means the acquisition, access, use, or disclosure of individually identifiable health information (IIHI) in a manner not permitted under paragraph (e)(2)(v) of this section that compromises the security or privacy of the IIHI.

(A) Breach excludes:

(*1*) Any unintentional acquisition, access, or use of IIHI by personnel, a contractor, or a subcontractor of a certified IDR entity that is acting under the authority of that certified IDR entity, if the acquisition, access, or use was made in good faith and within the scope of that authority and that does not result in further use or disclosure in a manner not permitted under paragraph (e)(2)(v) of this section.

(*2*) Any inadvertent disclosure by a person who is authorized to access IIHI at a certified IDR entity to another person authorized to access IIHI at the same certified IDR entity, and the information received as a result of the disclosure is not further used or disclosed in a manner not permitted under paragraph (e)(2)(v) of this section.

(*3*) A disclosure of IIHI in which a certified IDR entity has a good faith belief that an unauthorized person to whom the disclosure was made would not reasonably have been able to retain such information.

(B) Except as provided in paragraph (a)(2)(ii)(A) of this section, access, use, or disclosure of IIHI in a manner not permitted under paragraph (e)(2)(v) of this section is presumed to be a breach unless the certified IDR entity demonstrates that there is a low probability that the security or privacy of the IIHI has been compromised based on a risk assessment encompassing at least the following factors:

(*1*) The nature and extent of the IIHI involved, including the types of identifiers and the likelihood of re-identification;

(*2*) The unauthorized person who used the IIHI or to whom the disclosure was made;

(*3*) Whether the IIHI was actually acquired or viewed; and

(*4*) The extent to which the risk to the IIHI has been mitigated.

(iii) *Certified IDR entity* means an entity responsible for conducting determinations under paragraph (c) of this section that meets the certification criteria specified in paragraph (e) of this section and that has been certified by the Secretary, jointly with the Secretaries of Health and Human Services and the Treasury.

(iv) *Conflict of interest* means, with respect to a party to a payment determination, or certified IDR entity, a material relationship, status, or condition of the party, or certified IDR entity that impacts the ability of the certified IDR entity to make an unbiased and impartial payment determination. For purposes of this section, a conflict of interest exists when a certified IDR entity is:

(A) A group health plan; a health insurance issuer offering group health insurance coverage, individual health insurance coverage, or short-term, limited-duration insurance; a carrier offering a health benefits plan under 5 U.S.C. 8902; or a provider, a facility, or a provider of air ambulance services;

(B) An affiliate or a subsidiary of a group health plan; a health insurance issuer offering group health insurance coverage, individual health insurance coverage, or short-term limited-duration insurance; a carrier offering a health benefits plan under 5 U.S.C. 8902; or a provider, a facility, or a provider of air ambulance services;

(C) An affiliate or subsidiary of a professional or trade association representing group health plans; health insurance issuers offering group health insurance coverage, individual health insurance coverage, or short-term limited duration insurance; carriers offering a health benefits plan under 5 U.S.C. 8902; or providers, facilities, or providers of air ambulance services.

(D) A certified IDR entity, that has, or that has any personnel, contractors, or subcontractors assigned to a determination who have, a material familial, financial, or professional relationship with a party to the payment determination being disputed, or with any officer, director, or management employee of the plan, issuer, or carrier offering a health benefits plan under 5 U.S.C. 8902; the plan administrator, plan fiduciaries, or plan, issuer, or carrier employees; the health care provider, the health care provider's group or practice association; the provider of air ambulance services, the provider of air ambulance services' group or practice association, or the facility that is a party to the dispute.

(v) *Credible information* means information that upon critical analysis is worthy of belief and is trustworthy.

(vi) *IDR entity* means an entity that may apply or has applied for certification to conduct determinations under paragraph (c) of this section, and that currently is not certified by the Secretary, jointly with the Secretaries of Health and Human Services and the Treasury, pursuant to paragraph (e) of this section.

(vii) *Individually identifiable health information (IIHI)* means any information, including demographic data, that relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual; and

(A) That identifies the individual; or

(B) With respect to which there is a reasonable basis to believe the information can be used to identify the individual.

(viii) *Material difference* means a substantial likelihood that a reasonable person with the training and qualifications of a certified IDR entity making a payment determination would consider the submitted information significant in determining the out of network rate and would view the information as showing that the qualifying payment amount is not the appropriate out-of-network rate.

(ix) *Material familial relationship* means any relationship as a spouse, domestic partner, child, parent, sibling, spouse's or domestic partner's parent, spouse's or domestic partner's sibling, spouse's or domestic partner's child, child's parent, child's spouse or domestic partner, or sibling's spouse or domestic partner.

(x) *Material financial relationship* means any financial interest of more than five percent of total annual revenue or total annual income of a certified IDR entity, or an officer, director, or manager thereof, or of a reviewer or reviewing physician employed or engaged by a certified IDR entity to conduct or participate in any review in the Federal IDR process. The terms annual revenue and annual income do not include mediation fees received by mediators who are also arbitrators, provided that the mediator acts in the capacity of a mediator and does not represent a party in the mediation.

(xi) *Material professional relationship* means any physician-patient relationship, any partnership or employment relationship, any shareholder or similar ownership interest in a professional corporation, partnership, or other similar entity; or any independent contractor arrangement that constitutes a material financial relationship with any expert used by the certified IDR entity or any officer or director of the certified IDR entity.

(xii) *Qualified IDR item or service* means an item or service:

(A) That is an emergency service furnished by a nonparticipating provider or nonparticipating facility subject to the protections of 26 CFR 54.9816–4T, § 2590.716–4, or 45 CFR 149.110, as applicable, for which the conditions of 45 CFR 149.410(b) are not met, or an item or service furnished by a nonparticipating provider at a participating health care facility, subject to the requirements of 26 CFR 54.9816–T, § 2590.716–5, or 45 CFR 149.120, as applicable, for which the conditions of 45 CFR 149.420(c) through (i) are not met, or air ambulance services furnished by a nonparticipating provider of air ambulance services subject to the protections of 26 CFR 54.9817–1T, § 2590.717–1, or 45 CFR 149.130, as applicable, and for which the out-of-network rate is not determined by reference to an All-Payer Model Agreement under section 1115A of the Social Security Act or a specified State law as defined in § 2590.716–3;

(B) With respect to which a provider or facility (as applicable) or group health plan or health insurance issuer offering group health insurance coverage submits a notification under paragraph (b)(2) of this section;

(C) That is not an item or service that is the subject of an open negotiation under paragraph (b)(1) of this section; and

(D) That is not an item or service for which a notification under paragraph (b)(2) of this section is submitted during the 90-calendar-day period under paragraph (c)(4)(vi)(B) of this section, but that may include such an item or service if the notification is submitted during the subsequent 30-business-day period under paragraph (c)(4)(vi)(C) of this section.

(xiii) *Unsecured IIHI* means IIHI that is not rendered unusable, unreadable, or indecipherable to unauthorized persons through the use of a technology or methodology specified by the Secretary, jointly with the Secretary of the Treasury and the Secretary of Health and Human Services.

(b) *Determination of payment amount through open negotiation and initiation of the Federal IDR process*—(1) *Determination of payment amount through open negotiation*—(i) *In general.* With respect to an item or service that meets the requirements of paragraph (a)(2)(xii)(A) of this section, the provider, facility, or provider of air ambulance services or the group health plan or health insurance issuer offering group or individual health insurance coverage may, during the 30-business-day period beginning on the day the provider, facility, or provider of air ambulance services receives an initial payment or notice of denial of payment regarding the item or service, initiate an open negotiation period for purposes of determining the out-of-network rate for such item or service. To initiate the open negotiation period, a party must send a notice to the other party (open negotiation notice) in accordance with paragraph (b)(1)(ii) of this section.

(ii) *Open negotiation notice*—(A) *Content.* The open negotiation notice must include information sufficient to identify the item(s) and service(s) (including the date(s) the item(s) or service(s) were furnished, the service code, and initial payment amount, if applicable), an offer of an out-of-network rate, and contact information for the party sending the open negotiation notice.

(B) *Manner.* The open negotiation notice must be provided, using the standard form developed by the Secretary, in writing within 30 business days beginning on the day the provider, facility, or provider of air ambulance services receives an initial payment or a notice of denial of payment from the plan or issuer regarding the item or service. The day on which the open negotiation notice is first sent by a party is the date the 30-business-day open negotiation period begins. This notice may be provided to the other party electronically (such as by email) if the following two conditions are satisfied—

(*1*) The party sending the open negotiation notice has a good faith belief that the electronic method is readily accessible by the other party; and

(*2*) The notice is provided in paper form free of charge upon request.

(2) *Initiating the Federal IDR process*—(i) *In general.* With respect to an item or service for which the parties do not agree upon an out-of-network rate by the last day of the open negotiation period under paragraph (b)(1) of this section, either party may initiate the Federal IDR process. To initiate the Federal IDR process, a party must submit a written notice of IDR initiation to the other party and to the Secretary, using the standard form developed by the Secretary, during the 4-business-day period beginning on the 31st business day after the start of the open negotiation period.

(ii) *Exception for items and services provided by certain nonparticipating*

providers and facilities. A party may not initiate the Federal IDR process with respect to an item or service if, with respect to that item or service, the party knows (or reasonably should have known) that the provider or facility provided notice and received consent under 45 CFR 149.410(b) or 149.420(c) through (i).

(iii) *Notice of IDR initiation*—(A) *Content.* The notice of IDR initiation must include:

(*1*) Information sufficient to identify the qualified IDR items or services under dispute (and whether the qualified IDR items or services are designated as batched items and services as described in paragraph (c)(3) of this section), including the date(s) and location the item or service was furnished, the type of item or service (such as whether the qualified IDR item or service is an emergency service as defined in 26 CFR 54.9816–4T(c)(2)(i), § 2590.716–4(c)(2)(i), or 45 CFR 149.110(c)(2)(i), as applicable, an emergency service as defined in 26 CFR 54.9816–4T(c)(2)(ii), § 2590.716–4(c)(2)(ii), or 45 CFR 149.110(c)(2)(ii), as applicable, or a nonemergency service; and whether any service is a professional service or facility-based service), corresponding service codes, place of service code, the amount of cost sharing allowed, and the amount of the initial payment made for the qualified IDR item or service, if applicable;

(*2*) Names of the parties involved and contact information, including name, email address, phone number, and mailing address;

(*3*) State where the qualified IDR item or service was furnished;

(*4*) Commencement date of the open negotiation period under paragraph (b)(1) of this section;

(*5*) Preferred certified IDR entity;

(*6*) An attestation that the items and services under dispute are qualified IDR items or services;

(*7*) Qualifying payment amount;

(*8*) Information about the qualifying payment amount as described in § 2590.716–6(d); and

(*9*) General information describing the Federal IDR process as specified by the Secretary.

(B) *Manner.* The initiating party must provide written notice of IDR initiation to the other party. The initiating party may satisfy this requirement by furnishing the notice of IDR initiation to the other party electronically (such as by email) if the following two conditions are satisfied –

(*1*) The initiating party has a good faith belief that the electronic method is readily accessible by the other party; and

(*2*) The notice is provided in paper form free of charge upon request.

(C) *Notice to the Secretary.* The initiating party must also furnish the notice of IDR initiation to the Secretary by submitting the notice through the Federal IDR portal. The initiation date of the Federal IDR process will be the date of receipt by the Secretary.

(c) *Federal IDR process following initiation*—(1) *Selection of certified IDR entity*—(i) *In general.* The plan or issuer or the provider, facility, or provider of air ambulance services receiving the notice of IDR initiation under paragraph (b)(2) of this section may agree or object to the preferred certified IDR entity identified in the notice of IDR initiation. If the party in receipt of the notice of IDR initiation fails to object within 3 business days, the preferred certified IDR entity identified in the notice of IDR initiation will be selected and will be treated as jointly agreed to by the parties, provided that the certified IDR entity does not have a conflict of interest. If the party in receipt of the notice of IDR initiation objects, that party must notify the initiating party of the objection and propose an alternative certified IDR entity. The initiating party must then agree or object to the alternative certified IDR entity; if the initiating party fails to agree or object to the alternative certified IDR entity, the alternative certified IDR entity will be selected and will be treated as jointly agreed to by the parties. In order to select a preferred certified IDR entity, the plan or issuer and the provider, facility, or provider of air ambulance services must jointly agree on a certified IDR entity not later than 3 business days after the initiation date of the Federal IDR process. If the plan or issuer and the provider, facility, or provider of air ambulance services fail to agree upon a certified IDR entity within that time, the Secretary shall select a certified IDR entity in accordance with paragraph (c)(1)(iv) of this section.

(ii) *Requirements for selected certified IDR entity.* The certified IDR entity selected must be an IDR entity certified under paragraph (e) of this section, that:

(A) Does not have a conflict of interest as defined in paragraph (a)(2) of this section;

(B) Ensures that assignment of personnel to a payment determination and decisions regarding hiring, compensation, termination, promotion, or other similar matters related to personnel assigned to the dispute are not made based upon the likelihood that the assigned personnel will support a particular party to the determination being disputed other than as outlined under paragraph (c)(4)(iii) of this section; and

(C) Ensures that any personnel assigned to a payment determination do not have any conflicts of interests as defined in paragraph (a)(2) of this section regarding any party to the dispute within the 1 year immediately preceding an assignment of dispute determination, similar to the requirements laid out in 18 U.S.C. 207(b).

(iii) *Notice of certified IDR entity selection.* Upon the selection of a certified IDR entity, in accordance with paragraph (c)(1)(i) of this section, the plan or issuer or the provider or emergency facility that submitted the notice of IDR initiation under paragraph (b)(2) of this section must notify the Secretary of the selection as soon as reasonably practicable, but no later than 1 business day after such selection, through the Federal IDR portal. In addition, if the non-initiating party believes that the Federal IDR process is not applicable, the non-initiating party must also provide information regarding the Federal IDR process's inapplicability through the Federal IDR portal by the same date that the notice of certified IDR entity selection must be submitted.

(A) *Content.* If the parties have agreed on the selection of a certified IDR entity or the party in receipt of the notice of IDR initiation has not objected to the other party's selection, the notice of the certified IDR entity selection must include the following information:

(*1*) Name of the certified IDR entity;

(*2*) The certified IDR entity number; and

(*3*) Attestation by both parties, or by the initiating party if the non-initiating party fails to object to the selection of the certified IDR entity, that the selected certified IDR entity meets the requirements of paragraph (c)(1)(ii) of this section.

(B) [Reserved]

(iv) *Failure to select a certified IDR entity.* If the plan or issuer and the provider, facility, or provider of air ambulance services fail to select a certified IDR entity in accordance with paragraph (c)(1)(i) of this section, the initiating party must notify the Secretary of the failure no later than 1 business day after the date of such failure (or in other words, 4 business days after initiation of the Federal IDR process) by electronically submitting the notice as described in paragraph (c)(1)(iii) of this section but indicating that the parties have failed to select a certified IDR entity. In addition, if the non-initiating party believes that the Federal IDR process is not applicable, the non-initiating party must also

provide information regarding the Federal IDR process's inapplicability through the Federal IDR portal by the same date that the notice of failure to select must be submitted. Upon notification of the failure of the parties to select a certified IDR entity, the Secretary will select a certified IDR entity that charges a fee within the allowed range of certified IDR entity fees through a random selection method not later than 6 business days after the date of initiation of the Federal IDR process and will notify the plan or issuer and the provider or facility of the selection. If there are insufficient certified IDR entities that charge a fee within the allowed range of certified IDR entity fees available to arbitrate the dispute, the Secretary, jointly with the Secretary of Health and Human Services and Secretary of the Treasury, will select a certified IDR entity that has received approval, as described in paragraph (e)(2)(vi)(B) of this section, to charge a fee outside of the allowed range of certified IDR entity fees.

(v) *Review by certified IDR entity.* After selection by the parties (including when the initiating party selects a certified IDR entity and the other party does not object), or by the Secretary under paragraph (c)(1)(iv) of this section, the certified IDR entity must review the selection and attest that it meets the requirements of paragraph (c)(1)(ii) of this section. If the certified IDR entity is unable to attest that it meets the requirements of paragraph (c)(1)(ii) within 3 business days of selection, the parties, upon notification, must select another certified IDR entity under paragraph (c)(1) of this section, treating the date of notification of the failure to attest to the requirements of (c)(1)(ii) as the date of initiation of the Federal IDR process for purposes of the time periods in paragraphs (c)(1)(i) and (iv) of this section. Additionally, the certified IDR entity selected must review the information submitted in the notice of IDR initiation to determine whether the Federal IDR process applies. If the Federal IDR process does not apply, the certified IDR entity must notify the Secretary and the parties within 3 business days of making that determination.

(2) *Authority to continue negotiations*—(i) *In general.* If the parties to the Federal IDR process agree on an out-of-network rate for a qualified IDR item or service after providing the notice of IDR initiation to the Secretary consistent with paragraph (b)(2) of this section, but before the certified IDR entity has made its payment determination, the amount agreed to by the parties for the qualified IDR item or service will be treated as the out-of-network rate for the qualified IDR item or service. To the extent the amount exceeds the initial payment amount (or initial denial of payment) and any cost sharing paid or required to be paid by the participant or beneficiary, payment must be made directly by the plan or issuer to the nonparticipating provider, facility, or nonparticipating provider of air ambulance services, not later than 30 business days after the agreement is reached. In no instance may either party seek additional payment from the participant or beneficiary, including in instances in which the out-of-network rate exceeds the qualifying payment amount. The initiating party must send a notification to the Secretary and to the certified IDR entity (if selected) electronically, through the Federal IDR portal, as soon as possible, but no later than 3 business days after the date of the agreement. The notification must include the out-of-network rate for the qualified IDR item or service and signatures from authorized signatories for both parties.

(ii) *Method of allocation of the certified IDR entity fee.* In the case of an agreement described in paragraph (c)(2)(i) of this section, the certified IDR entity is required to return half of each parties' certified IDR entity fee, unless directed otherwise by both parties. The administrative fee under paragraph (d)(2) of this section will not be returned to the parties.

(3) *Treatment of batched items and services*—(i) *In general.* Batched items and services may be submitted and considered jointly as part of one payment determination by a certified IDR entity only if the batched items and services meet the requirements of this paragraph (c)(3)(i). Batched items and services submitted and considered jointly as part of one payment determination under this paragraph (c)(3)(i) are treated as a batched determination and subject to the fee for batched determinations under this section.

(A) The qualified IDR items and services are billed by the same provider or group of providers, the same facility, or the same provider of air ambulance services. Items and services are billed by the same provider or group of providers, the same facility, or the same provider of air ambulance services if the items or services are billed with the same National Provider Identifier or Tax Identification Number;

(B) Payment for the qualified IDR items and services would be made by the same plan or issuer;

(C) The qualified IDR items and services are the same or similar items and services. The qualified IDR items and services are considered to be the same or similar items or services if each is billed under the same service code, or a comparable code under a different procedural code system, such as Current Procedural Terminology (CPT) codes with modifiers, if applicable, Healthcare Common Procedure Coding System (HCPCS) with modifiers, if applicable, or Diagnosis-Related Group (DRG) codes with modifiers, if applicable; and

(D) All the qualified IDR items and services were furnished within the same 30-business-day period, or the same 90-calendar-day period under paragraph (c)(4)(vi)(B) of this section, as applicable.

(ii) *Treatment of bundled payment arrangements.* In the case of qualified IDR items and services billed by a provider, facility, or provider of air ambulance services as part of a bundled payment arrangement, or where a plan or issuer makes or denies an initial payment as a bundled payment, the qualified IDR items and services may be submitted as part of one payment determination. Bundled payment arrangements submitted under this paragraph (c)(3)(ii) are subject to the rules for batched determinations and the certified IDR entity fee for single determinations.

(4) *Payment determination for a qualified IDR item or service*—(i) *Submission of offers.* Not later than 10 business days after the selection of the certified IDR entity, the plan or issuer and the provider, facility, or provider of air ambulance services:

(A) Must each submit to the certified IDR entity:

(*1*) An offer of an out-of-network rate expressed as both a dollar amount and the corresponding percentage of the qualifying payment amount represented by that dollar amount;

(*2*) Information requested by the certified IDR entity relating to the offer.

(*3*) The following additional information, as applicable—

(*i*) For providers and facilities, information on the size of the provider's practice or of the facility (if applicable). Specifically, a group of providers must specify whether the providers' practice has fewer than 20 employees, 20 to 50 employees, 51 to 100 employees, 101 to 500 employees, or more than 500 employees. For facilities, the facility must specify whether the facility has 50 or fewer employees, 51 to 100 employees, 101 to 500 employees, or more than 500 employees;

(*ii*) For providers and facilities, information on the practice specialty or type, respectively (if applicable);

(*iii*) For plans and issuers, information on the coverage area of the plan or issuer, the relevant geographic region for purposes of the qualifying payment amount, whether the coverage is fully-insured or partially or fully self-insured; and

(*iv*) The qualifying payment amount for the applicable year for the same or similar item or service as the qualified IDR item or service.

(B) May each submit to the certified IDR entity any information relating to the offer that was submitted by either party, except that the information may not include information on factors described in paragraph (c)(4)(v) of this section.

(ii) *Payment determination and notification.* Not later than 30 business days after the selection of the certified IDR entity, the certified IDR entity must:

(A) Select as the out-of-network rate for the qualified IDR item or service one of the offers submitted under paragraph (c)(4)(i) of this section, taking into account the considerations specified in paragraph (c)(4)(iii) of this section (as applied to the information provided by the parties pursuant to paragraph (c)(4)(i) of this section). The certified IDR entity must select the offer closest to the qualifying payment amount unless the certified IDR entity determines that credible information submitted by either party under paragraph (c)(4)(i) clearly demonstrates that the qualifying payment amount is materially different from the appropriate out-of-network rate, or if the offers are equally distant from the qualifying payment amount but in opposing directions. In these cases, the certified IDR entity must select the offer as the out-of-network rate that the certified IDR entity determines best represents the value of the qualified IDR item or services, which could be either offer.

(B) Notify the plan or issuer and the provider or facility, as applicable, of the selection of the offer under paragraph (c)(4)(ii)(A) of this section, and provide the written decision required under (c)(4)(vi) of this section.

(iii) *Considerations in determination.* In determining which offer to select, the certified IDR entity must consider:

(A) The qualifying payment amount(s) for the applicable year for the same or similar item or service.

(B) Information requested by the certified IDR entity under paragraph (c)(4)(i)(A)(*2*) of this section relating to the offer, to the extent a party provides credible information.

(C) Additional information submitted by a party, provided the information is credible and relates to the circumstances described in paragraphs (c)(4)(iii)(C)(*1*) through (*5*) of this section, with respect to a qualified IDR item or service of a nonparticipating provider, facility, group health plan, or health insurance issuer of group or individual health insurance coverage that is the subject of a payment determination. This information must also clearly demonstrate that the qualifying payment amount is materially different from the appropriate out-of-network rate.

(*1*) The level of training, experience, and quality and outcomes measurements of the provider or facility that furnished the qualified IDR item or service (such as those endorsed by the consensus-based entity authorized in section 1890 of the Social Security Act).

(*2*) The market share held by the provider or facility or that of the plan or issuer in the geographic region in which the qualified IDR item or service was provided.

(*3*) The acuity of the participant, or beneficiary, receiving the qualified IDR item or service, or the complexity of furnishing the qualified IDR item or service to the participant or beneficiary.

(*4*) The teaching status, case mix, and scope of services of the facility that furnished the qualified IDR item or service, if applicable.

(*5*) Demonstration of good faith efforts (or lack thereof) made by the provider or facility or the plan or issuer to enter into network agreements with each other, and, if applicable, contracted rates between the provider or facility, as applicable, and the plan or issuer, as applicable, during the previous 4 plan years.

(D) Additional information submitted by a party, provided the information is credible and relates to the offer submitted by either party and does not include information on factors described in paragraph (c)(4)(v) of this section.

(iv) *Examples.* The rules of paragraph (c)(4)(iii) of this section are illustrated by the following examples:

(A) *Example 1*—(*1*) *Facts.* A nonparticipating provider and an issuer are parties to a payment determination in the Federal IDR process. The nonparticipating provider submits an offer and additional written information asserting that the provider has made good faith efforts to enter into network agreements with the issuer. The nonparticipating provider fails to provide any documentation of these efforts, such as correspondence or records of conversations with representatives of the issuer.

(*2*) *Conclusion.* In this *Example 1,* the nonparticipating provider has submitted additional information. However, this information is not credible, as the nonparticipating provider has failed to provide any documentation in support of the provider's assertions of good faith efforts to enter into network agreements with the issuer. Therefore, the certified IDR entity cannot consider the information.

(B) *Example 2*—(*1*) *Facts.* A nonparticipating provider and an issuer are parties to a payment determination in the Federal IDR process. The nonparticipating provider submits credible information relating to the provider's level of training, experience, and quality and outcome measurements from 2019. The provider also submits credible information that clearly demonstrates that the provider's level of training and expertise was necessary for providing the service that is the subject of the payment determination to the particular patient. Further, the provider submits credible information that clearly demonstrates that the qualifying payment amount generally presumes the service would be delivered by a provider with a lower level of training, experience, and quality and outcome measurements. This information, taken together, demonstrates that the qualifying payment amount is not an appropriate payment amount and the provider submits an offer that is higher than the qualifying payment amount and commensurate with the provider's level of training, experience, and quality and outcome measurements with respect to the service provided. The issuer submits the qualifying payment amount as its offer with no additional information.

(*2*) *Conclusion.* In this *Example 2,* the nonparticipating provider has submitted information that is credible. Moreover, the credible information clearly demonstrates that the qualifying payment amount does not adequately take into account the provider's level of training, experience, and quality and outcome measurements with respect to the service provided, and that the appropriate out-of-network rate should therefore be higher than the qualifying payment amount. Accordingly, the certified IDR entity must select the provider's offer, as that offer best represents the value of the service that is the subject of the payment determination.

(C) *Example 3*—(*1*) *Facts.* A nonparticipating provider and an issuer are parties to a payment determination in the Federal IDR process. The nonparticipating provider submits credible information to the certified IDR entity relating to the acuity of the patient that received the service, and the complexity of furnishing the service to

the patient, by providing details of the service at issue and the training required to furnish the complex service. The provider contends that this information demonstrates that the qualifying payment amount is not an appropriate payment amount, and the provider submits an offer that is higher than the qualifying payment amount and equal to what the provider believes is commensurate with the acuity of the patient and the complexity of the service that is the subject of the payment determination. However, the evidence submitted by the provider does not clearly demonstrate that the qualifying payment amount fails to encompass the acuity and complexity of the service. The issuer submits the qualifying payment amount as its offer, along with credible information that demonstrates how the qualifying payment amount was calculated for this particular service, taking into consideration the acuity of the patient and the complexity of the service.

(*2*) *Conclusion.* The information submitted by the provider to the certified IDR entity is credible with respect to the acuity of the patient and complexity of the service. However, in this example, the provider has not clearly demonstrated that the qualifying payment amount is materially different from the appropriate out-of-network rate, based on the acuity of the patient and the complexity of the service that is the subject of the payment determination. Accordingly, the certified IDR entity must select the offer closest to the qualifying payment amount, which is the issuer's offer.

(D) *Example 4*—(*1*) *Facts.* A nonparticipating provider and an issuer are parties to a payment determination in the Federal IDR process. The issuer submits credible information demonstrating that the patent for the item that is the subject of the payment determination has expired, including written documentation that demonstrates how much the cost of the item was at the time the provider rendered service and how the qualifying payment amount exceeds that cost. The issuer submits an offer that is lower than the qualifying payment amount and commensurate with the cost of the item at the time service was rendered. The nonparticipating provider submits the qualifying payment amount as its offer and also submits credible information demonstrating the provider's level of training, experience, and quality and outcome measurements from 2019, but the provider does not explain how this additional information is relevant to the cost of the item.

(*2*) *Conclusion.* In this *Example 4,* both the nonparticipating provider and issuer submitted information that is credible and that may be considered by the certified IDR entity. However, only the issuer provided credible information that was relevant to the service that is the subject of the payment determination. Moreover, the issuer has clearly demonstrated that the qualifying payment amount does not adequately take into account the complexity of the item furnished—in this case that the item is no longer patent protected. While the provider submitted credible information, the provider failed to show how the information was relevant to the item that is the subject of the payment determination. Accordingly, the certified IDR entity must select the offer that best represents the value of the item, which is the issuer's offer in this example.

(v) *Prohibition on consideration of certain factors.* In determining which offer to select, the certified IDR entity must not consider:

(A) Usual and customary charges (including payment or reimbursement rates expressed as a proportion of usual and customary charges);

(B) The amount that would have been billed by the provider or facility with respect to the qualified IDR item or service had the provisions of 45 CFR 149.410 and 149.420 (as applicable) not applied; or

(C) The payment or reimbursement rate for items and services furnished by the provider or facility payable by a public payor, including under the Medicare program under title XVIII of the Social Security Act; the Medicaid program under title XIX of the Social Security Act; the Children's Health Insurance Program under title XXI of the Social Security Act; the TRICARE program under chapter 55 of title 10, United States Code; chapter 17 of title 38, United States Code; or demonstration projects under section 1115 of the Social Security Act.

(vi) *Written decision.* (A) The certified IDR entity must explain its determination in a written decision submitted to the parties and the Secretary, in a form and manner specified by the Secretary;

(B) If the certified IDR entity does not choose the offer closest to the qualifying payment amount, the certified IDR entity's written decision must include an explanation of the credible information that the certified IDR entity determined demonstrated that the qualifying payment amount was materially different from the appropriate out-of-network rate, based on the considerations allowed under paragraphs (c)(4)(iii)(B) through (D) of this section, with respect to the qualified IDR item or service.

(vii) *Effects of determination*—(A) *Binding.* A determination made by a certified IDR entity under paragraph (c)(4)(ii) of this section:

(*1*) Is binding upon the parties, in the absence of fraud or evidence of intentional misrepresentation of material facts presented to the certified IDR entity regarding the claim; and

(*2*) Is not subject to judicial review, except in a case described in any of paragraphs (1) through (4) of section 10(a) of title 9, United States Code.

(B) *Suspension of certain subsequent IDR requests.* In the case of a determination made by a certified IDR entity under paragraph (c)(4)(ii) of this section, the party that submitted the initial notification under paragraph (b)(2) of this section may not submit a subsequent notification involving the same other party with respect to a claim for the same or similar item or service that was the subject of the initial notification during the 90-calendar-day period following the determination.

(C) *Subsequent submission of requests permitted.* If the end of the open negotiation period specified in paragraph (b)(1) of this section occurs during the 90-calendar-day suspension period regarding claims for the same or similar item or service that were the subject of the initial notice of IDR determination as described in paragraph (c)(4)(vi) of this section, either party may initiate the Federal IDR process for those claims by submitting a notification as specified in paragraph (b)(2) of this section during the 30-business-day period beginning on the day after the last day of the 90-calendar-day suspension period.

(viii) *Recordkeeping requirements.* The certified IDR entity must maintain records of all claims and notices associated with the Federal IDR process with respect to any determination for 6 years. The certified IDR entity must make these records available for examination by the plan, issuer, provider, facility, or provider of air ambulance services, or a State or Federal oversight agency upon request, except to the extent the disclosure would violate either State or Federal privacy law.

(ix) *Payment.* If applicable, the amount of the offer selected by the certified IDR entity (less the sum of the initial payment and any cost sharing paid or owed by the participant or beneficiary) must be paid directly to the provider, facility, or provider of air ambulance services not later than 30 calendar days after the determination by

the certified IDR entity. If the offer selected by the certified IDR entity is less than the sum of the initial payment and any cost sharing paid by the participant or beneficiary, the provider, facility, or provider of air ambulance services will be liable to the plan or issuer for the difference. The provider, facility, or provider of air ambulance services must pay the difference directly to the plan or issuer not later than 30 calendar days after the determination by the certified IDR entity.

(d) *Costs of IDR process*—(1) *Certified IDR entity fee.* (i) With respect to the Federal IDR process described in paragraph (c) of this section, the party whose offer submitted to the certified IDR entity under paragraph (c)(4)(ii)(A) of this section is not selected is responsible for the payment to the certified IDR entity of the predetermined fee charged by the certified IDR entity.

(ii) Each party to a determination for which a certified IDR entity is selected under paragraph (c)(1) of this section must pay the predetermined certified IDR entity fee charged by the certified IDR entity to the certified IDR entity at the time the parties submit their offers under (c)(4)(i) of this section. The certified IDR entity fee paid by the prevailing party whose offer is selected by the certified IDR entity will be returned to that party within 30 business days following the date of the certified IDR entity's determination.

(2) *Administrative fee.* (i) Each party to a determination for which a certified IDR entity is selected under paragraph (c)(1) of this section must, at the time the certified IDR entity is selected under paragraph (c)(1), pay to the certified IDR entity a non-refundable administrative fee due to the Secretary for participating in the Federal IDR process described in this section.

(ii) The administrative fee amount will be established in guidance published annually by the Secretary in a manner such that the total fees paid for a year are estimated to be equal to the projected amount of expenditures by the Departments of the Treasury, Labor, and Health and Human Services for the year in carrying out the Federal IDR process.

(e) *Certification of IDR entity*—(1) *In general.* In order to be selected under paragraph (c)(1) of this section—

(i) An IDR entity must meet the standards described in this paragraph (e) and be certified by the Secretary, jointly with the Secretaries of Health and Human Services and the Treasury, as set forth in this paragraph (e) of this section and guidance promulgated by the Secretary. Once certified, the IDR entity will be provided with a certified IDR entity number.

(ii) An IDR entity must provide written documentation to the Secretary regarding general company information (such as contact information, Taxpayer Identification Number, and website), as well as the applicable service area in which the IDR entity intends to conduct payment determinations under the Federal IDR process. IDR entities may choose to submit their application for all States, or self-limit to a particular subset of States.

(iii) An IDR entity that the Secretary, jointly with the Secretary of the Treasury and the Secretary of Health and Human Services, certifies must enter into an agreement as a condition of certification. The agreement shall include specified provisions encompassed by this section, including, but not limited to, the requirements applicable to certified IDR entities when making payment determinations as well as the requirements regarding certification and revocation (such as specifications for wind down activities and reallocation of certified IDR entity fees, where warranted).

(2) *Requirements.* An IDR entity must provide written documentation to the Secretary through the Federal IDR portal that demonstrates that the IDR entity satisfies the following standards to be a certified IDR entity under this paragraph (e):

(i) Possess (directly or through contracts or other arrangements) sufficient arbitration and claims administration of health care services, managed care, billing and coding, medical and legal expertise to make the payment determinations described in paragraph (c) of this section within the time prescribed in paragraph (c)(4)(ii) of this section.

(ii) Employ (directly or through contracts or other arrangements) a sufficient number of personnel to make the determinations described in paragraph (c) of this section within the time prescribed by (c)(4)(ii) of this section. To satisfy this standard, the written documentation must include a description of the IDR entity's organizational structure and capabilities, including an organizational chart and the credentials, responsibilities, and number of personnel employed to make determinations described in paragraph (c) of this section.

(iii) Maintain a current accreditation from a nationally recognized and relevant accrediting organization, such as URAC, or ensure that it otherwise possesses the requisite training to conduct payment determinations (for example, providing documentation that personnel employed by the IDR entity have completed arbitration training by the American Arbitration Association, the American Health Law Association, or a similar organization);

(iv) Have a process to ensure that no conflict of interest, as defined in paragraph (a)(2) of this section, exists between the parties and the personnel the certified IDR entity assigns to a payment determination to avoid violating paragraph (c)(1)(ii) of this section, including policies and procedures for conducting ongoing audits for conflicts of interest, to ensure that should any arise, the certified IDR entity has procedures in place to inform the Secretary, jointly with the Secretary of the Treasury and the Secretary of Health and Human Services of the conflict of interest and to mitigate the risk by reassigning the dispute to other personnel in the event that any personnel previously assigned have a conflict of interest.

(v) Have a process to maintain the confidentiality of IIHI obtained in the course of conducting determinations. A certified IDR entity's responsibility to comply with these confidentiality requirements shall survive revocation of the IDR entity's certification for any reason, and IDR entities must comply with the record retention and disposal requirements described in this section. Under this process, once certified, the certified IDR entity must comply with the following requirements:

(A) *Privacy.* The certified IDR entity may create, collect, handle, disclose, transmit, access, maintain, store, and/or use IIHI, only to perform:

(*1*) The certified IDR entity's required duties described in this section; and

(*2*) Functions related to carrying out additional obligations as may be required under applicable Federal or State laws or regulations.

(B) *Security.* (*1*) The certified IDR entity must ensure the confidentiality of all IIHI it creates, obtains, maintains, stores, and transmits;

(*2*) The certified IDR entity must protect against any reasonably anticipated threats or hazards to the security of this information;

(*3*) The certified IDR entity must ensure that IIHI is securely destroyed or disposed of in an appropriate and reasonable manner 6 years from either the date of its creation or the first date on which the certified IDR entity had access to it, whichever is earlier;

(*4*) The certified IDR entity must implement policies and procedures to prevent, detect, contain, and correct security violations in the event of a breach of IIHI;

(C) *Breach notification.* The certified IDR entity must, following the discovery of a breach of unsecured IIHI, notify of the breach the provider, facility, or provider of air ambulance services; the plan and issuer; the Secretary, jointly with the Secretary of the Treasury and the Secretary of Health and Human Services; and each individual whose unsecured IIHI has been, or is reasonably believed to have been, subject to the breach, to the extent possible.

(*1*) *Breaches treated as discovered.* For purposes of this paragraph (e)(2)(v)(C), a breach shall be treated as discovered by a certified IDR entity as of the first day on which the breach is known to the certified IDR entity or, by exercising reasonable diligence, would have been known to the certified IDR entity. A certified IDR entity shall be deemed to have knowledge of a breach if the breach is known, or by exercising reasonable diligence would have been known, to any person, other than the person committing the breach, who is an employee, officer, or other agent of the certified IDR entity;

(*2*) *Timing of notification.* A certified IDR entity must provide the notification required by this paragraph (e)(2)(v)(C) without unreasonable delay and in no case later than 60 calendar days after discovery of a breach.

(*3*) *Content of notification.* The notification required by this paragraph (e)(2)(v)(C) must include, to the extent possible:

(*i*) The identification of each individual whose unsecured IIHI has been, or is reasonably believed by the certified IDR entity to have been, subject to the breach;

(*ii*) A brief description of what happened, including the date of the breach and the date of the discovery of the breach, to the extent known;

(*iii*) A description of the types of unsecured IIHI that were involved in the breach (for example whether full name, social security number, date of birth, home address, account number, diagnosis, disability code, or other types of information were involved);

(*iv*) A brief description of what the certified IDR entity involved is doing to investigate the breach, to mitigate harm to the affected parties, and to protect against any further breaches; and

(*v*) Contact procedures for individuals to ask questions or learn additional information, which must include a toll-free telephone number, email address, website, or postal address.

(*4*) *Method for providing notification.* A certified IDR entity must submit the notification required by this paragraph (e)(2)(v)(C) in written form (in clear and understandable language) either on paper or electronically through the Federal IDR portal or electronic mail.

(D) *Application to contractor and subcontractors.* The certified IDR entity must ensure compliance with this paragraph (e)(2)(v) of this section by any contractor or subcontractor with access to IIHI performing any duties related to the Federal IDR process.

(vi) Meet appropriate indicators of fiscal integrity and stability by demonstrating that the certified IDR entity has a system of safeguards and controls in place to prevent and detect improper financial activities by its employees and agents to assure fiscal integrity and accountability for all certified IDR entity fees and administrative fees received, held, and disbursed and by submitting 3 years of financial statements or, if not available, other information to demonstrate fiscal stability of the IDR entity;

(vii) Provide a fixed fee for single determinations and a separate fixed fee for batched determinations within the upper and lower limits for each, as set forth in guidance issued by the Secretary. The certified IDR entity may not charge a fee that is not within the approved limits as set forth in guidance unless the certified IDR entity or IDR entity seeking certification receives written approval from the Secretary to charge a flat rate beyond the upper or lower limits approved by the Secretary for fees. The certified IDR entity or IDR entity seeking certification may update its fees and seek approval from the Secretary to charge a flat fee beyond the upper or lower limits for fees, annually as provided in guidance. In order for the certified IDR entity to receive the Secretary's written approval to charge a flat fee beyond the upper or lower limits for fees as set forth in guidance, it must satisfy both conditions in paragraphs (e)(2)(vii)(A) and (B) of this section as follows:

(A) Submit, in writing, a proposal to the Secretary that includes:

(*1*) The alternative flat fee the certified IDR entity or IDR entity seeking certification believes is appropriate for the certified IDR entity or IDR entity seeking certification to charge;

(*2*) A description of the circumstances that require the alternative fee; and

(*3*) A description of how the alternative flat rate will be used to mitigate the effects of these circumstances; and

(B) Receive from the Secretary, jointly with the Secretary of the Treasury and the Secretary of Health and Human Services, written approval to charge the fee documented in the certified IDR entity's or the IDR entity seeking certification's written proposal.

(viii) Have a procedure in place to retain the certified IDR entity fees described in paragraph (d)(1) of this section paid by both parties in a trust or escrow account and to return the certified IDR entity fee paid by the prevailing party of an IDR payment determination, or half of each party's certified IDR entity fee in the case of an agreement described in paragraph (c)(2)(i) of this section, within 30 business days following the date of the determination;

(ix) Have a procedure in place to retain the administrative fees described in paragraph (d)(2) of this section and to remit the administrative fees to the Secretary in accordance with the timeframe and procedures set forth in guidance published by the Secretary;

(x) Discharge its responsibilities in accordance with paragraph (c) of this section, including not making any determination with respect to which the certified IDR entity would not be eligible for selection pursuant to paragraph (c)(1) of this section; and

(xi) Collect the information required to be reported to the Secretary under paragraph (f) of this section and report the information on a timely basis in the form and manner provided in guidance published by the Secretary.

(3) *Conflict-of-interest standards.* In addition to the general standards set forth in paragraph (e)(2)(iv) of this section, an IDR entity must provide written documentation that the IDR entity satisfies the standards to be a certified IDR entity under this paragraph (e)(3).

(i) The IDR entity must provide an attestation indicating that it does not have a conflict of interest as defined in paragraph (a)(2) of this section;

(ii) The IDR entity must have procedures in place to ensure that personnel assigned to a determination do not have any conflicts of interest regarding any party to the dispute within the 1 year immediately preceding an assignment of dispute determination, similar to the requirements laid out in 18 U.S.C. 207(b). In order to satisfy this requirement, if certified, the IDR entity must ensure that any personnel assigned to a determination do not have any conflicts of interest as defined in paragraph (a)(2) of this section.

(iii) Following certification under this paragraph (e), if a certified IDR entity acquires control of, becomes controlled by, or comes under common control with any entity described in paragraph (e)(3)(i) of this section, the certified IDR entity must notify the Secretary in

writing no later than 3 business days after the acquisition or exercise of control and shall be subject to the revocation of certification under paragraph (e)(6)(ii) of this section.

(4) *Period of certification.* Subject to paragraphs (e)(5) and (6) of this section, each certification (including a recertification) of a certified IDR entity under the process described in paragraph (e)(1) of this section will be effective for a 5-year period.

(5) *Petition for denial or revocation*—(i) *In general.* An individual, provider, facility, provider of air ambulance services, plan, or issuer may petition for a denial of a certification for an IDR entity or a revocation of a certification for a certified IDR entity for failure to meet a requirement of this section using the standard form and manner set forth in guidance to be issued by the Secretary. The petition for denial of a certification must be submitted within the timeframe set forth in guidance issued by the Secretary.

(ii) *Content of petition.* The individual, provider, facility, provider of air ambulance services, plan, or issuer seeking denial or revocation of certification must submit a written petition using the standard form issued by the Secretary including the following information:

(A) The identity of the IDR entity seeking certification or certified IDR entity that is the subject of the petition;

(B) The reason(s) for the petition;

(C) Whether the petition seeks denial or revocation of a certification;

(D) Documentation to support the reasons outlined in the petition; and

(E) Other information as may be required by the Secretary.

(iii) *Process.* (A) The Secretary, jointly with the Secretary of the Treasury and the Secretary of Health and Human Services, will acknowledge receipt of the petition within 10 business days of receipt of the petition.

(B) If the Secretary finds that the petition adequately shows a failure of the IDR entity seeking certification or the certified IDR entity to follow the requirements of this paragraph (e), the Secretary, jointly with the Secretary of the Treasury and the Secretary of Health and Human Services, will notify the IDR entity seeking certification or the certified IDR entity by providing a de-identified copy of the petition. Following the notification, the IDR entity seeking certification or certified IDR entity will have 10 business days to provide a response. After the time period for providing the response has passed, the Secretary, jointly with the Secretary of the Treasury and the Secretary of Health and Human Services, will review the response (if any), determine whether a denial or revocation of a certification is warranted, and issue a notice of the decision to the IDR entity or certified IDR entity and to the petitioner. This decision will be subject to the appeal requirements of paragraph (e)(6)(v) of this section.

(C) Effect on certification under petition. Regarding a petition for revocation of a certified IDR entity's certification, if the Secretary, jointly with the Secretary of the Treasury and the Secretary of Health and Human Services, finds that the petition adequately shows a failure to comply with the requirements of this paragraph (e), following the Secretary's notification of the failure to the certified IDR entity under paragraph (e)(5)(iii)(B) of this section, the certified IDR entity may continue to work on previously assigned determinations but may not accept new determinations until the Secretary issues a notice of the decision to the certified IDR entity finding that a revocation of certification is not warranted.

(6) *Denial of IDR entity certification or revocation of certified IDR entity certification*—(i) *Denial of IDR entity certification.* The Secretary, jointly with the Secretary of the Treasury and the Secretary of Health and Human Services, may deny the certification of an IDR entity under paragraph (e)(1) of this section if, during the process of certification, including as a result of a petition described in paragraph (e)(5) of this section, the Secretary determines the following:

(A) The IDR entity fails to meet the applicable standards set forth under this paragraph (e);

(B) The IDR entity has committed or participated in fraudulent or abusive activities, including, during the certification process, submitting fraudulent data, or submitting information or data the IDR entity knows to be false to the Secretary, the Secretary of the Treasury or the Secretary of Health and Human Services;

(C) The IDR entity has failed to comply with requests for information from the Secretary, the Secretary of the Treasury, or the Secretary of Health and Human Services as part of the certification process;

(D) In conducting payment determinations, including those outside the Federal IDR process, the IDR entity has failed to meet the standards that applied to those determinations or reviews, including standards of independence and impartiality; or

(E) The IDR entity is otherwise not fit or qualified to make determinations under the Federal IDR process.

(ii) *Revocation of certification of a certified IDR entity.* The Secretary, jointly with the Secretary of the Treasury and the Secretary of Health and Human Services, may revoke the certification of a certified IDR entity under paragraph (e)(1) of this section if, as a result of an audit, a petition described in paragraph (e)(5) of this section, or otherwise, the Secretary determines the following:

(A) The certified IDR entity has a pattern or practice of noncompliance with any requirements of this paragraph (e);

(B) The certified IDR entity is operating in a manner that hinders the efficient and effective administration of the Federal IDR process;

(C) The certified IDR entity no longer meets the applicable standards for certification set forth under this paragraph (e);

(D) The certified IDR entity has committed or participated in fraudulent or abusive activities, including submission of false or fraudulent data to the Secretary, the Secretary of the Treasury, or the Secretary of Health and Human Services;

(E) The certified IDR entity lacks the financial viability to provide arbitration under the Federal IDR process;

(F) The certified IDR entity has failed to comply with requests from the Secretary, the Secretary of the Treasury, or the Secretary of Health and Human Services made as part of an audit, including failing to submit all records of the certified IDR entity that pertain to its activities within the Federal IDR process; or

(G) The certified IDR entity is otherwise no longer fit or qualified to make determinations.

(iii) *Notice of denial or revocation.* The Secretary, jointly with the Secretary of the Treasury and the Secretary of Health and Human Services, will issue a written notice of denial to the IDR entity or revocation to the certified IDR entity within 10 business days of the Secretary's decision, including the effective date of denial or revocation, the reason(s) for denial or revocation, and the opportunity to request appeal of the denial or revocation.

(iv) *Request for appeal of denial or revocation.* To request an appeal, the IDR entity or certified IDR entity must submit a request for appeal to the Secretary within 30 business days of the date of the notice under paragraph (e)(6)(iii) of this section of denial or revocation and in the manner prescribed by the instructions to the notice. During

this time period, the Secretary, jointly with the Secretary of the Treasury and the Secretary of Health and Human Services, will not issue a notice of final denial or revocation and a certified IDR entity may continue to work on previously assigned determinations but may not accept new determinations. If the IDR entity or certified IDR entity does not timely submit a request for appeal of the denial or revocation, the Secretary, jointly with the Secretary of the Treasury and the Secretary of Health and Human Services, will issue a notice of final denial or revocation to the IDR entity or certified IDR entity (if applicable) and the petitioner.

(v) *Denial or final revocation.* Upon notice of denial or final revocation, the IDR entity shall not be considered a certified IDR entity and therefore shall not be eligible to accept payment determinations under the Federal IDR process. Moreover, after a notice of final revocation, the IDR entity may not re-apply to be a certified IDR entity until on or after the 181st day after the date of the notice of denial or final revocation.

(f) *Reporting of information relating to the Federal IDR process*—(1) *Reporting of information.* Within 30 business days of the close of each month, for qualified IDR items and services furnished on or after January 1, 2022, each certified IDR entity must, in a form and manner specified by the Secretary, report:

(i) The number of notices of IDR initiation submitted under paragraph (b)(2) of this section to the certified IDR entity during the immediately preceding month;

(ii) The size of the provider practices and the size of the facilities submitting notices of IDR initiation under paragraph (b)(2) of this section during the immediately preceding month, as required to be provided to the certified IDR entity under paragraph (c)(4)(i)(A)(*2*) of this section;

(iii) The number of such notices of IDR initiation with respect to which a determination was made under paragraph (c)(4)(ii) of this section;

(iv) The number of times during the month that the out-of-network rate determined (or agreed to) under this section has exceeded the qualifying payment amount, specified by qualified IDR items and services;

(v) With respect to each notice of IDR initiation under paragraph (b)(2) of this section for which such a determination was made, the following information:

(A) A description of the qualified IDR items and services included with respect to the notification, including the relevant billing and service codes;

(B) The relevant geographic region for purposes of the qualifying payment amount for the qualified IDR items and services with respect to which the notification was provided;

(C) The amount of the offer submitted under paragraph (c)(4)(i) of this section by the plan or issuer (as applicable) and by the provider or facility (as applicable) expressed as a dollar amount and as a percentage of the qualifying payment amount;

(D) Whether the offer selected by the certified IDR entity under paragraph (c)(4) of this section was the offer submitted by the plan or issuer (as applicable) or by the provider or facility (as applicable);

(E) The amount of the selected offer expressed as a dollar amount and as a percentage of the qualifying payment amount;

(F) The rationale for the certified IDR entity's decision, including the extent to which the decision relied on the criteria in paragraph (c)(4)(iv) of this section;

(G) The practice specialty or type of each provider or facility, respectively, involved in furnishing each qualified IDR item or service;

(H) The identity for each plan or issuer, and provider or facility, with respect to the notification. Specifically, each certified IDR entity must provide each party's name and address, as applicable; and

(I) For each determination, the number of business days elapsed between selection of the certified IDR entity and the determination of the out-of-network rate by the certified IDR entity.

(vi) The total amount of certified IDR entity fees paid to the certified IDR entity under paragraph (d)(1) of this section during the month.

(2) [Reserved]

(g) *Extension of time periods for extenuating circumstances*—(1) *General.* The time periods specified in this section (other than the time for payment, if applicable, under paragraph (c)(4)(ix) of this section) may be extended in extenuating circumstances at the Secretary's discretion if:

(i) An extension is necessary to address delays due to matters beyond the control of the parties or for good cause; and

(ii) The parties attest that prompt action will be taken to ensure that the determination under this section is made as soon as administratively practicable under the circumstances.

(2) *Process to request an extension.* The parties may request an extension by submitting a request for extension due to extenuating circumstances through the Federal IDR portal if the extension is necessary to address delays due to matters beyond the control of the parties or for good cause.

(h) *Applicability date.* The provisions of this section are applicable with respect to plan years beginning on or after January 1, 2022, except that the provisions regarding IDR entity certification at paragraphs (a) and (e) of this section are applicable beginning on October 7, 2021.

■ 14. Section 2590.717–2 is added to read as follows:

§ 2590.717–2 Independent dispute resolution process for air ambulance services.

(a) *Definitions.* Unless otherwise stated, the definitions in § 2590.716–3 apply.

(b) *Determination of out-of-network rates to be paid by health plans and health insurance issuers; independent dispute resolution process*—(1) *In general.* Except as provided in paragraphs (b)(2) and (3) of this section, in determining the out-of-network rate to be paid by group health plans and health insurance issuers offering group health insurance coverage for out-of-network air ambulance services, plans and issuers must comply with the requirements of § 2590.716–8, except that references in § 2590.716–8 to the additional circumstances in § 2590.716–8(c)(4)(iii)(C) shall be understood to refer to paragraph (b)(2) of this section.

(2) *Additional information.* Additional information submitted by a party, provided the information is credible, relates to the circumstances described in paragraphs (b)(2)(i) through (vi) of this section, with respect to a qualified IDR service of a nonparticipating provider of air ambulance services or health insurance issuer of group or individual health insurance coverage that is the subject of a payment determination. This information must also clearly demonstrate that the qualifying payment amount is materially different from the appropriate out-of-network rate.

(i) The quality and outcomes measurements of the provider that furnished the services.

(ii) The acuity of the condition of the participant or beneficiary receiving the service, or the complexity of furnishing the service to the participant or beneficiary.

(iii) The training, experience, and quality of the medical personnel that furnished the air ambulance services.

(iv) Ambulance vehicle type, including the clinical capability level of the vehicle.

(v) Population density of the point of pick-up (as defined in 42 CFR 414.605)

for the air ambulance (such as urban, suburban, rural, or frontier).

(vi) Demonstrations of good faith efforts (or lack thereof) made by the nonparticipating provider of air ambulance services or the plan or issuer to enter into network agreements with each other and, if applicable, contracted rates between the provider of air ambulance services and the plan or issuer, as applicable, during the previous 4 plan years.

(3) *Reporting of information relating to the IDR process.* In applying the requirements of § 2590.716–8(f), within 30 business days of the close of each month, for services furnished on or after January 1, 2022, the information the certified IDR entity must report, in a form and manner specified by the Secretary, with respect to the Federal IDR process involving air ambulance services is:

(i) The number of notices of IDR initiation submitted under the Federal IDR process to the certified IDR entity that pertain to air ambulance services during the immediately preceding month;

(ii) The number of such notices of IDR initiation with respect to which a final determination was made under § 2590.716–8(c)(4)(ii) of this part (as applied by paragraph (b)(1) of this section);

(iii) The number of times the payment amount determined (or agreed to) under this subsection has exceeded the qualifying payment amount, specified by services;

(iv) With respect to each notice of IDR initiation under § 2590.716–8(b)(2) of this part (as applied by paragraph (b)(1) of this section) for which a determination was made, the following information:

(A) A description of each air ambulance service included in such notification, including the relevant billing and service codes;

(B) The point of pick-up (as defined in 42 CFR 414.605) for the services included in such notification;

(C) The amount of the offers submitted under § 2590.716–8(c)(4)(i) (as applied by paragraph (b)(1) of this section) by the group health plan or health insurance issuer (as applicable) and by the nonparticipating provider of air ambulance services, expressed as a dollar amount and as a percentage of the qualifying payment amount;

(D) Whether the offer selected by the certified IDR entity under § 2590.716–8(c)(4)(ii) of this part (as applied by paragraph (b)(1) of this section) to be the payment amount applied was the offer submitted by the plan or issuer (as applicable) or by the provider of air ambulance services;

(E) The amount of the selected offer expressed as a dollar amount and as a percentage of the qualifying payment amount;

(F) The rationale for the certified IDR entity's decision, including the extent to which the decision relied on the criteria in paragraph (b)(2) of this section;

(G) Air ambulance vehicle type, including the clinical capability level of such vehicle (to the extent this information has been provided to the certified IDR entity);

(H) The identity for each plan or issuer and provider of air ambulance services, with respect to the notification. Specifically, each certified IDR entity must provide each party's name and address, as applicable; and

(I) For each determination, the number of business days elapsed between selection of the certified IDR entity and the selection of the payment amount by the certified IDR entity.

(v) The total amount of certified IDR entity fees paid to the certified IDR entity under paragraph § 2590.716–8(d)(1) of this part (as applied by paragraph (b)(1) of this section) during the month for determinations involving air ambulance services.

(c) *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 set forth in the preamble, the Department of Health and Human Services amends 45 CFR parts 147 and 149 as set forth below:

PART 147—HEALTH INSURANCE REFORM REQUIREMENTS FOR THE GROUP AND INDIVIDUAL HEALTH INSURANCE MARKETS

■ 15. The authority citation for part 147 continues to read as follows:

Authority: 42 U.S.C. 300gg through 300gg–63, 300gg–91, 300gg–92, and 300gg–111 through 300gg–139, as amended, and section 3203, Pub. L. 116–136, 134 Stat. 281.

■ 16. Section 147.136 is amended by:

■ a. Revising paragraphs (a)(1), (c)(2)(i), and (d)(1)(i)(A) and (B);

■ b. Adding paragraph (d)(1)(i)(C);

■ c. Adding Examples 3 through 7 to paragraph (d)(1)(ii); and

■ d. Revising paragraph (g).

The revisions and additions read as follows:

§ 147.136 Internal claims and appeals and external review processes.

(a) *Scope and definitions*—(1) *Scope*—(i) *In general.* This section sets forth requirements with respect to internal claims and appeals and external review processes for group health plans and health insurance issuers. Paragraph (b) of this section provides requirements for internal claims and appeals processes. Paragraph (c) of this section sets forth rules governing the applicability of State external review processes. Paragraph (d) of this section sets forth a Federal external review process for plans and issuers not subject to an applicable State external review process. Paragraph (e) of this section prescribes requirements for ensuring that notices required to be provided under this section are provided in a culturally and linguistically appropriate manner. Paragraph (f) of this section describes the authority of the Secretary to deem certain external review processes in existence on March 23, 2010 as in compliance with paragraph (c) or (d) of this section.

(ii) *Application to grandfathered health plans and health insurance coverage.* The provisions of this section generally do not apply to coverage offered by health insurance issuers and group health plans that are grandfathered health plans, as defined under § 147.140. However, the external review process requirements under paragraphs (c) and (d) of this section, and related notice requirements under paragraph (e) of this section, apply to grandfathered health plans or coverage with respect to adverse benefit determinations involving items and services within the scope of the requirements for out-of-network emergency services, nonemergency services performed by nonparticipating providers at participating facilities, and air ambulance services furnished by nonparticipating providers of air ambulance services under PHS Act sections 2799A–1 and 2799A–2 and §§ 149.110 through 149.130.

* * * * *

(c) * * *

(2) * * *

(i) The State process must provide for the external review of adverse benefit determinations (including final internal adverse benefit determinations) by issuers (or, if applicable, plans) that are based on the issuer's (or plan's) requirements for medical necessity, appropriateness, health care setting, level of care, or effectiveness of a covered benefit, as well as a consideration of whether a plan or issuer is complying with the surprise

billing and cost-sharing protections under PHS Act sections 2799A–1 and 2799A–2 and §§ 149.110 through 149.130.

* * * * *

(d) * * *

(1) * * *

(i) * * *

(A) An adverse benefit determination (including a final internal adverse benefit determination) by a plan or issuer that involves medical judgment (including, but not limited to, those based on the plan's or issuer's requirements for medical necessity, appropriateness, health care setting, level of care, or effectiveness of a covered benefit; its determination that a treatment is experimental or investigational; its determination whether a participant, beneficiary, or enrollee is entitled to a reasonable alternative standard for a reward under a wellness program; its determination whether a plan or issuer is complying with the nonquantitative treatment limitation provisions of PHS Act section 2726 and §§ 146.136 and 147.160, which generally require, among other things, parity in the application of medical management techniques), as determined by the external reviewer. (A denial, reduction, termination, or a failure to provide payment for a benefit based on a determination that a participant, beneficiary, or enrollee fails to meet the requirements for eligibility under the terms of a group health plan or health insurance coverage is not eligible for the Federal external review process under this paragraph (d));

(B) An adverse benefit determination that involves consideration of whether a plan or issuer is complying with the surprise billing and cost-sharing protections set forth in PHS Act sections 2799A–1 and 2799A–2 and §§ 149.110 through 149.130; and

(C) A rescission of coverage (whether or not the rescission has any effect on any particular benefit at that time).

(ii) * * *

Example 3. (i) *Facts.* A group health plan generally provides benefits for services in an emergency department of a hospital or independent freestanding emergency department. Individual *C* receives pre-stabilization emergency treatment in an out-of-network emergency department of a hospital. The group health plan determines that protections for emergency services under § 149.110 do not apply because the treatment did not involve ''emergency services'' within the meaning of § 149.110(c)(2)(i). *C* receives an adverse benefit determination and the plan imposes cost-sharing requirements that are greater than the requirements that would apply if the same services were provided in an in-network emergency department.

(ii) *Conclusion.* In this *Example 3,* the plan's determination that treatment received by *C* did not include emergency services involves medical judgment and consideration of whether the plan complied with § 149.110. Accordingly, the claim is eligible for external review under paragraph (d)(1)(i) of this section.

Example 4. (i) *Facts.* A group health plan generally provides benefits for anesthesiology services. Individual *D* undergoes a surgery at an in-network health care facility and during the course of the surgery, receives anesthesiology services from an out-of-network provider. The plan decides the claim for these services without regard to the protections related to items and services furnished by out-of-network providers at in-network facilities under § 149.120. As a result, *D* receives an adverse benefit determination for the services and is subject to cost-sharing liability that is greater than it would be if cost sharing had been calculated in a manner consistent with the requirements of § 149.120.

(ii) *Conclusion.* In this *Example 4,* whether the plan was required to decide the claim in a manner consistent with the requirements of § 149.120 involves considering whether the plan complied with § 149.120, as well as medical judgment, because it requires consideration of the health care setting and level of care. Accordingly, the claim is eligible for external review under paragraph (d)(1)(i) of this section.

Example 5. (i) *Facts.* A group health plan generally provides benefits for services in an emergency department of a hospital or independent freestanding emergency department. Individual *E* receives emergency services in an out-of-network emergency department of a hospital, including certain post-stabilization services. The plan processes the claim for the post-stabilization services as not being for emergency services under § 149.110(c)(2)(ii) based on representations made by the treating provider that *E* was in a condition to receive notice from the provider about cost-sharing and surprise billing protections for these services, and subsequently gave informed consent to waive those protections. *E* receives an adverse benefit determination and is subject to cost-sharing requirements that are greater than the cost-sharing requirements that would apply if the services were processed in a manner consistent with § 149.110.

(ii) *Conclusion.* In this *Example 5,* whether *E* was in a condition to receive notice about the availability of cost-sharing and surprise billing protections and give informed consent to waive those protections involves medical judgment and consideration of whether the plan complied with the requirements under § 149.110(c)(2)(ii). Accordingly, the claim is eligible for external review under paragraph (d)(1)(i) of this section.

Example 6. (i) *Facts.* Individual *F* gives birth to a baby at an in-network hospital. The baby is born prematurely and receives certain neonatology services from a nonparticipating provider during the same visit as the birth. *F* was given notice about cost-sharing and surprise billing protections for these services, and subsequently gave informed consent to waive those protections. The claim for the neonatology services is coded as a claim for routine post-natal services and the plan decides the claim without regard to the requirements under § 149.120(a) and the fact that those protections may not be waived for neonatology services under § 149.120(b).

(ii) *Conclusion.* In this *Example 6,* medical judgment is necessary to determine whether the correct code was used and compliance with § 149.120(a) and (b) must also be considered. Accordingly, the claim is eligible for external review under paragraph (d)(1)(i) of this section. The Departments also note that, to the extent the nonparticipating provider balance bills Individual *F* for the outstanding amounts not paid by the plan for the neonatology services, such provider would be in violation of PHS Act section 2799B–2 and its implementing regulations at 45 CFR 149.420(a).

Example 7. (i) *Facts.* A group health plan generally provides benefits to cover knee replacement surgery. Individual *G* receives a knee replacement surgery at an in-network facility and, after receiving proper notice about the availability of cost-sharing and surprise billing protections, provides informed consent to waive those protections. However, during the surgery, certain anesthesiology services are provided by an out-of-network nurse anesthetist. The claim for these anesthesiology services is decided by the plan without regard to the requirements under § 149.120(a) or to the fact that those protections may not be waived for ancillary services such as anesthesiology services provided by an out-of-network provider at an in-network facility under § 149.120(b). *G* receives an adverse benefit determination and is subject to cost-sharing requirements that are

greater than the cost-sharing requirements that would apply if the services were provided in a manner consistent with § 149.120(a) and (b).

(ii) *Conclusion.* In this *Example 7,* consideration of whether the plan complied with the requirements in § 149.120(a) and (b) is necessary to determine whether cost-sharing requirements were applied appropriately. Accordingly, the claim is eligible for external review under paragraph (d)(1)(i) of this section.

* * * * *

(g) *Applicability date.* The provisions of this section generally are applicable to group health plans and health insurance issuers for plan years (in the individual market, policy years) beginning on or after January 1, 2017. The external review scope provision at paragraph (d)(1)(i)(B) of this section is applicable for plan years (in the individual market, policy years) beginning on or after January 1, 2022. The external review provisions described in paragraphs (c) and (d) of this section are applicable to grandfathered health plans and grandfathered individual market policies, with respect to the types of claims specified under paragraph (a)(1)(ii) of this section, for plan years (in the individual market, policy years) beginning on or after January 1, 2022.

PART 149—SURPRISE BILLING AND TRANSPARENCY REQUIREMENTS

■ 17. The authority citation for part 149 is amended to read as follows:

Authority: 42 U.S.C. 300gg–92 and 300gg–111 through 300gg–139, as amended.

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

§ 149.10 Basis and scope.

* * * * *

(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. This part also establishes an independent dispute resolution process, and standards for certifying independent dispute resolution entities. This part also establishes a Patient-Provider Dispute Resolution Process and standards for certifying Selected Dispute Resolution entities.

■ 17. Section 149.20 is amended by adding paragraphs (a)(3) and (4) and revising paragraph (b) introductory text to read as follows:

§ 149.20 Applicability.

(a) * * *

(3) The requirements in subpart F of this part apply to certified IDR entities, health care providers, health care facilities, and providers of air ambulance services and 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.

(4) The requirements in subpart G of this part apply to Selected Dispute Resolution Entities, health care providers, providers of air ambulance services, health care facilities and uninsured (or self-pay) individuals, as defined in subpart G.

(b) *Exceptions.* The requirements in subparts B, D, E, and F of this part do not apply to the following:

* * * * *

■ 18. Section 149.450 is amended by revising paragraphs (a)(1) and (a)(2)(i) to read as follows:

§ 149.450 Complaint process for balance billing and good faith estimates 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 or subpart G of this part, which may warrant an investigation.

(2) * * *

(i) Complaint means a communication, written, or oral, that indicates there has been a potential violation of the requirements under this subpart or subpart G of this part, whether or not a violation actually occurred.

* * * * *

■ 20. Subpart F, consisting of §§ 149.510 and 149.520. is added to read as follows:

Subpart F—Independent Dispute Resolution Process

§ 149.510 Independent dispute resolution process.

(a) *Scope and definitions*—(1) *Scope.* This section sets forth requirements with respect to the independent dispute resolution (IDR) process (referred to in this section as the Federal IDR process) under which a nonparticipating provider, nonparticipating emergency facility, or nonparticipating provider of air ambulance services (as applicable), and a group health plan or health insurance issuer offering group or individual health insurance coverage completes a requisite open negotiation period and at least one party submits a notification under paragraph (b) of this section to initiate the Federal IDR process under paragraph (c) of this section, and under which an IDR entity (as certified under paragraph (e) of this section) determines the amount of payment under the plan or coverage for an item or service furnished by the provider or facility.

(2) *Definitions.* Unless otherwise stated, the definitions in § 149.30 of this part apply to this section. Additionally, for purposes of this section, the following definitions apply:

(i) *Batched items and services* means multiple qualified IDR items or services that are considered jointly as part of one payment determination by a certified IDR entity for purposes of the Federal IDR process. In order for a qualified IDR item or service to be included in a batched item or service, the qualified IDR item or service must meet the criteria set forth in paragraph (c)(3) of this section.

(ii) *Breach* means the acquisition, access, use, or disclosure of individually identifiable health information (IIHI) in a manner not permitted under paragraph (e)(2)(v) of this section that compromises the security or privacy of the IIHI.

(A) Breach excludes:

(*1*) Any unintentional acquisition, access, or use of IIHI by personnel, a contractor, or a subcontractor of a certified IDR entity that is acting under the authority of that certified IDR entity, if the acquisition, access, or use was made in good faith and within the scope of that authority and that does not result in further use or disclosure in a manner not permitted under paragraph (e)(2)(v) of this section.

(*2*) Any inadvertent disclosure by a person who is authorized to access IIHI at a certified IDR entity to another person authorized to access IIHI at the same certified IDR entity, and the information received as a result of the disclosure is not further used or disclosed in a manner not permitted under paragraph (e)(2)(v) of this section.

(*3*) A disclosure of IIHI in which a certified IDR entity has a good faith belief that an unauthorized person to whom the disclosure was made would not reasonably have been able to retain such information.

(B) Except as provided in paragraph (a)(2)(ii)(A) of this definition, access, use, or disclosure of IIHI in a manner not permitted under paragraph (e)(2)(v)

of this section is presumed to be a breach unless the certified IDR entity demonstrates that there is a low probability that the security or privacy of the IIHI has been compromised based on a risk assessment encompassing at least the following factors:

(*1*) The nature and extent of the IIHI involved, including the types of identifiers and the likelihood of re-identification;

(*2*) The unauthorized person who used the IIHI or to whom the disclosure was made;

(*3*) Whether the IIHI was actually acquired or viewed; and

(*4*) The extent to which the risk to the IIHI has been mitigated.

(iii) *Certified IDR entity* means an entity responsible for conducting determinations under paragraph (c) of this section that meets the certification criteria specified in paragraph (e) of this section and that has been certified by the Secretary, jointly with the Secretaries of Labor and the Treasury.

(iv) *Conflict of interest* means, with respect to a party to a payment determination, or certified IDR entity, a material relationship, status, or condition of the party, or certified IDR entity that impacts the ability of the certified IDR entity to make an unbiased and impartial payment determination. For purposes of this section, a conflict of interest exists when a certified IDR entity is:

(A) A group health plan; a health insurance issuer offering group health insurance coverage, individual health insurance coverage, or short-term, limited-duration insurance; a carrier offering a health benefits plan under 5 U.S.C. 8902; or a provider, a facility, or a provider of air ambulance services;

(B) An affiliate or a subsidiary of a group health plan; a health insurance issuer offering group health insurance coverage, individual health insurance coverage, or short-term limited-duration insurance; a carrier offering a health benefits plan under 5 U.S.C. 8902; or a provider, a facility, or a provider of air ambulance services;

(C) An affiliate or subsidiary of a professional or trade association representing group health plans; health insurance issuers offering group health insurance coverage, individual health insurance coverage, or short-term limited duration insurance; carriers offering a health benefits plan under 5 U.S.C. 8902; or providers, facilities, or providers of air ambulance services.

(D) A certified IDR entity, that has, or that has any personnel, contractors, or subcontractors assigned to a determination who have, a material familial, financial, or professional relationship with a party to the payment determination being disputed, or with any officer, director, or management employee of the plan, issuer, or carrier offering a health benefits plan under 5 U.S.C. 8902; the plan or coverage administrator, plan or coverage fiduciaries, or plan, issuer or carrier employees; the health care provider, the health care provider's group or practice association; the provider of air ambulance services, the provider of air ambulance services' group or practice association, or the facility that is a party to the dispute.

(v) *Credible information* means information that upon critical analysis is worthy of belief and is trustworthy.

(vi) *IDR entity* means an entity that may apply or has applied for certification to conduct determinations under paragraph (c) of this section, and that currently is not certified by the Secretary, jointly with the Secretaries of Labor and the Treasury, pursuant to paragraph (e) of this section.

(vii) *Individually identifiable health information (IIHI)* means any information, including demographic data, that relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual; and

(A) That identifies the individual; or

(B) With respect to which there is a reasonable basis to believe the information can be used to identify the individual.

(viii) *Material difference* means a substantial likelihood that a reasonable person with the training and qualifications of a certified IDR entity making a payment determination would consider the submitted information significant in determining the out-of-network rate and would view the information as showing that the qualifying payment amount is not the appropriate out-of-network rate.

(ix) *Material familial relationship* means any relationship as a spouse, domestic partner, child, parent, sibling, spouse's or domestic partner's parent, spouse's or domestic partner's sibling, spouse's or domestic partner's child, child's parent, child's spouse or domestic partner, or sibling's spouse or domestic partner.

(x) *Material financial relationship* means any financial interest of more than five percent of total annual revenue or total annual income of a certified IDR entity or an officer, director, or manager thereof, or of a reviewer or reviewing physician employed or engaged by a certified IDR entity to conduct or participate in any review in the Federal IDR process. The terms annual revenue and annual income do not include mediation fees received by mediators who are also arbitrators, provided that the mediator acts in the capacity of a mediator and does not represent a party in the mediation.

(xi) *Material professional relationship* means any physician-patient relationship, any partnership or employment relationship, any shareholder or similar ownership interest in a professional corporation, partnership, or other similar entity; or any independent contractor arrangement that constitutes a material financial relationship with any expert used by the certified IDR entity or any officer or director of the certified IDR entity.

(xii) *Qualified IDR item or service* means an item or service:

(A) That is an emergency service furnished by a nonparticipating provider or nonparticipating facility subject to the protections of 26 CFR 54.9816–4T, 29 CFR 2590.716–4, or § 149.110, as applicable, for which the conditions of § 149.410(b) are not met, or an item or service furnished by a nonparticipating provider at a participating health care facility, subject to the requirements of 26 CFR 54.9816–5T, 29 CFR 2590.717–5, or § 149.120, as applicable, for which the conditions of § 149.420(c)–(i) are not met, or air ambulance services furnished by a nonparticipating provider of air ambulance services subject to the protections of 26 CFR 54.9817–1T, 29 CFR 2590.717–1, or § 149.130, as applicable, and for which the out-of-network rate is not determined by reference to an All-Payer Model Agreement under section 1115A of the Social Security Act or a specified State law as defined in § 149.30;

(B) With respect to which a provider or facility (as applicable) or group health plan or health insurance issuer offering group or individual health insurance coverage submits a notification under paragraph (b)(2) of this section;

(C) That is not an item or service that is the subject of an open negotiation under paragraph (b)(1) of this section; and

(D) That is not an item or service for which a notification under paragraph (b)(2) of this section is submitted during the 90-calendar-day period under paragraph (c)(4)(vi)(B) of this section, but that may include such an item or service if the notification is submitted during the subsequent 30-business-day period under paragraph (c)(4)(vi)(C) of this section.

(xiii) *Unsecured IIHI* means IIHI that is not rendered unusable, unreadable, or indecipherable to unauthorized persons through the use of a technology or methodology specified by the Secretary, jointly with the Secretary of the Treasury and the Secretary of Labor.

(b) *Determination of payment amount through open negotiation and initiation of the Federal IDR process*—(1) *Determination of payment amount through open negotiation*—(i) *In general.* With respect to an item or service that meets the requirements of paragraph (a)(2)(xii)(A) of this section, the provider, facility, or provider of air ambulance services or the group health plan or health insurance issuer offering group or individual health insurance coverage may, during the 30-business-day period beginning on the day the provider, facility, or provider of air ambulance services receives an initial payment or notice of denial of payment regarding the item or service, initiate an open negotiation period for purposes of determining the out-of-network rate for such item or service. To initiate the open negotiation period, a party must send a notice to the other party (open negotiation notice) in accordance with paragraph (b)(1)(ii) of this section.

(ii) *Open negotiation notice*—(A) *Content.* The open negotiation notice must include information sufficient to identify the item(s) and service(s) (including the date(s) the item(s) or service(s) were furnished, the service code, and initial payment amount, if applicable), an offer of an out-of-network rate, and contact information for the party sending the open negotiation notice.

(B) *Manner.* The open negotiation notice must be provided, using the standard form developed by the Secretary, in writing within 30 business days beginning on the day the provider, facility, or provider of air ambulance services receives an initial payment or a notice of denial of payment from the plan or issuer regarding the item or service. The day on which the open negotiation notice is first sent by a party is the date the 30-business-day open negotiation period begins. This notice may be provided to the other party electronically (such as by email) if the following two conditions are satisfied—

(*1*) The party sending the open negotiation notice has a good faith belief that the electronic method is readily accessible by the other party; and

(*2*) The notice is provided in paper form free of charge upon request.

(2) *Initiating the Federal IDR process*—(i) *In general.* With respect to an item or service for which the parties do not agree upon an out-of-network rate by the last day of the open negotiation period under paragraph (b)(1) of this section, either party may initiate the Federal IDR process. To initiate the Federal IDR process, a party must submit a written notice of IDR initiation to the other party and to the Secretary, using the standard form developed by the Secretary, during the 4-business-day period beginning on the 31st business day after the start of the open negotiation period.

(ii) *Exception for items and services provided by certain nonparticipating providers and facilities.* A party may not initiate the Federal IDR process with respect to an item or service if, with respect to that item or service, the party knows (or reasonably should have known) that the provider or facility provided notice and received consent under 45 CFR 149.410(b) or 149.420(c) through (i).

(iii) *Notice of IDR initiation*—(A) *Content.* The notice of IDR initiation must include:

(*1*) Information sufficient to identify the qualified IDR items or services under dispute (and whether the qualified IDR items or services are designated as batched items and services as described in paragraph (c)(3) of this section), including the date(s) and location the item or service was furnished, the type of item or service (such as whether the qualified IDR item or service is an emergency service as defined in 26 CFR 54.9816–4T(c)(2)(i), 29 CFR 2590.716–4(c)(2)(i), or § 149.110(c)(2)(i), as applicable, an emergency service as defined in 26 CFR 54.9816–4T(c)(2)(ii), 29 CFR 2590.716–4(c)(2)(ii), or § 149.110(c)(2)(ii), as applicable, or a nonemergency service; and whether any service is a professional service or facility-based service), corresponding service codes, place of service code, the amount of cost sharing allowed, and the amount of the initial payment made for the qualified IDR item or service, if applicable;

(*2*) Names of the parties involved and contact information, including name, email address, phone number, and mailing address;

(*3*) State where the qualified IDR item or service was furnished;

(*4*) Commencement date of the open negotiation period under paragraph (b)(1) of this section;

(*5*) Preferred certified IDR entity;

(*6*) An attestation that the items and services under dispute are qualified IDR items or services;

(*7*) Qualifying payment amount;

(*8*) Information about the qualifying payment amount as described in § 149.140(d); and

(*9*) General information describing the Federal IDR process as specified by the Secretary.

(B) Manner. The initiating party must provide written notice of IDR initiation to the other party. The initiating party may satisfy this requirement by furnishing the notice of IDR initiation to the other party electronically (such as by email) if the following two conditions are satisfied—

(*1*) The initiating party has a good faith belief that the electronic method is readily accessible by the other party; and

(*2*) The notice is provided in paper form free of charge upon request.

(C) Notice to the Secretary. The initiating party must also furnish the notice of IDR initiation to the Secretary by submitting the notice through the Federal IDR portal. The initiation date of the Federal IDR process will be the date of receipt by the Secretary.

(c) *Federal IDR process following initiation*—(1) *Selection of certified IDR entity*—(i) *In general.* The plan or issuer or the provider, facility, or provider of air ambulance services receiving the notice of IDR initiation under paragraph (b)(2) of this section may agree or object to the preferred certified IDR entity identified in the notice of IDR initiation. If the party in receipt of the notice of IDR initiation fails to object within 3 business days, the preferred certified IDR entity identified in the notice of IDR initiation will be selected and will be treated as jointly agreed to by the parties, provided that the certified IDR entity does not have a conflict of interest. If the party in receipt of the notice of IDR initiation objects, that party must notify the initiating party of the objection and propose an alternative certified IDR entity. The initiating party must then agree or object to the alternative certified IDR entity; if the initiating party fails to agree or object to the alternative certified IDR entity, the alternative certified IDR entity will be selected and will be treated as jointly agreed to by the parties. In order to select a preferred certified IDR entity, the plan or issuer and the provider, facility, or provider of air ambulance services must jointly agree on a certified IDR entity not later than 3 business days after the initiation date of the Federal IDR process. If the plan or issuer and the provider, facility, or provider of air ambulance services fail to agree upon a certified IDR entity within that time, the Secretary shall select a certified IDR entity in accordance with paragraph (c)(1)(iv) of this section.

(ii) *Requirements for selected certified IDR entity.* The certified IDR entity

selected must be an IDR entity certified under paragraph (e) of this section, that:

(A) Does not have a conflict of interest as defined in paragraph (a)(2) of this section;

(B) Ensures that assignment of personnel to a payment determination and decisions regarding hiring, compensation, termination, promotion, or other similar matters related to personnel assigned to the dispute are not made based upon the likelihood that the assigned personnel will support a particular party to the determination being disputed other than as outlined under paragraph (c)(4)(iii) of this section; and

(C) Ensures that any personnel assigned to a payment determination do not have any conflicts of interests as defined in paragraph (a)(2) of this section regarding any party to the dispute within the 1 year immediately preceding an assignment of dispute determination, similar to the requirements laid out in 18 U.S.C. 207(b).

(iii) *Notice of certified IDR entity selection.* Upon the selection of a certified IDR entity, in accordance with paragraph (c)(1)(i) of this section, the plan or issuer or the provider or emergency facility that submitted the notice of IDR initiation under paragraph (b)(2) of this section must notify the Secretary of the selection as soon as reasonably practicable, but no later than 1 business day after such selection, through the Federal IDR portal. In addition, if the non-initiating party believes that the Federal IDR process is not applicable, the non-initiating party must also provide information regarding the Federal IDR process's inapplicability through the Federal IDR portal by the same date that the notice of certified IDR entity selection must be submitted.

(A) *Content.* If the parties have agreed on the selection of a certified IDR entity or the party in receipt of the notice of IDR initiation has not objected to the other party's selection, the notice of the certified IDR entity selection must include the following information:

(*1*) Name of the certified IDR entity;

(*2*) The certified IDR entity number; and

(*3*) Attestation by both parties, or by the initiating party if the non-initiating party fails to object to the selection of the certified IDR entity, that the selected certified IDR entity meets the requirements of paragraph (c)(1)(ii) of this section.

(B) {Reserved]

(iv) *Failure to select a certified IDR entity.* If the plan or issuer and the provider, facility, or provider of air ambulance services fail to select a certified IDR entity in accordance with paragraph (c)(1)(i) of this section, the initiating party must notify the Secretary of the failure no later than 1 business day after the date of such failure (or in other words, 4 business days after initiation of the Federal IDR process) by electronically submitting the notice as described in paragraph (c)(1)(iii) of this section but indicating that the parties have failed to select a certified IDR entity. In addition, if the non-initiating party believes that the Federal IDR process is not applicable, the non-initiating party must also provide information regarding Federal IDR process's inapplicability through the Federal IDR portal by the same date that the notice of failure to select must be submitted. Upon notification of the failure of the parties to select a certified IDR entity, the Secretary will select a certified IDR entity that charges a fee within the allowed range of certified IDR entity fees through a random selection method not later than 6 business days after the date of initiation of the Federal IDR process and will notify the plan or issuer and the provider or facility of the selection. If there are insufficient certified IDR entities that charge a fee within the allowed range of certified IDR entity fees available to arbitrate the dispute, the Secretary, jointly with the Secretary of the Treasury and Secretary of Labor, will select a certified IDR entity that has received approval, as described in paragraph (e)(2)(vi)(B) of this section, to charge a fee outside of the allowed range of certified IDR entity fees.

(v) *Review by certified IDR entity.* After selection by the parties (including when the initiating party selects a certified IDR entity and the other party does not object), or by the Secretary under paragraph (c)(1)(iv) of this section, the certified IDR entity must review the selection and attest that it meets the requirements of paragraph (c)(1)(ii) of this section. If the certified IDR entity is unable to attest that it meets the requirements of paragraph (c)(1)(ii) of this section within 3 business days of selection, the parties, upon notification, must select another certified IDR entity under paragraph (c)(1) of this section, treating the date of notification of the failure to attest to the requirements of (c)(1)(ii) as the date of initiation of the Federal IDR process for purposes of the time periods in paragraphs (c)(1)(i) and (iv) of this section. Additionally, the certified IDR entity selected must review the information submitted in the notice of IDR initiation to determine whether the Federal IDR process applies. If the Federal IDR process does not apply, the certified IDR entity must notify the Secretary and the parties within 3 business days of making that determination.

(2) *Authority to continue negotiations*—(i) *In general.* If the parties to the Federal IDR process agree on an out-of-network rate for a qualified IDR item or service after providing the notice of IDR initiation to the Secretary consistent with paragraph (b)(2) of this section, but before the certified IDR entity has made its payment determination, the amount agreed to by the parties for the qualified IDR item or service will be treated as the out-of-network rate for the qualified IDR item or service. To the extent the amount exceeds the initial payment amount (or initial denial of payment) and any cost sharing paid or required to be paid by the participant or beneficiary, payment must be made directly by the plan or issuer to the nonparticipating provider, facility, or nonparticipating provider of air ambulance services not later than 30 business days after the agreement is reached. In no instance may either party seek additional payment from the participant or beneficiary, including in instances in which the out-of-network rate exceeds the qualifying payment amount. The initiating party must send a notification to the Secretary and to the certified IDR entity (if selected) electronically, through the Federal IDR portal, as soon as possible, but no later than 3 business days after the date of the agreement. The notification must include the out-of-network rate for the qualified IDR item or service and signatures from authorized signatories for both parties.

(ii) *Method of allocation of the certified IDR entity fee.* In the case of an agreement described in paragraph (c)(2)(i) of this section, the certified IDR entity is required to return half of each parties' certified IDR entity fee, unless directed otherwise by both parties. The administrative fee under paragraph (d)(2) of this section will not be returned to the parties.

(3) *Treatment of batched items and services*—(i) *In general.* Batched items and services may be submitted and considered jointly as part of one payment determination by a certified IDR entity only if the batched items and services meet the requirements of this paragraph (c)(3)(i). Batched items and services submitted and considered jointly as part of one payment determination under this paragraph (c)(3)(i) are treated as a batched determination and subject to the fee for batched determinations under this section.

(A) The qualified IDR items and services are billed by the same provider or group of providers, the same facility, or the same provider of air ambulance services. Items and services are billed by the same provider or group of providers, the same facility, or the same provider of air ambulance services if the items or services are billed with the same National Provider Identifier or Tax Identification Number;

(B) Payment for the qualified IDR items and services would be made by the same plan or issuer;

(C) The qualified IDR items and services are the same or similar items and services. The qualified IDR items and services are considered to be the same or similar items or services if each is billed under the same service code, or a comparable code under a different procedural code system, such as Current Procedural Terminology (CPT) codes with modifiers, if applicable, Healthcare Common Procedure Coding System (HCPCS) with modifiers, if applicable, or Diagnosis-Related Group (DRG) codes with modifiers, if applicable; and

(D) All the qualified IDR items and services were furnished within the same 30-business-day period, or the same 90-calendar-day period under paragraph (c)(4)(vi)(B) of this section, as applicable.

(ii) *Treatment of bundled payment arrangements.* In the case of qualified IDR items and services billed by a provider, facility, or provider of air ambulance services as part of a bundled payment arrangement, or where a plan or issuer makes or denies an initial payment as a bundled payment, the qualified IDR items and services may be submitted as part of one payment determination. Bundled payment arrangements submitted under this paragraph (c)(3)(ii) are subject to the rules for batched determinations and the certified IDR entity fee for single determinations.

(4) *Payment determination for a qualified IDR item or service*—(i) *Submission of offers.* Not later than 10 business days after the selection of the certified IDR entity, the plan or issuer and the provider, facility, or provider of air ambulance services:

(A) Must each submit to the certified IDR entity:

(*1*) An offer of an out-of-network rate expressed as both a dollar amount and the corresponding percentage of the qualifying payment amount represented by that dollar amount;

(*2*) Information requested by the certified IDR entity relating to the offer.

(*3*) The following additional information, as applicable—

(*i*) For providers and facilities, information on the size of the provider's practice or of the facility (if applicable). Specifically, a group of providers must specify whether the providers' practice has fewer than 20 employees, 20 to 50 employees, 51 to 100 employees, 101 to 500 employees, or more than 500 employees. For facilities, the facility must specify whether the facility has 50 or fewer employees, 51 to 100 employees, 101 to 500 employees, or more than 500 employees;

(*ii*) For providers and facilities, information on the practice specialty or type, respectively (if applicable);

(*iii*) For plans and issuers, information on the coverage area of the plan or issuer, the relevant geographic region for purposes of the qualifying payment amount, whether the coverage is fully-insured or partially or fully self-insured (or a FEHB carrier if the item or service relates to FEHB plans); and

(*iv*) The qualifying payment amount for the applicable year for the same or similar item or service as the qualified IDR item or service.

(B) May each submit to the certified IDR entity any information relating to the offer that was submitted by either party, except that the information may not include information on factors described in paragraph (c)(4)(v) of this section.

(ii) *Payment determination and notification.* Not later than 30 business days after the selection of the certified IDR entity, the certified IDR entity must:

(A) Select as the out-of-network rate for the qualified IDR item or service one of the offers submitted under paragraph (c)(4)(i) of this section, taking into account the considerations specified in paragraph (c)(4)(iii) of this section (as applied to the information provided by the parties pursuant to paragraph (c)(4)(i) of this section). The certified IDR entity must select the offer closest to the qualifying payment amount unless the certified IDR entity determines that credible information submitted by either party under paragraph (c)(4)(i) clearly demonstrates that the qualifying payment amount is materially different from the appropriate out-of-network rate, or if the offers are equally distant from the qualifying payment amount but in opposing directions. In these cases, the certified IDR entity must select the offer as the out-of-network rate that the certified IDR entity determines best represents the value of the qualified IDR item or services, which could be either offer.

(B) Notify the plan or issuer and the provider or facility, as applicable, of the selection of the offer under paragraph (c)(4)(ii)(A) of this section, and provide the written decision required under (c)(4)(vi) of this section.

(iii) *Considerations in determination.* In determining which offer to select, the certified IDR entity must consider:

(A) The qualifying payment amount(s) for the applicable year for the same or similar item or service.

(B) Information requested by the certified IDR entity under paragraph (c)(4)(i)(A)(*2*) of this section relating to the offer, to the extent a party provides credible information.

(C) Additional information submitted by a party, provided the information is credible and relates to the circumstances described in paragraphs (c)(4)(iii)(C)(*1*) through (*5*) of this section, with respect to a qualified IDR item or service of a nonparticipating provider, facility, group health plan, or health insurance issuer of group or individual health insurance coverage that is the subject of a payment determination. This information must also clearly demonstrate that the qualifying payment amount is materially different from the appropriate out-of-network rate.

(*1*) The level of training, experience, and quality and outcomes measurements of the provider or facility that furnished the qualified IDR item or service (such as those endorsed by the consensus-based entity authorized in section 1890 of the Social Security Act).

(*2*) The market share held by the provider or facility or that of the plan or issuer in the geographic region in which the qualified IDR item or service was provided.

(*3*) The acuity of the participant, beneficiary, or enrollee receiving the qualified IDR item or service, or the complexity of furnishing the qualified IDR item or service to the participant, beneficiary, or enrollee.

(*4*) The teaching status, case mix, and scope of services of the facility that furnished the qualified IDR item or service, if applicable.

(*5*) Demonstration of good faith efforts (or lack thereof) made by the provider or facility or the plan or issuer to enter into network agreements with each other, and, if applicable, contracted rates between the provider or facility, as applicable, and the plan or issuer, as applicable, during the previous 4 plan years.

(D) Additional information submitted by a party, provided the information is credible and relates to the offer submitted by either party and does not include information on factors described in paragraph (c)(4)(v) of this section.

(iv) *Examples.* The rules of paragraph (c)(4)(iii) of this section are illustrated by the following examples:

(A) *Example 1*—(*1*) *Facts.* A nonparticipating provider and an issuer are parties to a payment determination in the Federal IDR process. The nonparticipating provider submits an offer and additional written information asserting that the provider has made good faith efforts to enter into network agreements with the issuer. The nonparticipating provider fails to provide any documentation of these efforts, such as correspondence or records of conversations with representatives of the issuer.

(*2*) *Conclusion.* In this *Example 1,* the nonparticipating provider has submitted additional information. However, this information is not credible, as the nonparticipating provider has failed to provide any documentation in support of the provider's assertions of good faith efforts to enter into network agreements with the issuer. Therefore, the certified IDR entity cannot consider the information.

(B) *Example 2*—(*1*) *Facts.* A nonparticipating provider and an issuer are parties to a payment determination in the Federal IDR process. The nonparticipating provider submits credible information relating to the provider's level of training, experience, and quality and outcome measurements from 2019. The provider also submits credible information that clearly demonstrates that the provider's level of training and expertise was necessary for providing the service that is the subject of the payment determination to the particular patient. Further, the provider submits credible information that clearly demonstrates that the qualifying payment amount generally presumes the service would be delivered by a provider with a lower level of training, experience, and quality and outcome measurements. This information, taken together, demonstrates that the qualifying payment amount is not an appropriate payment amount and the provider submits an offer that is higher than the qualifying payment amount and commensurate with the provider's level of training, experience, and quality and outcome measurements with respect to the service provided. The issuer submits the qualifying payment amount as its offer with no additional information.

(*2*) *Conclusion.* In this *Example 2,* the nonparticipating provider has submitted information that is credible. Moreover, the credible information clearly demonstrates that the qualifying payment amount does not adequately take into account the provider's level of training, experience, and quality and outcome measurements with respect to the service provided, and that the appropriate out-of-network rate should therefore be higher than the qualifying payment amount. Accordingly, the certified IDR entity must select the provider's offer, as that offer best represents the value of the service that is the subject of the payment determination.

(C) *Example 3*—(*1*) *Facts.* A nonparticipating provider and an issuer are parties to a payment determination in the Federal IDR process. The nonparticipating provider submits credible information to the certified IDR entity relating to the acuity of the patient that received the service, and the complexity of furnishing the service to the patient, by providing details of the service at issue and the training required to furnish the complex service. The provider contends that this information demonstrates that the qualifying payment amount is not an appropriate payment amount, and the provider submits an offer that is higher than the qualifying payment amount and equal to what the provider believes is commensurate with the acuity of the patient and the complexity of the service that is the subject of the payment determination. However, the evidence submitted by the provider does not clearly demonstrate that the qualifying payment amount fails to encompass the acuity and complexity of the service. The issuer submits the qualifying payment amount as its offer, along with credible information that demonstrates how the qualifying payment amount was calculated for this particular service, taking into consideration the acuity of the patient and the complexity of the service.

(*2*) *Conclusion.* The information submitted by the provider to the certified IDR entity is credible with respect to the acuity of the patient and complexity of the service. However, in this example, the provider has not clearly demonstrated that the qualifying payment amount is materially different from the appropriate out-of-network rate, based on the acuity of the patient and the complexity of the service that is the subject of the payment determination. Accordingly, the certified IDR entity must select the offer closest to the qualifying payment amount, which is the issuer's offer.

(D) *Example 4*—(*1*) *Facts.* A nonparticipating provider and an issuer are parties to a payment determination in the Federal IDR process. The issuer submits credible information demonstrating that the patent for the item that is the subject of the payment determination has expired, including written documentation that demonstrates how much the cost of the item was at the time the provider rendered service and how the qualifying payment amount exceeds that cost. The issuer submits an offer that is lower than the qualifying payment amount and commensurate with the cost of the item at the time service was rendered. The nonparticipating provider submits the qualifying payment amount as its offer and also submits credible information demonstrating the provider's level of training, experience, and quality and outcome measurements from 2019, but the provider does not explain how this additional information is relevant to the cost of the item.

(*2*) *Conclusion.* In this *Example 4,* both the nonparticipating provider and issuer submitted information that is credible and that may be considered by the certified IDR entity. However, only the issuer provided credible information that was relevant to the service that is the subject of the payment determination. Moreover, the issuer has clearly demonstrated that the qualifying payment amount does not adequately take into account the complexity of the item furnished—in this case that the item is no longer patent protected. While the provider submitted credible information, the provider failed to show how the information was relevant to the item that is the subject of the payment determination. Accordingly, the certified IDR entity must select the offer that best represents the value of the item, which is the issuer's offer in this example.

(v) *Prohibition on consideration of certain factors.* In determining which offer to select, the certified IDR entity must not consider:

(A) Usual and customary charges (including payment or reimbursement rates expressed as a proportion of usual and customary charges);

(B) The amount that would have been billed by the provider or facility with respect to the qualified IDR item or service had the provisions of 45 CFR 149.410 and 149.420 (as applicable) not applied; or

(C) The payment or reimbursement rate for items and services furnished by the provider or facility payable by a public payor, including under the Medicare program under title XVIII of the Social Security Act; the Medicaid program under title XIX of the Social Security Act; the Children's Health Insurance Program under title XXI of the Social Security Act; the TRICARE program under chapter 55 of title 10, United States Code; chapter 17 of title 38, United States Code; or

demonstration projects under section 1115 of the Social Security Act.

(vi) *Written decision.* (A) The certified IDR entity must explain its determination in a written decision submitted to the parties and the Secretary, in a form and manner specified by the Secretary;

(B) If the certified IDR entity does not choose the offer closest to the qualifying payment amount, the certified IDR entity's written decision must include an explanation of the credible information that the certified IDR entity determined demonstrated that the qualifying payment amount was materially different from the appropriate out-of-network rate, based on the considerations allowed under paragraph (c)(4)(iii)(B) through (D) of this section, with respect to the qualified IDR item or service.

(vii) *Effects of determination*—(A) *Binding.* A determination made by a certified IDR entity under paragraph (c)(4)(ii) of this section:

(*1*) Is binding upon the parties, in the absence of fraud or evidence of intentional misrepresentation of material facts presented to the certified IDR entity regarding the claim; and

(*2*) Is not subject to judicial review, except in a case described in any of paragraphs (1) through (4) of section 10(a) of title 9, United States Code.

(B) *Suspension of certain subsequent IDR requests.* In the case of a determination made by a certified IDR entity under paragraph (c)(4)(ii) of this section, the party that submitted the initial notification under paragraph (b)(2) of this section may not submit a subsequent notification involving the same other party with respect to a claim for the same or similar item or service that was the subject of the initial notification during the 90-calendar-day period following the determination.

(C) *Subsequent submission of requests permitted.* If the end of the open negotiation period specified in paragraph (b)(1) of this section occurs during the 90-calendar-day suspension period regarding claims for the same or similar item or service that were the subject of the initial notice of IDR determination as described in paragraph (c)(4)(vi) of this section, either party may initiate the Federal IDR process for those claims by submitting a notification as specified in paragraph (b)(2) of this section during the 30-business-day period beginning on the day after the last day of the 90-calendar-day suspension period.

(viii) *Recordkeeping requirements.* The certified IDR entity must maintain records of all claims and notices associated with the Federal IDR process with respect to any determination for 6 years. The certified IDR entity must make these records available for examination by the plan, issuer, FEHB carrier, provider, facility, or provider of air ambulance services, or a State or Federal oversight agency upon request, except to the extent the disclosure would violate either State or Federal privacy law.

(ix) *Payment.* If applicable, the amount of the offer selected by the certified IDR entity (less the sum of the initial payment and any cost sharing paid or owed by the participant or beneficiary) must be paid directly to the provider, facility, or provider of air ambulance services not later than 30 calendar days after the determination by the certified IDR entity. If the offer selected by the certified IDR entity is less than the sum of the initial payment and any cost sharing paid by the participant or beneficiary, the provider, facility, or provider of air ambulance services will be liable to the plan or issuer for the difference. The provider, facility, or provider of air ambulance services must pay the difference directly to the plan or issuer not later than 30 calendar days after the determination by the certified IDR entity.

(d) *Costs of IDR process*—(1) *Certified IDR entity fee.* (i) With respect to the Federal IDR process described in paragraph (c) of this section, the party whose offer submitted to the certified IDR entity under paragraph (c)(4)(ii)(A) of this section is not selected is responsible for the payment to the certified IDR entity of the predetermined fee charged by the certified IDR entity.

(ii) Each party to a determination for which a certified IDR entity is selected under paragraph (c)(1) of this section must pay the predetermined certified IDR entity fee charged by the certified IDR entity to the certified IDR entity at the time the parties submit their offers under (c)(4)(i) of this section. The certified IDR entity fee paid by the prevailing party whose offer is selected by the certified IDR entity will be returned to that party within 30 business days following the date of the certified IDR entity's determination.

(2) *Administrative fee.* (i) Each party to a determination for which a certified IDR entity is selected under paragraph (c)(1) of this section must, at the time the certified IDR entity is selected under paragraph (c)(1) of this section, pay to the certified IDR entity a non-refundable administrative fee due to the Secretary for participating in the Federal IDR process described in this section.

(ii) The administrative fee amount will be established in guidance published annually by the Secretary in a manner such that the total fees paid for a year are estimated to be equal to the projected amount of expenditures by the Departments of the Treasury, Labor, and Health and Human Services for the year in carrying out the Federal IDR process.

(e) *Certification of IDR entity*—(1) *In general.* In order to be selected under paragraph (c)(1) of this section—(i) An IDR entity must meet the standards described in this paragraph (e) and be certified by the Secretary, jointly with the Secretaries of Labor and the Treasury, as set forth in this paragraph (e) of this section and guidance promulgated by the Secretary. Once certified, the IDR entity will be provided with a certified IDR entity number.

(ii) An IDR entity must provide written documentation to the Secretary regarding general company information (such as contact information, Taxpayer Identification Number, and website), as well as the applicable service area in which the IDR entity intends to conduct payment determinations under the Federal IDR process. IDR entities may choose to submit their application for all States or self-limit to a particular subset of States.

(iii) An IDR entity that the Secretary, jointly with the Secretary of Labor and the Secretary of the Treasury, certifies must enter into an agreement as a condition of certification. The agreement shall include specified provisions encompassed by this section, including, but not limited to, the requirements applicable to certified IDR entities when making payment determinations as well as the requirements regarding certification and revocation (such as specifications for wind down activities and reallocation of certified IDR entity fees, where warranted).

(2) *Requirements.* An IDR entity must provide written documentation to the Secretary through the Federal IDR portal that demonstrates that the IDR entity satisfies the following standards to be a certified IDR entity under this paragraph (e):

(i) Possess (directly or through contracts or other arrangements) sufficient arbitration and claims administration of health care services, managed care, billing and coding, medical and legal expertise to make the payment determinations described in paragraph (c) of this section within the time prescribed in paragraph (c)(4)(ii) of this section.

(ii) Employ (directly or through contracts or other arrangements) a sufficient number of personnel to make the determinations described in

paragraph (c) of this section within the time prescribed by (c)(4)(ii) of this section. To satisfy this standard, the written documentation must include a description of the IDR entity's organizational structure and capabilities, including an organizational chart and the credentials, responsibilities, and number of personnel employed to make determinations described in paragraph (c) of this section.

(iii) Maintain a current accreditation from a nationally recognized and relevant accrediting organization, such as URAC, or ensure that it otherwise possesses the requisite training to conduct payment determinations (for example, providing documentation that personnel employed by the IDR entity have completed arbitration training by the American Arbitration Association, the American Health Law Association, or a similar organization);

(iv) Have a process to ensure that no conflict of interest, as defined in paragraph (a)(2) of this section, exists between the parties and the personnel the certified IDR entity assigns to a payment determination to avoid violating paragraph (c)(1)(ii) of this section, including policies and procedures for conducting ongoing audits for conflicts of interest, to ensure that should any arise, the certified IDR entity has procedures in place to inform the Secretary, jointly with the Secretary of the Treasury and the Secretary of Labor, of the conflict of interest and to mitigate the risk by reassigning the dispute to other personnel in the event that any personnel previously assigned have a conflict of interest.

(v) Have a process to maintain the confidentiality of IIHI obtained in the course of conducting determinations. A certified IDR entity's responsibility to comply with these confidentiality requirements shall survive revocation of the IDR entity's certification for any reason, and IDR entities must comply with the record retention and disposal requirements described in this section. Under this process, once certified, the certified IDR entity must comply with the following requirements:

(A) *Privacy.* The certified IDR entity may create, collect, handle, disclose, transmit, access, maintain, store, and/or use IIHI, only to perform:

(*1*) The certified IDR entity's required duties described in this section; and

(*2*) Functions related to carrying out additional obligations as may be required under applicable Federal or State laws or regulations.

(B) *Security.* (*1*) The certified IDR entity must ensure the confidentiality of all IIHI it creates, obtains, maintains, stores, and transmits;

(*2*) The certified IDR entity must protect against any reasonably anticipated threats or hazards to the security of this information;

(*3*) The certified IDR entity must ensure that IIHI is securely destroyed or disposed of in an appropriate and reasonable manner 6 years from either the date of its creation or the first date on which the certified IDR entity had access to it, whichever is earlier.

(*4*) The certified IDR entity must implement policies and procedures to prevent, detect, contain, and correct security violations in the event of a breach of IIHI;

(C) *Breach notification.* The certified IDR entity must, following the discovery of a breach of unsecured IIHI, notify of the breach the provider, facility, or provider of air ambulance services; the plan and issuer; the Secretary, jointly with the Secretary of the Treasury and the Secretary of Labor; and each individual whose unsecured IIHI has been, or is reasonably believed to have been, subject to the breach, to the extent possible.

(*1*) *Breaches treated as discovered.* For purposes of this paragraph (e)(2)(v)(C), a breach shall be treated as discovered by a certified IDR entity as of the first day on which the breach is known to the certified IDR entity or, by exercising reasonable diligence, would have been known to the certified IDR entity. A certified IDR entity shall be deemed to have knowledge of a breach if the breach is known, or by exercising reasonable diligence would have been known, to any person, other than the person committing the breach, who is an employee, officer, or other agent of the certified IDR entity;

(*2*) *Timing of notification.* A certified IDR entity must provide the notification required by this paragraph (e)(2)(v)(C) without unreasonable delay and in no case later than 60 calendar days after discovery of a breach.

(*3*) *Content of notification.* The notification required by this paragraph (e)(2)(v)(C) must include, to the extent possible:

(*i*) The identification of each individual whose unsecured IIHI has been, or is reasonably believed by the certified IDR entity to have been, subject to the breach;

(*ii*) A brief description of what happened, including the date of the breach and the date of the discovery of the breach, to the extent known;

(*iii*) A description of the types of unsecured IIHI that were involved in the breach (for example whether full name, social security number, date of birth, home address, account number, diagnosis, disability code, or other types of information were involved);

(*iv*) A brief description of what the certified IDR entity involved is doing to investigate the breach, to mitigate harm to the affected parties, and to protect against any further breaches; and

(*v*) Contact procedures for individuals to ask questions or learn additional information, which must include a toll-free telephone number, email address, website, or postal address.

(*4*) *Method for providing notification.* A certified IDR entity must submit the notification required by this paragraph (e)(2)(v)(C) in written form (in clear and understandable language) either on paper or electronically through the Federal IDR portal or electronic mail.

(D) *Application to contractor and subcontractors.* The certified IDR entity must ensure compliance with this paragraph (e)(2)(v) of this section by any contractor or subcontractor with access to IIHI performing any duties related to the Federal IDR process.

(vi) Meet appropriate indicators of fiscal integrity and stability by demonstrating that the certified IDR entity has a system of safeguards and controls in place to prevent and detect improper financial activities by its employees and agents to assure fiscal integrity and accountability for all certified IDR entity fees and administrative fees received, held, and disbursed and by submitting 3 years of financial statements or, if not available, other information to demonstrate fiscal stability of the IDR entity;

(vii) Provide a fixed fee for single determinations and a separate fixed fee for batched determinations within the upper and lower limits for each, as set forth in guidance issued by the Secretary. The certified IDR entity may not charge a fee that is not within the approved limits as set forth in guidance unless the certified IDR entity or IDR entity seeking certification receives written approval from the Secretary to charge a flat rate beyond the upper or lower limits approved by the Secretary for fees. The certified IDR entity or IDR entity seeking certification may update its fees and seek approval from the Secretary to charge a flat fee beyond the upper or lower limits for fees, annually as provided in guidance. In order for the certified IDR entity to receive the Secretary's written approval to charge a flat fee beyond the upper or lower limits for fees as set forth in guidance, it must satisfy both conditions in paragraphs (e)(2)(v)(A) and (B) of this section, as follows:

(A) Submit, in writing, a proposal to the Secretary that includes:

(*1*) The alternative flat fee the certified IDR entity or IDR entity seeking certification believes is appropriate for the certified IDR entity or IDR entity seeking certification to charge;

(*2*) A description of the circumstances that require the alternative fee; and

(*3*) A description of how the alternative flat rate will be used to mitigate the effects of these circumstances; and

(B) Receive from the Secretary, jointly with the Secretary of the Treasury and the Secretary of Labor written approval to charge the fee documented in the certified IDR entity's or the IDR entity seeking certification's written proposal.

(viii) Have a procedure in place to retain the certified IDR entity fees described in paragraph (d)(1) of this section paid by both parties in a trust or escrow account and to return the certified IDR entity fee paid by the prevailing party of an IDR payment determination, or half of each party's certified IDR entity fee in the case of an agreement described in paragraph (c)(2)(i) of this section, within 30 business days following the date of the determination;

(ix) Have a procedure in place to retain the administrative fees described in paragraph (d)(2) of this section and to remit the administrative fees to the Secretary in accordance with the timeframe and procedures set forth in guidance published by the Secretary;

(x) Discharge its responsibilities in accordance with paragraph (c) of this section, including not making any determination with respect to which the certified IDR entity would not be eligible for selection pursuant to paragraph (c)(1) of this section; and

(xi) Collect the information required to be reported to the Secretary under paragraph (f) of this section and report the information on a timely basis in the form and manner provided in guidance published by the Secretary.

(3) Conflict-of-interest standards. In addition to the general standards set forth in paragraph (e)(2)(iv) of this section, an IDR entity must provide written documentation that the IDR entity satisfies the standards to be a certified IDR entity under this paragraph (e)(3).

(i) The IDR entity must provide an attestation indicating that it does not have a conflict of interest as defined in paragraph (a)(2) of this section;

(ii) The IDR entity must have procedures in place to ensure that personnel assigned to a determination do not have any conflicts of interest regarding any party to the dispute within the 1 year immediately preceding an assignment of dispute determination, similar to the requirements laid out in 18 U.S.C. 207(b). In order to satisfy this requirement, if certified, the IDR entity must ensure that any personnel assigned to a determination do not have any conflicts of interest as defined in paragraph (a)(2) of this section.

(iii) Following certification under this paragraph (e), if a certified IDR entity acquires control of, becomes controlled by, or comes under common control with any entity described in paragraph (e)(3)(i) of this section, the certified IDR entity must notify the Secretary in writing no later than 3 business days after the acquisition or exercise of control and shall be subject to the revocation of certification under paragraph (e)(6)(ii) of this section.

(4) *Period of certification.* Subject to paragraphs (e)(5) and (6) of this section, each certification (including a recertification) of a certified IDR entity under the process described in paragraph (e)(1) of this section will be effective for a 5-year period.

(5) *Petition for denial or revocation*—(i) *In general.* An individual, provider, facility, provider of air ambulance services, plan, or issuer may petition for a denial of a certification for an IDR entity or a revocation of a certification for a certified IDR entity for failure to meet a requirement of this section using the standard form and manner set forth in guidance to be issued by the Secretary. The petition for denial of a certification must be submitted within the timeframe set forth in guidance issued by the Secretary.

(ii) *Content of petition.* The individual, provider, facility, provider of air ambulance services, plan, or issuer seeking denial or revocation of certification must submit a written petition using the standard form issued by the Secretary including the following information:

(A) The identity of the IDR entity seeking certification or certified IDR entity that is the subject of the petition;

(B) The reason(s) for the petition;

(C) Whether the petition seeks denial or revocation of a certification;

(D) Documentation to support the reasons outlined in the petition; and

(E) Other information as may be required by the Secretary.

(iii) *Process.* (A) The Secretary, jointly with the Secretary of the Treasury and the Secretary of Labor will acknowledge receipt of the petition within 10 business days of receipt of the petition.

(B) If the Secretary finds that the petition adequately shows a failure of the IDR entity seeking certification or the certified IDR entity to follow the requirements of this paragraph (e), the Secretary, jointly with the Secretary of the Treasury and the Secretary of Labor, will notify the IDR entity seeking certification or the certified IDR entity by providing a de-identified copy of the petition. Following the notification, the IDR entity seeking certification or certified IDR entity will have 10 business days to provide a response. After the time period for providing the response has passed, the Secretary, jointly with the Secretary of the Treasury and the Secretary of Labor, will review the response (if any), determine whether a denial or revocation of a certification is warranted, and issue a notice of the decision to the IDR entity or certified IDR entity and to the petitioner. This decision will be subject to the appeal requirements of paragraph (e)(6)(v) of this section.

(C) Effect on certification under petition. Regarding a petition for revocation of a certified IDR entity's certification, if the Secretary, jointly with the Secretary of the Treasury and the Secretary of Labor, finds that the petition adequately shows a failure to comply with the requirements of this paragraph (e), following the Secretary's notification of the failure to the certified IDR entity under paragraph (e)(5)(iii)(B) of this section, the certified IDR entity may continue to work on previously assigned determinations but may not accept new determinations until the Secretary issues a notice of the decision to the certified IDR entity finding that a revocation of certification is not warranted.

(6) *Denial of IDR entity certification or revocation of certified IDR entity certification*—(i) *Denial of IDR entity certification.* The Secretary, jointly with the Secretary of the Treasury and the Secretary of Labor, may deny the certification of an IDR entity under paragraph (e)(1) of this section if, during the process of certification, including as a result of a petition described in paragraph (e)(5) of this section, the Secretary determines the following:

(A) The IDR entity fails to meet the applicable standards set forth under this paragraph (e);

(B) The IDR entity has committed or participated in fraudulent or abusive activities, including, during the certification process, submitting fraudulent data, or submitting information or data the IDR entity knows to be false to the Secretary, the Secretary of the Treasury or the Secretary of Labor;

(C) The IDR entity has failed to comply with requests for information from the Secretary, the Secretary of the

Treasury, or the Secretary of Labor as part of the certification process;

(D) In conducting payment determinations, including those outside the Federal IDR process, the IDR entity has failed to meet the standards that applied to those determinations or reviews, including standards of independence and impartiality; or

(E) The IDR entity is otherwise not fit or qualified to make determinations under the Federal IDR process.

(ii) *Revocation of certification of a certified IDR entity.* The Secretary, jointly with the Secretary of the Treasury and the Secretary of Labor, may revoke the certification of a certified IDR entity under paragraph (e)(1) of this section if, as a result of an audit, a petition described in paragraph (e)(5) of this section, or otherwise, the Secretary determines the following:

(A) The certified IDR entity has a pattern or practice of noncompliance with any requirements of this paragraph (e);

(B) The certified IDR entity is operating in a manner that hinders the efficient and effective administration of the Federal IDR process;

(C) The certified IDR entity no longer meets the applicable standards for certification set forth under this paragraph (e);

(D) The certified IDR entity has committed or participated in fraudulent or abusive activities, including submission of false or fraudulent data to the Secretary, the Secretary of the Treasury, or the Secretary of Labor;

(E) The certified IDR entity lacks the financial viability to provide arbitration under the Federal IDR process;

(F) The certified IDR entity has failed to comply with requests from the Secretary, the Secretary of the Treasury, or the Secretary of Labor made as part of an audit, including failing to submit all records of the certified IDR entity that pertain to its activities within the Federal IDR process; or

(G) The certified IDR entity is otherwise no longer fit or qualified to make determinations.

(iii) *Notice of denial or revocation.* The Secretary, jointly with the Secretary of the Treasury and the Secretary of Labor, will issue a written notice of denial to the IDR entity or revocation to the certified IDR entity within 10 business days of the Secretary's decision, including the effective date of denial or revocation, the reason(s) for denial or revocation, and the opportunity to request appeal of the denial or revocation.

(iv) *Request for appeal of denial or revocation.* To request an appeal, the IDR entity or certified IDR entity must submit a request for appeal to the Secretary within 30 business days of the date of the notice under paragraph (e)(6)(iii) of this section of denial or revocation and in the manner prescribed by the instructions to the notice. During this time period, the Secretary, jointly with the Secretary of the Treasury and the Secretary of Labor, will not issue a notice of final denial or revocation and a certified IDR entity may continue to work on previously assigned determinations but may not accept new determinations. If the IDR entity or certified IDR entity does not timely submit a request for appeal of the denial or revocation, the Secretary, jointly with the Secretary of the Treasury and the Secretary of Labor, will issue a notice of final denial or revocation to the IDR entity or certified IDR entity (if applicable) and the petitioner.

(v) *Denial or final revocation.* Upon notice of denial or final revocation, the IDR entity shall not be considered a certified IDR entity and therefore shall not be eligible to accept payment determinations under the Federal IDR process. Moreover, after a notice of final revocation, the IDR entity may not re-apply to be a certified IDR entity until on or after the 181st day after the date of the notice of denial or final revocation.

(f) *Reporting of information relating to the Federal IDR process*—(1) *Reporting of information.* Within 30 business days of the close of each month, for qualified IDR items and services furnished on or after January 1, 2022, each certified IDR entity must, in a form and manner specified by the Secretary, report:

(i) The number of notices of IDR initiation submitted under paragraph (b)(2) of this section to the certified IDR entity during the immediately preceding month;

(ii) The size of the provider practices and the size of the facilities submitting notices of IDR initiation under paragraph (b)(2) of this section during the immediately preceding month, as required to be provided to the certified IDR entity under paragraph (c)(4)(i)(A)(*2*) of this section;

(iii) The number of such notices of IDR initiation with respect to which a determination was made under paragraph (c)(4)(ii) of this section;

(iv) The number of times during the month that the out-of-network rate determined (or agreed to) under this section has exceeded the qualifying payment amount, specified by qualified IDR items and services;

(v) With respect to each notice of IDR initiation under paragraph (b)(2) of this section for which such a determination was made, the following information:

(A) A description of the qualified IDR items and services included with respect to the notification, including the relevant billing and service codes;

(B) The relevant geographic region for purposes of the qualifying payment amount for the qualified IDR items and services with respect to which the notification was provided;

(C) The amount of the offer submitted under paragraph (c)(4)(i) of this section by the plan or issuer (as applicable) and by the provider or facility (as applicable) expressed as a dollar amount and as a percentage of the qualifying payment amount;

(D) Whether the offer selected by the certified IDR entity under paragraph (c)(4) of this section was the offer submitted by the plan or issuer (as applicable) or by the provider or facility (as applicable);

(E) The amount of the selected offer expressed as a dollar amount and as a percentage of the qualifying payment amount;

(F) The rationale for the certified IDR entity's decision, including the extent to which the decision relied on the criteria in paragraph (c)(4)(iv) of this section;

(G) The practice specialty or type of each provider or facility, respectively, involved in furnishing each qualified IDR item or service;

(H) The identity for each plan or issuer, and provider or facility, with respect to the notification. Specifically, each certified IDR entity must provide each party's name and address, as applicable; and

(I) For each determination, the number of business days elapsed between selection of the certified IDR entity and the determination of the out-of-network rate by the certified IDR entity.

(vi) The total amount of certified IDR entity fees paid to the certified IDR entity under paragraph (d)(1) of this section during the month.

(2) [Reserved]

(g) *Extension of time periods for extenuating circumstances*—(1) *General.* The time periods specified in this section (other than the time for payment, if applicable, under paragraph (c)(4)(ix) of this section) may be extended in extenuating circumstances at the Secretary's discretion if:

(i) An extension is necessary to address delays due to matters beyond the control of the parties or for good cause; and

(ii) The parties attest that prompt action will be taken to ensure that the determination under this section is made as soon as administratively practicable under the circumstances.

(2) *Process to request an extension.* The parties may request an extension by submitting a request for extension due to extenuating circumstances through the Federal IDR portal if the extension is necessary to address delays due to matters beyond the control of the parties or for good cause.

(h) *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, except that the provisions regarding IDR entity certification at paragraphs (a) and (e) of this section are applicable beginning on October 7, 2021.

§ 149.520 Independent dispute resolution process for air ambulance services.

(a) *Definitions.* Unless otherwise stated, the definitions in § 149.30 apply.

(b) *Determination of out-of-network rates to be paid by health plans and health insurance issuers; independent dispute resolution process*—(1) *In general.* Except as provided in paragraphs (b)(2) and (3) of this section, in determining the out-of-network rate to be paid by group health plans and health insurance issuers offering group or individual health insurance coverage for out-of-network air ambulance services, plans and issuers must comply with the requirements of § 149.510, except that references in § 149.510 to the additional circumstances in § 149.510(c)(4)(iii)(C) shall be understood to refer to paragraph (b)(2) of this section.

(2) *Additional information.* Additional information submitted by a party, provided the information is credible, relates to the circumstances described in paragraphs (b)(2)(i) through (vi) of this section, with respect to a qualified IDR service of a nonparticipating provider of air ambulance services or health insurance issuer of group or individual health insurance coverage that is the subject of a payment determination. This information must also clearly demonstrate that the qualifying payment amount is materially different from the appropriate out-of-network rate.

(i) The quality and outcomes measurements of the provider that furnished the services.

(ii) The acuity of the condition of the participant, beneficiary, or enrollee receiving the service, or the complexity of furnishing the service to the participant, beneficiary, or enrollee.

(iii) The training, experience, and quality of the medical personnel that furnished the air ambulance services.

(iv) Ambulance vehicle type, including the clinical capability level of the vehicle.

(v) Population density of the point of pick-up (as defined in 42 CFR 414.605) for the air ambulance (such as urban, suburban, rural, or frontier).

(vi) Demonstrations of good faith efforts (or lack thereof) made by the nonparticipating provider of air ambulance services or the plan or issuer to enter into network agreements with each other and, if applicable, contracted rates between the provider of air ambulance services and the plan or issuer, as applicable, during the previous 4 plan years.

(3) *Reporting of information relating to the IDR process.* In applying the requirements of § 149.510(f), within 30 business days of the close of each month, for services furnished on or after January 1, 2022, the information the certified IDR entity must report, in a form and manner specified by the Secretary, with respect to the Federal IDR process involving air ambulance services is:

(i) The number of notices of IDR initiation submitted under the Federal IDR process to the certified IDR entity that pertain to air ambulance services during the immediately preceding month;

(ii) The number of such notices of IDR initiation with respect to which a final determination was made under § 149.510(c)(4)(ii) (as applied by paragraph (b)(1) of this section);

(iii) The number of times the payment amount determined (or agreed to) under this subsection has exceeded the qualifying payment amount, specified by services;

(iv) With respect to each notice of IDR initiation under § 149.510(b)(2) of this part (as applied by paragraph (b)(1) of this section) for which a determination was made, the following information:

(A) A description of each air ambulance service included in such notification, including the relevant billing and service codes;

(B) The point of pick-up (as defined in 42 CFR 414.605) for the services included in such notification;

(C) The amount of the offers submitted under § 149.510(c)(4)(i) (as applied by paragraph (b)(1) of this section) by the group health plan or health insurance issuer (as applicable) and by the nonparticipating provider of air ambulance services, expressed as a dollar amount and as a percentage of the qualifying payment amount;

(D) Whether the offer selected by the certified IDR entity under § 149.510(c)(4)(ii) (as applied by paragraph (b)(1) of this section) to be the payment amount applied was the offer submitted by the plan or issuer (as applicable) or by the provider of air ambulance services;

(E) The amount of the selected offer expressed as a dollar amount and as a percentage of the qualifying payment amount;

(F) The rationale for the certified IDR entity's decision, including the extent to which the decision relied on the criteria in paragraph (b)(2) of this section;

(G) Air ambulance vehicle type, including the clinical capability level of such vehicle (to the extent this information has been provided to the certified IDR entity);

(H) The identity for each plan or issuer and provider of air ambulance services, with respect to the notification. Specifically, each certified IDR entity must provide each party's name and address, as applicable; and

(I) For each determination, the number of business days elapsed between selection of the certified IDR entity and the selection of the payment amount by the certified IDR entity.

(v) The total amount of certified IDR entity fees paid to the certified IDR entity under paragraph § 149.510(d)(1) (as applied by paragraph (b)(1) of this section) during the month for determinations involving air ambulance services.

(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.

■ 21. Subpart G, consisting of §§ 149.610 and 149.620, is added to read as follows:

Subpart G—Protection of Uninsured or Self-Pay Individuals

§ 149.610 Requirements for provision of good faith estimates of expected charges for uninsured (or self-pay) individuals.

(a) *Scope and definitions*—(1) *Scope.* This section sets forth requirements for health care providers and health care facilities related to the issuance of good faith estimates of expected charges for uninsured (or self-pay) individuals (or their authorized representatives), upon request or upon scheduling an item or service.

(2) *Definitions.* For purposes of this section, the following definitions apply:

(i) *Authorized representative* means an individual authorized under State law to provide consent on behalf of the uninsured (or self-pay) individual, provided that the individual is not a provider affiliated with a facility or an employee of a provider or facility represented in the good faith estimate,

unless such provider or employee is a family member of the uninsured (or self-pay) individual.

(ii) *Convening health care provider or convening health care facility (convening provider or convening facility)* means the provider or facility who receives the initial request for a good faith estimate from an uninsured (or self-pay) individual and who is or, in the case of a request, would be responsible for scheduling the primary item or service.

(iii) *Co-health care provider or co-health care facility (co-provider or co-facility)* means a provider or facility other than a convening provider or a convening facility that furnishes items or services that are customarily provided in conjunction with a primary item or service.

(iv) *Diagnosis code* means the code that describes an individual's disease, disorder, injury, or other related health conditions using the International Classification of Diseases (ICD) code set.

(v) *Expected charge* means, for an item or service, the cash pay rate or rate established by a provider or facility for an uninsured (or self-pay) individual, reflecting any discounts for such individuals, where the good faith estimate is being provided to an uninsured (or self-pay) individual; or the amount the provider or facility would expect to charge if the provider or facility intended to bill a plan or issuer directly for such item or service when the good faith estimate is being furnished to a plan or issuer.

(vi) *Good faith estimate* means a notification of expected charges for a scheduled or requested item or service, including items or services that are reasonably expected to be provided in conjunction with such scheduled or requested item or service, provided by a convening provider, convening facility, co-provider, or co-facility.

(vii) *Health care facility (facility)* means an institution (such as a hospital or hospital outpatient department, critical access hospital, ambulatory surgical center, rural health center, federally qualified health center, laboratory, or imaging center) in any State in which State or applicable local law provides for the licensing of such an institution, that is licensed as such an institution pursuant to such law or is approved by the agency of such State or locality responsible for licensing such institution as meeting the standards established for such licensing.

(viii) *Health care provider (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, including a provider of air ambulance services.

(ix) *Items or services* has the meaning given in 45 CFR 147.210(a)(2).

(x) *Period of care* means the day or multiple days during which the good faith estimate for a scheduled or requested item or service (or set of scheduled or requested items or services) are furnished or are anticipated to be furnished, regardless of whether the convening provider, convening facility, co-providers, or co-facilities are furnishing such items or services, including the period of time during which any facility equipment and devices, telemedicine services, imaging services, laboratory services, and preoperative and postoperative services that would not be scheduled separately by the individual, are furnished.

(xi) *Primary item or service* means the item or service to be furnished by the convening provider or convening facility that is the initial reason for the visit.

(xii) *Service code* means the code that identifies and describes an item or service using the Current Procedural Terminology (CPT), Healthcare Common Procedure Coding System (HCPCS), Diagnosis-Related Group (DRG) or National Drug Codes (NDC) code sets.

(xiii) *Uninsured (or self-pay) individual* means:

(A) An individual who does not have benefits for an item or service under a group health plan, group or individual health insurance coverage offered by a health insurance issuer, Federal health care program (as defined in section 1128B(f) of the Social Security Act), or a health benefits plan under chapter 89 of title 5, United States Code; or

(B) An individual who has benefits for such item or service under a group health plan, or individual or group health insurance coverage offered by a health insurance issuer, or a health benefits plan under chapter 89 of title 5, United States Code but who does not seek to have a claim for such item or service submitted to such plan or coverage.

(b) *Requirements of providers and facilities*—(1) *Requirements for convening providers and convening facilities.* A convening provider or convening facility must determine if an individual is an uninsured (or self-pay) individual by:

(i) Inquiring if an individual is enrolled in a group health plan, group or individual health insurance coverage offered by a health insurance issuer, Federal health care program (as defined in section 1128B(f) of the Social Security Act), or a health benefits plan under chapter 89 of title 5, United States Code;

(ii) Inquiring whether an individual who is enrolled in a group health plan, or group or individual health insurance coverage offered by a health insurance issuer or a health benefits plan under chapter 89 of title 5, United States Code is seeking to have a claim submitted for the primary item or service with such plan or coverage; and

(iii) Informing all uninsured (or self-pay) individuals of the availability of a good faith estimate of expected charges upon scheduling an item or service or upon request; information regarding the availability of good faith estimates for uninsured (or self-pay) individuals must be:

(A) Written in a clear and understandable manner, prominently displayed (and easily searchable from a public search engine) on the convening provider's or convening facility's website, in the office, and on-site where scheduling or questions about the cost of items or services occur;

(B) Orally provided when scheduling an item or service or when questions about the cost of items or services occur; and

(C) Made available in accessible formats, and in the language(s) spoken by individual(s) considering or scheduling items or services with such convening provider or convening facility.

(iv) Convening providers and convening facilities shall consider any discussion or inquiry regarding the potential costs of items or services under consideration as a request for a good faith estimate;

(v) Upon the request for a good faith estimate from an uninsured (or self-pay) individual or upon scheduling a primary item or service to be furnished for such an individual, the convening provider or convening facility must contact, no later than 1 business day of such scheduling or such request, all co-providers and co-facilities who are reasonably expected to provide items or services in conjunction with and in support of the primary item or service and request that the co-providers or co-facilities submit good faith estimate information (as specified in paragraphs (b)(2) and (c)(2) of this section) to the convening provider or facility; the request must also include the date that good faith estimate information must be received by the convening provider or facility;

(vi) Provide a good faith estimate (as specified in paragraph (c)(1) of this section) to uninsured (or self-pay)

individuals within the following timeframes:

(A) When a primary item or service is scheduled at least 3 business days before the date the item or service is scheduled to be furnished: Not later than 1 business day after the date of scheduling;

(B) When a primary item or service is scheduled at least 10 business days before such item or service is scheduled to be furnished: Not later than 3 business days after the date of scheduling; or

(C) When a good faith estimate is requested by an uninsured (or self-pay) individual: Not later than 3 business days after the date of the request.

(vii) A convening provider or convening facility must provide an uninsured (or self-pay) individual who has scheduled an item or service with a new good faith estimate if a convening provider, convening facility, co-provider, or co-facility anticipates or is notified of any changes to the scope of a good faith estimate (such as anticipated changes to the expected charges, items, services, frequency, recurrences, duration, providers, or facilities) previously furnished at the time of scheduling; a new good faith estimate must be issued to the uninsured (or self-pay) individual no later than 1 business day before the items or services are scheduled to be furnished.

(viii) If any changes in expected providers or facilities represented in a good faith estimate occur less than 1 business day before the item or service is scheduled to be furnished, the replacement provider or facility must accept as its good faith estimate of expected charges the good faith estimate for the relevant items or services included in the good faith estimate for the items or services being furnished that was provided by the replaced provider or facility.

(ix) For good faith estimates provided upon request of an uninsured (or self-pay) individual, upon scheduling of the requested item or service, the convening provider or convening facility must provide the uninsured (or self-pay) individual with a new good faith estimate for the scheduled item or service within the timeframes specified in paragraphs (b)(1)(vi)(A) and (B) of this section; and

(x) A convening provider or convening facility may issue a single good faith estimate for recurring primary items or services if the following requirements are met, in addition to the requirements under this section:

(A) The good faith estimate for recurring items or services must include, in a clear and understandable manner, the expected scope of the recurring primary items or services (such as timeframes, frequency, and total number of recurring items or services); and

(B) The scope of a good faith estimate for recurring primary items or services must not exceed 12 months. If additional recurrences of furnishing such items or services are expected beyond 12 months (or as specified under paragraph (b)(vii) of this section), a convening provider or convening facility must provide an uninsured (or self-pay) individual with a new good faith estimate, and communicate such changes (such as timeframes, frequency, and total number of recurring items or services) upon delivery of the new good faith estimate to help patients understand what has changed between the initial good faith estimate and the new good faith estimate.

(2) *Requirements for co-providers and co-facilities.* (i) Co-providers and co-facilities must submit good faith estimate information (as specified in paragraph (c)(2) of this section) upon the request of the convening provider or convening facility. The co-provider or co-facility must provide, and the convening provider or convening facility must receive, the good faith estimate information no later than 1 business day after the co-provider or co-facility receives the request from the convening provider or convening facility.

(ii) Co-providers and co-facilities must notify and provide new good faith estimate information to a convening provider or convening facility if the co-provider or co-facility anticipates any changes to the scope of good faith estimate information previously submitted to a convening provider or convening facility (such as anticipated changes to the expected charges, items, services, frequency, recurrences, duration, providers, or facilities).

(iii) If any changes in the expected co-providers or co-facilities represented in a good faith estimate occur less than 1 business day before that the item or service is scheduled to be furnished, the replacement co-provider or co-facility must accept as its good faith estimate of expected charges the good faith estimate for the relevant items or services included in the good faith estimate for the item or service being furnished that was provided by the replaced provider or facility.

(iv) In the event that an uninsured (or self-pay) individual separately schedules or requests a good faith estimate from a provider or facility that would otherwise be a co-provider or co-facility, that provider or facility is considered a convening provider or convening facility for such item or service and must meet all requirements in paragraphs (b)(1) and (c)(1) of this section for issuing a good faith estimate to an uninsured (or self-pay) individual.

(c) *Content requirements of a good faith estimate issued to an uninsured (or self-pay) individual.* (1) A good faith estimate issued to an uninsured (or self-pay) individual must include:

(i) Patient name and date of birth;

(ii) Description of the primary item or service in clear and understandable language (and if applicable, the date the primary item or service is scheduled);

(iii) Itemized list of items or services, grouped by each provider or facility, reasonably expected to be furnished for the primary item or service, and items or services reasonably expected to be furnished in conjunction with the primary item or service, for that period of care including:

(A) Items or services reasonably expected to be furnished by the convening provider or convening facility for the period of care; and

(B) Items or services reasonably expected to be furnished by co-providers or co-facilities (as specified in paragraphs (b)(2) and (c)(2) of this section);

(iv) Applicable diagnosis codes, expected service codes, and expected charges associated with each listed item or service;

(v) Name, National Provider Identifier, and Tax Identification Number of each provider or facility represented in the good faith estimate, and the State(s) and office or facility location(s) where the items or services are expected to be furnished by such provider or facility;

(vi) List of items or services that the convening provider or convening facility anticipates will require separate scheduling and that are expected to occur before or following the expected period of care for the primary item or service. The good faith estimate must include a disclaimer directly above this list that includes the following information: Separate good faith estimates will be issued to an uninsured (or self-pay) individual upon scheduling or upon request of the listed items or services; notification that for items or services included in this list, information such as diagnosis codes, service codes, expected charges and provider or facility identifiers do not need to be included as that information will be provided in separate good faith estimates upon scheduling or upon

request of such items or services; and include instructions for how an uninsured (or self-pay) individual can obtain good faith estimates for such items or services;

(viii) A disclaimer that informs the uninsured (or self-pay) individual that there may be additional items or services the convening provider or convening facility recommends as part of the course of care that must be scheduled or requested separately and are not reflected in the good faith estimate;

(ix) A disclaimer that informs the uninsured (or self-pay) individual that the information provided in the good faith estimate is only an estimate regarding items or services reasonably expected to be furnished at the time the good faith estimate is issued to the uninsured (or self-pay) individual and that actual items, services, or charges may differ from the good faith estimate; and

(x) A disclaimer that informs the uninsured (or self-pay) individual of the uninsured (or self-pay) individual's right to initiate the patient-provider dispute resolution process if the actual billed charges are substantially in excess of the expected charges included in the good faith estimate, as specified in § 149.620; this disclaimer must include instructions for where an uninsured (or self-pay) individual can find information about how to initiate the patient-provider dispute resolution process and state that the initiation of the patient-provider dispute resolution process will not adversely affect the quality of health care services furnished to an uninsured (or self-pay) individual by a provider or facility; and

(xi) A disclaimer that the good faith estimate is not a contract and does not require the uninsured (or self-pay) individual to obtain the items or services from any of the providers or facilities identified in the good faith estimate.

(2) [Reserved]

(d) *Content Requirements for Good Faith Estimate Information Submitted by Co-Providers or Co-Facilities to Convening Providers or Convening Facilities.* (1) Good faith estimate information submitted to convening providers or convening facilities by co-providers or co-facilities for inclusion in the good faith estimate (described in paragraph (c)(1) of this section) must include:

(i) Patient name and date of birth;

(ii) Itemized list of items or services expected to be provided by the co-provider or co-facility that are reasonably expected to be furnished in conjunction with the primary item or service as part of the period of care;

(iii) Applicable diagnosis codes, expected service codes, and expected charges associated with each listed item or service;

(iv) Name, National Provider Identifiers, and Tax Identification Numbers of the co-provider or co-facility, and the State(s) and office or facility location(s) where the items or services are expected to be furnished by the co-provider or co-facility; and

(v) A disclaimer that the good faith estimate is not a contract and does not require the uninsured (or self-pay) individual to obtain the items or services from any of the co-providers or co-facilities identified in the good faith estimate.

(2) [Reserved]

(e) *Required Methods for Providing Good Faith Estimates for Uninsured (or Self-Pay) Individuals.* (1) A good faith estimate must be provided in written form either on paper or electronically, pursuant to the uninsured (or self-pay) individual's requested method of delivery, and within the timeframes described in paragraph (b) of this section. Good faith estimates provided electronically must be provided in a manner that the uninsured (or self-pay) individual can both save and print. A good faith estimate must be provided and written using clear and understandable language and in a manner calculated to be understood by the average uninsured (or self-pay) individual.

(2) To the extent that an uninsured (or self-pay) individual requests a good faith estimate in a method other than paper or electronically (for example, by phone or orally in person), the convening provider may orally inform the uninsured (or self-pay) individual of information contained in the good faith estimate using the method requested by the uninsured (or self-pay) individual; however, in order for a convening provider or convening facility to meet the requirements of this section, the convening provider or convening facility must issue the good faith estimate to the uninsured (or self-pay) individual in written form as specified in paragraph (e)(1) of this section.

(f) *Additional compliance provisions.* (1) A good faith estimate issued to uninsured (or self-pay) individual under this section is considered part of the patient's medical record and must be maintained in the same manner as a patient's medical record. Convening providers and convening facilities must provide a copy of any previously issued good faith estimate furnished within the last 6 years to an uninsured (or self-pay) individual upon the request of the uninsured (or self-pay) individual.

(2) Providers or facilities that issue good faith estimates issued under State processes that do not meet the requirements set forth in this section fail to comply with the requirements of this section.

(3) A provider or facility will not fail to comply with this section solely because, despite acting in good faith and with reasonable due diligence, the provider or facility makes an error or omission in a good faith estimate required under this section, provided that the provider or facility corrects the information as soon as practicable. If items or services are furnished before an error in a good faith estimate is addressed, the provider or facility may be subject to patient-provider dispute resolution if the actual billed charges are substantially in excess of the good faith estimate (as described in § 149.620).

(4) To the extent compliance with this section requires a provider or facility to obtain information from any other entity or individual, the provider or facility will not fail to comply with this section if it relied in good faith on the information from the other entity, unless the provider or facility knows, or reasonably should have known, that the information is incomplete or inaccurate. If the provider or facility learns that the information is incomplete or inaccurate, the provider or facility must provide corrected information to the uninsured (or self-pay) individual as soon as practicable. If items or services are furnished before an error in a good faith estimate is addressed, the provider or facility may be subject to patient-provider dispute resolution if the actual billed charges are substantially in excess of the good faith estimate (as described in § 149.620).

(g) *Applicability*—(1) *Applicability date.* The requirements of this section are applicable for good faith estimates requested on or after January 1, 2022 or for good faith estimates required to be provided in connection with items or services scheduled on or after January 1, 2022.

(2) *Applicability with other laws.* Nothing in this section alters or otherwise affects a provider's or facility's requirement to comply with other applicable State or Federal laws, including those governing the accessibility, privacy, or security of information required to be disclosed under this section, or those governing the ability of properly authorized representatives to access uninsured (or self-pay) individuals' information held by providers or facilities, except to the

extent a state law prevents the application of this section.

§ 149.620 Requirements for the patient-provider dispute resolution process.

(a) *Scope and definitions*—(1) *Scope.* This section sets forth requirements for the patient-provider dispute resolution process, under which an uninsured (or self-pay) individual, with respect to eligible items or services under paragraph (b) of this section, may submit notification under paragraph (c) of this section to initiate the patient-provider dispute resolution process. This section sets forth in paragraph (d) of this section the certification requirements for a dispute resolution entity to become a Selected Dispute Resolution (SDR) entity contracted to resolve the patient-provider dispute, and the process for HHS to select SDR entities for patient-provider disputes under paragraph (e) of this section. This section sets forth in paragraph (f) the process and requirements regarding how SDR entities will determine the amount to be paid by an uninsured (or self-pay) individual to a provider or facility. This section also sets forth requirements for an administrative fee under paragraph (g) of this section and minimum requirements under paragraph (h) of this section for states that wish to establish processes for performing patient-provider dispute resolution in place of the Federal process.

(2) *Definitions.* Unless otherwise stated, the definitions in § 149.610(a)(2) apply to this section. Definitions related to confidentiality set forth in § 149.510(a)(2), including the definitions for *breach, individually identifiable health information (IIHI),* and *unsecured IIHI* also apply to this section. Additionally, for purposes of this section, the following definitions apply:

(i) *Billed charge(s)* means the amount billed by a provider or facility for an item or service.

(ii) *Substantially in excess* means, with respect to the total billed charges by a provider or facility, an amount that is at least $400 more than the total amount of expected charges listed on the good faith estimate for the provider or facility.

(iii) *Total billed charge(s)* means the total of billed charges, by a provider or-facility, for all primary items or services and all other items or services furnished in conjunction with the primary items or services to an uninsured (or self-pay) individual, regardless of whether such items or services were included in the good faith estimate.

(b) *Eligibility for patient-provider dispute resolution*—(1) *In general.* In general, an item or service provided by a convening provider, convening facility, co-provider, or co-facility is eligible for the patient-provider dispute resolution process if the total billed charges (by the particular convening provider, convening facility, or co-provider or co-facility listed in the good faith estimate), are substantially in excess of the total expected charges for that specific provider or facility listed on the good faith estimate, as required under § 149.610.

(2) *Special rule for co-provider or co-facility substitution.* If a co-provider or co-facility that provided an estimate of the expected charge for an item or service in the good faith estimate is substituted for a different co-provider or co-facility, an item or service billed by the replacement co-provider or co-facility is eligible for dispute resolution if the billed charge is substantially in excess of the total expected charges included in the good faith estimate for the original co-provider or co-facility. If the replacement provider or facility provides the uninsured (or self-pay) individual with a new good faith estimate in accordance with § 149.610(b)(2), then the determination of whether an item or service billed by the replacement co-provider or co-facility is eligible for dispute resolution is based on whether the total billed charge for the replacement co-provider or co-facility is substantially in excess of the total expected charges included in the good faith estimate provided by the replacement co-provider or co-facility.

(c) *Initiation of the Patient Provider dispute resolution process*—(1) *In general.* With respect to an item or service that meets the requirements in paragraph (b) of this section, an uninsured (or self-pay) individual (or their authorized representative, excluding any providers directly represented in the good faith estimate, providers associated with these providers, non-clinical staff associated with these providers, or individuals employed or associated with a facility that had included services in the good faith estimate) may initiate the patient-provider dispute resolution process by submitting a notification (initiation notice) to HHS as specified in paragraph (c)(2) of this section postmarked within 120 calendar days of receiving the initial bill containing charges for the item or service that is substantially in excess of the expected charges in the good faith estimate. In addition, the uninsured (or self-pay) individual must submit an administrative fee as described in paragraph (g) of this section to the SDR entity in an amount and in a manner that will be clarified in guidance by HHS.

(2) *Initiation notice*—(i) *Content.* The notice to initiate the patient-provider dispute resolution process must include:

(A) Information sufficient to identify the item or service under dispute, including the date the item or service was provided, and a description of the item or service;

(B) A copy of the provider or facility bill for the item and service under dispute (the copy can be a photocopy or an electronic image so long as the document is readable);

(C) A copy of the good faith estimate for the item or service under dispute (the copy can be a photocopy or an electronic image so long as the document is readable);

(D) If not included on the good faith estimate, contact information of the provider or facility involved, including, if available, name, email address, phone number, and mailing address;

(E) The State where the items or services in dispute were furnished; and

(F) The uninsured (or self-pay) individual's communication preference, through the Federal IDR portal, or electronic or paper mail.

(ii) *Manner.* The uninsured (or self-pay) individual or their authorized representative must submit the initiation notice, to the Secretary by submitting the notice via the Federal IDR portal, electronically, or on paper, in the form and manner specified by the Secretary. The date of initiation of the patient-provider dispute resolution process will be the date the Secretary receives such initiation notice. In addition, the uninsured (or self-pay) individual must submit an administrative fee as described in paragraph (g) of this section to the SDR entity in an amount and in a manner that will be clarified in guidance by HHS.

(3) *Notification of SDR entity receipt.* Upon receipt of the initiation notice described in paragraph (c)(1) of this section, HHS will select an SDR entity according to the process described in paragraph (e) of this section. Upon selection, the SDR entity will, through the Federal IDR portal, or electronic or paper mail, notify the uninsured (or self-pay) individual, and the provider or facility that a patient-provider dispute resolution request has been received and is under review. Such notice shall also include:

(i) Sufficient information to identify the item or service under dispute;

(ii) The date the initiation notice was received;

(iii) Notice of the additional requirements for providers or facilities specified in paragraphs (c)(5) and (6) of this section while the patient-provider dispute resolution process is pending; and

(iv) Information to the uninsured (or self-pay) individual about the availability of consumer assistance resources that can assist the individual with the dispute.

(4) *Validation of initiation notice.* After the selection of the SDR entity, as described in paragraph (c)(2) of this section, the SDR entity shall review the initiation notice to ensure the items or services in dispute meet the eligibility criteria described in paragraph (b) of this section and the initiation notice contains the required information described in paragraph (c)(2). The SDR entity will notify the uninsured (or self-pay) individual of the outcome of the review, including, if applicable, providing the individual with 21 calendar days to submit supplemental information when the initiation notice is determined to be incomplete or the items or services are determined ineligible for dispute resolution.

(i) If the SDR entity determines that the item or service meets the eligibility criteria, and the initiation notice contains the required information, the SDR entity will notify the uninsured (or self-pay) individual and the provider or facility that the that the item or service has been determined eligible for dispute resolution. The SDR entity shall request the provider or facility provide the information described in paragraph (f)(2) of this section within 10 business days.

(ii) If the SDR entity determines that the item or service does not meet the eligibility criteria or that the initiation notice does not contain the required information, the SDR entity will provide an insufficiency notice to the uninsured (or self-pay) individual of the determination and the reasons for the determination and will notify the uninsured (or self-pay) individual that the individual may submit supplemental information, postmarked within 21 calendar days, to resolve any deficiencies identified. If the insufficiency notice is not made available to an individual in a format that is accessible to individuals with disabilities or with low-English proficiency within 14 calendar days of such a request from the individual, a 14-calendar-day extension will be granted so that the individual will have a total of 35 calendar days to submit supplemental information.

(5) *Prohibitions on collections.* While the patient-provider dispute resolution process is pending, the provider or facility must not move the bill for the disputed item or service into collection or threaten to do so, or if the bill has already moved into collection, the provider or facility should cease collection efforts. The provider or facility must also suspend the accrual of any late fees on unpaid bill amounts until after the dispute resolution process has concluded.

(6) *Prohibitions on retributive action.* The provider or facility must not take or threaten to take any retributive action against an uninsured (or self-pay) individual for utilizing the patient-provider dispute resolution process to seek resolution for a disputed item or service.

(d) *Certification of SDR entities*—(1) *In general.* The Secretary shall contract with and certify only that number of SDR entities the Secretary believes will be necessary to timely resolve the volume of patient-provider disputes. As part of the contract process with HHS, a potential SDR entity must satisfy the Federal IDR entity certification criteria specified in § 149.510(e), subject to the exceptions set forth in paragraphs (d)(2) of this section. In addition, the SDR entity must also meet the conflict-of-interest mitigation policy requirements specified in paragraph (d)(3) of this section. Through this contract process, HHS will assess the dispute resolution entity for compliance with all applicable SDR entity certification requirements.

(2) *Exception for SDR entity certification.* With respect to certified IDR entity requirements that do not apply to an SDR entity, potential SDR entities are not required to make the following submissions:

(i) Information regarding the service area(s) for which the entity will arbitrate cases, however, a potential SDR entity will need to submit information on their ability to operate nationwide through the contract process;

(ii) Fee schedule for batched and non-batched claims;

(iii) Policies and procedures to hold dispute resolution entity fees in a trust or escrow account, however, a potential SDR entity must submit policies and procedures to hold administrative fees, as described in paragraph (g) of this section, and remit them to HHS in a manner specified by HHS.

(3) *Conflict of interest mitigation policies.* A potential SDR entity must also provide additional information on the SDR entity's conflict-of-interest policies and procedures, including outlining a mitigation plan in the event of an entity-level conflict of interest, under which no dispute resolution personnel affiliated with the SDR entity can fairly and impartially adjudicate a case, in compliance with the standards in Federal Acquisition Regulation-subpart 9.5 (48 CFR subpart 9.5). Such conflict of interest mitigation plan could include utilizing a subcontractor without a conflict of interest that meets SDR entity requirements to conduct the patient-provider dispute resolution for the case.

(e) *Selection of an SDR entity.* (1) After the Secretary has received the initiation notice as described in paragraph (c) of this section, the Secretary will assign an SDR entity that is certified and contracted under paragraph (d) of this section to conduct the dispute resolution process for the item or service. Upon receiving an assignment from the Secretary to make a determination for an item or service as described in paragraph (c)(3) of this section, the SDR entity shall ensure that no conflict of interest exists, and in such case, shall notify the uninsured (or self-pay) individual and the provider or facility of the selection of the SDR entity.

(2) Should a conflict of interest exist, the SDR entity must submit notice to the Secretary of such conflict no later than 3 business days following selection by the Secretary. The Secretary will then automatically select a new SDR entity to conduct the patient-provider dispute resolution process for the item or service. In the event that no SDR entities are available to resolve the dispute, the initially-selected SDR entity will be required to initiate their entity-level conflict of interest mitigation plan as described in paragraph (d)(3) of this section. If no other contracted SDR entity, and no subcontracted entity, is able to provide the patient-provider dispute resolution services due to conflicts of interest that cannot be sufficiently mitigated or any other reason, HHS may seek to contract with an additional SDR entity as needed. In the event that HHS needs to contract with an additional SDR entity, the time periods specified in this section may be extended at HHS' discretion to allow for HHS to contract with that SDR entity.

(3) Conflict of interest means, with respect to a party to a payment determination, or SDR entity, a material relationship, status, or condition of the party, or SDR entity that impacts the ability of the SDR entity to make an unbiased and impartial payment determination. For purposes of this section, a conflict of interest exists when an SDR entity is:

(i) A provider or a facility;

(ii) An affiliate or a subsidiary of a provider or facility;

(iii) An affiliate or subsidiary of a professional or trade association representing a provider or facility; or

(iv) An SDR entity, or any personnel assigned to a determination has a material familial, financial, or professional relationship with a party to the payment determination being disputed, or with any officer, director, or management employee of the provider, the provider's group or practice association, or the facility that is a party to the dispute.

(4) Either party to the dispute resolution process (the uninsured (or self-pay) individual, or the provider or facility) may attest that a conflict of interest exists in relation to the SDR entity assigned to a payment dispute, in which case the SDR entity must notify the Secretary of HHS no later than 3 business days receiving the attestation.

(f) *Payment determination for Patient-Provider dispute resolution*—(1) *Determination of payment amount through settlement*—(i) *In general.* If the parties to a dispute resolution process agree on a payment amount (through either an offer of financial assistance or an offer of a lower amount, or an agreement by the uninsured (or self-pay) individual to pay the billed charges in full) after the dispute resolution process has been initiated but before the date on which a determination is made under paragraph (f)(3) of this section, the provider or facility will notify the SDR entity through the Federal IDR Portal, electronically, or in paper form as soon as possible, but no later than 3 business days after the date of the agreement. The settlement notification must contain at a minimum, the settlement amount, the date of such settlement, and documentation demonstrating that the provider or facility and uninsured (or self-pay) individual have agreed to the settlement. The settlement notice must also document that the provider or facility has applied a reduction to the uninsured (or self-pay) individual's settlement amount equal to at least half the amount of the administrative fee paid as set forth in paragraph (g) of this section. Once the SDR entity receives the settlement notice, the SDR entity shall close the dispute resolution case as settled and the agreed upon payment amount will apply for the items or services.

(ii) *Treatment of payments made prior to determination.* Payment of the billed charges (or a portion of the billed charges) by the uninsured (or self-pay) individual (or by another party on behalf of the uninsured (or self-pay) individual) prior to a determination under paragraph (f)(3) of this section does not demonstrate agreement by the uninsured (or self-pay) individual to settle at that amount or any other amount.

(2) *Determination of payment amount through the patient-provider dispute resolution process*—(i) *In general.* With respect to an item or service to which an agreement described in paragraph (f)(1) of this section does not apply, not later than 10 business days after the receipt of the selection notice from the SDR entity described in paragraph (c)(4)(i) of this section, the provider or facility must submit to the SDR entity:

(A) A copy of the good faith estimate provided to the uninsured (or self-pay) individual for the item or service under dispute (the copy can be a photocopy or an electronic image so long as the document is readable);

(B) A copy of the billed charges provided to the uninsured (or self-pay) individual for the item or service under dispute (the copy can be a photocopy or an electronic image so long as the document is readable); and

(C) If available, documentation demonstrating that the difference between the billed charge and the expected charges in the good faith estimate reflects the cost of a medically necessary item or service and is based on unforeseen circumstances that could not have reasonably been anticipated by the provider or facility when the good faith estimate was provided.

(ii) *Timeframe for SDR entity determination.* Not later than 30 business days after receipt of the information described in paragraph (f)(2)(i) of this section, the SDR entity must make a determination regarding the amount to be paid by such uninsured (or self-pay) individual, taking into account the requirements in paragraph (f)(3) of this section.

(3) *Payment determination by an SDR entity*—(i) *In general.* The SDR entity must review any documentation submitted by the uninsured (or self-pay) individual, and the provider or the facility, and make a separate determination for each unique item or service charged as to whether the provider or facility has provided credible information to demonstrate that the difference between the billed charge and the expected charge for the item or service in the good faith estimate reflects the costs of a medically necessary item or service and is based on unforeseen circumstances that could not have reasonably been anticipated by the provider or facility when the good faith estimate was provided.

(ii) *Definition of credible information.* Credible information means information that upon critical analysis is worthy of belief and is trustworthy.

(iii) *Payment determination process.* (A) For an item or service that appears on the good faith estimate:

(*1*) If the billed charge is equal to or less than the expected charge for the item or service in the good faith estimate, the SDR entity must determine the amount to be paid for the item or service as the billed charge.

(*2*) If the billed charge for the item or service is greater than the expected charge in the good faith estimate, and the SDR entity determines that information submitted by the provider or facility does not provide credible information that the difference between the billed charge and the expected charge-for the item or service in the good faith estimate reflects the costs of a medically necessary item or service and is based on unforeseen circumstances that could not have reasonably been anticipated by the provider or facility when the good faith estimate was provided, the SDR entity must determine the amount to be paid for the item or service to be equal to the expected charge for the item or service in the good faith estimate.

(*3*) If the billed charge for the item or service is greater than the expected charge in the good faith estimate, and the SDR entity determines that information submitted by the provider or facility provides credible information that the difference between the billed charge and the expected charge for the item or service in the good faith estimate reflects the costs of a medically necessary item or service and is based on unforeseen circumstances that could not have reasonably been anticipated by the provider or facility when the good faith estimate was provided, the SDR entity must determine as the amount to be paid for the item or service, the lesser of:

(*i*) The billed charge; or

(*ii*) The median payment amount paid by a plan or issuer for the same or similar service, by a same or similar provider in the geographic area as defined in § 149.140(a)(7) where the services were provided, that is reflected in an independent database as defined in § 149.140(a)(3) using the methodology described in § 149.140(c)(3), except that in cases where the amount determined by an independent database is determined to be less than the expected charge for the item or service listed on the good faith estimate, the amount to be paid will equal to the expected charge for the item or service listed on the good faith estimate. When comparing the billed charge with the amount contained in an independent database, the SDR entity

should account for any discounts offered by the provider or facility.

(B) For an item or service that does not appear on the good faith estimate (new item or service):

(*1*) If the SDR entity determines that the information submitted by the provider or facility does not provide credible information that the billed charge for the new item or service reflects the costs of a medically necessary item or service and is based on unforeseen circumstances that could not have reasonably been anticipated by the provider or facility when the good faith estimate was provided, then the SDR entity must determine that amount to be paid for the new item or service to be equal to $0.

(*2*) If the SDR entity determines that the information submitted by the provider or facility provides credible information that the billed charge for the new item or service reflects the costs of a medically necessary item or service and is based on unforeseen circumstances that could not have reasonably been anticipated by the provider or facility when the good faith estimate was provided, the SDR entity must select as the amount to be paid for the new item or service, the lesser of:

(*i*) The billed charge; or

(*ii*) The median payment amount paid by a plan or issuer for the same or similar service, by a same or similar provider in the geographic area as defined in § 149.140(a)(7) where the services were provided, that is reflected in an independent database as defined in § 149.140(a)(3) using the methodology described in § 149.140(c)(3). When comparing the billed charge with the amounts contained in an independent database, the SDR entity should account for any discounts offered by the provider or facility.

(C) To calculate the final payment determination amount, the SDR entity must add together the amounts to be paid for all items or services subject to the determination. In cases where the final amount determined by the SDR entity is lower than the billed charges, the SDR entity must reduce the total amount determined by the amount paid by the individual for the administrative fee described in paragraph (g) of this section to calculate the final payment determination amount to be paid by the individual for the items or services. Once the final payment determination amount has been calculated, the SDR entity will inform the uninsured (or self-pay) individual and the provider or facility, through the Federal IDR portal, or by electronic or paper mail, of such determination, the determination amount and the SDR entity's justification for making the determination. After such notification is made, the SDR entity will close the case.

(4) *Effects of determination.* A determination made by an SDR entity under this paragraph (f) will be binding upon the parties involved, in the absence of a fraud or evidence of misrepresentation of facts presented to the selected SDR entity regarding the claim, except that the provider or facility may provide financial assistance or agree to an offer for a lower payment amount than the SDR entity's determination, the uninsured (or self-pay) individual may agree to pay the billed charges in full, or the uninsured (or self-pay) individual and the provider or facility may agree to a different payment amount.

(g) *Costs of patient-provider dispute resolution process*—(1) *Administrative fee to participate in the patient-provider dispute resolution process.* (i) The uninsured (or self-pay) individual shall pay to the SDR entity the administrative fee amount described in section (g)(2) of this section at the initiation of the patient-provider dispute resolution process described in paragraph (c) of this section. The SDR entity shall remit all administrative fees collected to the Secretary upon receiving an invoice from HHS.

(ii) In cases where the SDR entity issues a determination and the provider or facility is the non-prevailing party as described in section (g)(1)(iv) of this section, the provider or facility must pay an amount equal to the administrative fee to the uninsured (or self-pay) individual in the form of a reduction in the payment amount that is applied by the SDR entity to the final payment determination amount as described in paragraph (f)(3) of this section.

(iii) If the SDR entity issues a determination and the provider or facility is the prevailing party as described in paragraph (g)(1)(iv) of this section, the provider or facility is not required to pay an amount equal to the administrative fee to the uninsured (or self-pay) individual in the form of a reduction in the payment amount that is applied by the SDR entity to the final payment determination amount as described in paragraph (f)(3) of this section.

(iv) For purposes of paragraphs (g)(1)(ii) and (iii) of this section, the prevailing party is the provider or facility in cases where the SDR entity determines the amount to be paid as equal to the billed charges; and the prevailing party is the uninsured (or self-pay) individual in cases where the SDR entity determines the-amount to be paid as less than the billed charges.

(v) Allocation of administrative fee in the case of settlement. In case of a settlement described in paragraph (f)(1) of this section, the provider or facility must pay an amount equal to half of the administrative fee to the uninsured (or self-pay) individual in the form of a reduction in the payment amount that is applied to the final settlement amount. The provider or facility will document in the settlement notice described in paragraph (f)(1) that it has applied a payment reduction of at least half of the administrative fee amount to the uninsured (or self-pay) individual's settlement amount.

(2) Establishment of the administrative fee. The amount of the administrative fee described in paragraph (g)(1) of this section will be specified by the Secretary through guidance.

(h) *Deferral to State patient-provider dispute resolution processes*—(1) *In general.* If the Secretary determines that a-state law provides a process to determine the amount to be paid by an uninsured (or self-pay) individual to a provider or facility, and that such process meets or exceeds the requirements in paragraph (h)(2) of this section, the Secretary shall defer to the State process and direct any patient-provider dispute resolution requests received from uninsured (or self-pay) individuals in such state to the State process to adjudicate the dispute resolution initiation request.

(2) *Minimum Federal requirements.* A State process described in paragraph (h)(1) of this section shall at a minimum:

(i) Be binding, unless the provider or facility offer for the uninsured (or self-pay) individual to pay a lower payment amount than the determination amount;

(ii) Take into consideration a good faith estimate, that meets the minimum standards established in § 149.160, provided by the provider or facility to the uninsured (or self-pay) individual;

(iii) If the State has a fee charged to uninsured (or self-pay) individuals to participate in the patient-provider dispute resolution process, the fee must be equal to or less than the Federal administrative fee-established in paragraph (g) of this section; and

(iv) Have in place conflict-of-interest standards that at a minimum meets the requirements set forth in paragraphs (d) and (e) of this section.

(3) *HHS determination of State process.* HHS will review the State process to determine whether it meets or exceeds the minimum Federal requirements set forth in paragraph

(h)(2) of this section—HHS will communicate with the state and determine whether such process meets or exceeds such requirements. HHS will notify the state in writing of such determination.

(4) *HHS review of State process.* HHS will review changes to the State process on an annual basis (or at other times if HHS receives information from the state that would indicate the state process no longer meets the minimum Federal requirements) to ensure the state process continues to meet or exceed the minimum Federal standards set forth in this section.

(5) *State process termination.* In the event that the State process is terminated, or HHS determines that the State process no longer meets the minimum Federal requirements described in paragraph (h)(2) of this section, HHS will make the Federal process available to uninsured (or self-pay) individuals in that State to ensure that the state's residents have access to a patient-provider dispute resolution process that meets the minimum Federal requirements.

(i) *Extension of time periods for extenuating circumstances*—(1) *In general.* The time periods specified in this section (other than the time for payment of the administrative fees under paragraph (d)(2) of this section) may be extended in extenuating circumstances at the Secretary's discretion if:

(i) An extension is necessary to address delays due to matters beyond the control of the parties or for good cause; and

(ii) The parties attest that prompt action will be taken to ensure that the determination under this section is made as soon as administratively practicable under the circumstances.

(2) *Process to request an extension.* The time periods specified in this section may be extended in the case of extenuating circumstances at HHS' discretion. The parties may request an extension by submitting a request for extension due to extenuating circumstances through the Federal IDR portal, or electronic or paper mail if the extension is necessary to address delays due to matters beyond the control of the parties or for good cause.

(j) *Applicability date.* The provisions of this section are applicable to uninsured (or self-pay) individuals; providers (including providers of air ambulance services) and facilities; and SDR entities, generally beginning on or after January 1, 2022. The provisions regarding SDR entity certification in paragraphs (a) and (d) of this section, are applicable beginning on October 7, 2021.

[FR Doc. 2021–21441 Filed 9–30–21; 4:15 pm]

BILLING CODE 4510–29–P

Exhibit 5

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

ASSOCIATION OF AIR MEDICAL SERVICES,
909 N. Washington Street, Suite 410
Alexandria, VA 22314,

Plaintiff,

v.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES,
200 Independence Avenue SW
Washington, DC 20201,

XAVIER BECERRA, in his official capacity as Secretary of Health and Human Services,
200 Independence Avenue SW
Washington, DC 20201,

U.S. OFFICE OF PERSONNEL MANAGEMENT,
1900 E Street NW
Washington, DC 20415,

KIRAN AHUJA, in her official capacity as Director of the U.S. Office of Personnel Management,
1900 E Street NW
Washington, DC 20415,

LAURIE BODENHEIMER, in her official capacity as Associate Director, Healthcare and Insurance, in the U.S. Office of Personnel Management,
1900 E Street NW
Washington, DC 20415,

U.S. DEPARTMENT OF LABOR,
200 Constitution Avenue NW
Washington, DC 20210,

MARTIN J. WALSH, in his official capacity as Secretary of Labor,
200 Constitution Avenue NW
Washington, DC 20210,

Civ. No. 1:21-cv-3031

U.S. EMPLOYEE BENEFITS SECURITY ADMINISTRATION,
200 Constitution Avenue NW
Washington, DC 20210,

ALI KHAWAR, in his official capacity as the Acting Assistant Secretary for the Employee Benefits Security Administration,
200 Constitution Avenue NW
Washington, DC 20210

U.S. DEPARTMENT OF THE TREASURY,
1500 Pennsylvania Avenue NW
Washington, DC 20220,

JANET YELLEN, in her official capacity as Secretary of the Treasury,
1500 Pennsylvania Avenue NW
Washington, DC 20220,

LILY L. BATCHELDER, in her official capacity as Assistant Secretary of the Treasury (Tax Policy),
1500 Pennsylvania Avenue NW
Washington, DC 20220,

INTERNAL REVENUE SERVICE,
1111 Constitution Avenue NW,
Washington, DC 20224,

CHARLES RETTIG, in his official capacity as Commissioner of the Internal Revenue Service,
1111 Constitution Avenue NW,
Washington, DC 20224,

and

DOUGLAS W. O'DONNELL, in his official capacity as Deputy Commissioner for Services and Enforcement in the Internal Revenue Service,
1111 Constitution Avenue NW
Washington, DC, 20224,

Defendants.

DECLARATION OF GRAYSON MICHAEL FOSTER, JR.

I, Grayson Michael Foster, Jr, allege as follows:

1. I am over the age of eighteen. If called as a witness in this action, I could testify to the facts stated herein.

BACKGROUND

2. I am the Chief Financial Officer at PHI Health, LLC. PHI Health, LLC is a for-profit provider of air ambulance services. PHI Health, LLC delivers rotor-wing air ambulance services from 77 air bases located in 15 states across the US. PHI Health, LLC delivers fixed-wing air ambulance services from 3 air bases located in California and Missouri.

3. I have served as Chief Financial Officer at PHI Health, LLC for 3 months. Prior to serving as Chief Financial Officer, I was employed directly by PHI's shareholders for the financial oversight of PHI Health, LLC.

4. In my role as Chief Financial Officer, I am responsible for the analysis, internal reporting, and projection of the financial performance of PHI Health, LLC's air bases. To fulfill my responsibility, I lead a team of financial personnel that monitors and analyzes the costs of operating PHI Health, LLC's air bases; the health coverage of the individual patients transported by PHI Health, LLC; the anticipated and collected payments by third-party payors such as group health plans, private insurance plans, and government healthcare programs; and the patient liabilities (*e.g.*, coinsurance) and collections after third-party payments. We use the same data to project the future financial performance.

5. I am involved in PHI Health, LLC's contracting with commercial third-party payors such as group health plans and health insurance issuers. PHI Health, LLC generally favors entering into network contracts with commercial third-party payors because such arrangements foster greater financial certainty and administrative efficiency. PHI Health, LLC generally uses good

faith, reasonable efforts to try to procure in-network contracts with commercial third-party payors. But we are often unable to procure such contracts because the commercial third-party payors decline to offer or accept rates that align with the cost structure of PHI Health, LLC.

6. To deliver services, PHI Health, LLC necessarily incurs costs related to air bases, aircraft, maintenance, specialized equipment, training, certifications and licenses, and regulatory compliance. Those costs are fixed, substantial, and generally unavoidable. They are also common to all air ambulance providers (though they may vary somewhat by geography).

7. The revenue that PHI Health, LLC receives for transporting patients covered by commercial third-party payors is integral to PHI Health, LLC's ability to operate because most of PHI Health, LLC's patients are covered through government healthcare programs or uninsured. Government healthcare programs such as Medicare and Medicaid pay rates that do not cover the costs of transports. Most transports of uninsured patients are conducted on a charitable basis and generate a nominal amount of revenue at best. PHI Health, LLC must either make up the difference on transports of patients covered by commercial third-party payors, or shutter air bases with payor mixes that yield aggregate revenues below costs.

8. My experience is that the operation and financial performance of every air base is unique in certain respects. Notably, the financial performance of air bases varies based on the overall number of transports, the percentage of the transports that are for patients with commercial health coverage, and the amounts actually paid by commercial third-party payors, regardless of whether PHI Health, LLC has entered into a network contract with the payor. Air bases with lower percentages of transports of patients with commercial health coverage are more financially sensitive to changes in the amounts paid by commercial third-party payors than air bases with higher percentages of such patients. Likewise, air bases that operate in states where the predominant commercial third-party payors decline to offer or accept rates aligned with costs are

more financially sensitive to changes in the amounts paid than air bases in states where the predominant commercial third-party payors are willing to align rates with costs.

9. The analysis of the financial performance of an air base involves a measure of business judgment because the overall number of transports and the payor mix varies weekly, monthly, and yearly. Those variations are outside the control of PHI Health, LLC because first responders (e.g., fire departments, emergency medical services and law enforcement) and other providers (e.g., hospital based physicians) are the ones that request PHI Health, LLC conduct transports. PHI Health, LLC responds when called so long as flight conditions allow it. In some locations, as a condition of licensure state laws or regulations include a Duty to Act, requiring PHI Health, LLC to respond, so long as flight conditions allow it. The nature and extent of the patient's health coverage have no bearing on whether PHI Health, LLC responds.

10. Consequently, my prospective financial analyses of air bases customarily take into account historical and current data on flight volume, historical and current data on payor mix, applicable legal and regulatory mandates, current market conditions with commercial third-party payors, rate information supplied by third-party healthcare payment databases, and the business judgment that PHI Health, LLC's management team has developed through years of experience in the industry.

THE NO SURPRISES ACT

11. I am presently evaluating the impact that implementation of the federal No Surprises Act will have on the future financial performance of PHI Health, LLC's air bases. I assume that implementation of the Act under the Interim Final Rules promulgated by the Departments of Health and Human Services, the Treasury, and Labor and the Office of Personnel Management will drive payments by group health plans or issuers to a level at or below the group health plan's or issuer's median in-network rate for an air ambulance transport. I draw that assumption because the group health plan or issuer will have no rational business reason to enter

into a network contract with an air ambulance provider at a rate exceeding the maximum amount which the group health plan or issuer must pay under the Act. I further assume that the maximum amount payable under the Act is the group health plan's or issuer's median in-network rate.

12. One of the data points that I am considering in my evaluation is the recent report by FAIR Health that from 2017 to 2020, "[t]he average estimated allowed amount [for the base rate for an air ambulance transport] rose 60.8 percent, from $11,608 to $18,668." *Air Ambulance Services in the United States: A Study of Private and Medicare Claims, A FAIR Health White Paper, September 28, 2021*, at p. 2, n.1. These costs "do not include mileage fees." *Id.*

13. FAIR Health states in its report that "[a]n allowed amount is the total fee negotiated between an insurance plan and a provider for an in-network service; the allowed amount includes both the insurer's and the member's share of the total fee. Because payors' contracted network rates are proprietary, FAIR Health employs an imputation methodology to determine benchmarks for allowed amounts. First, FAIR Health calculates the ratios of actual allowed amounts to charges for groups of procedure codes on a regional basis. The resulting ratios are applied to the actual charges for each specific procedure at the local (geozip) level to develop an 'imputed' or 'estimated' allowed amount for each claim line." *Id.* at p. 7, n.12

14. FAIR Health describes itself as "an independent nonprofit that collects data for and manages the nation's largest database of privately billed health insurance claims and is entrusted with Medicare Parts A, B and D claims data for 2013 to the present." FAIR Health – About Us, *available at*: https://www.fairhealth.org/about-us (last visited Oct. 28, 2021). FAIR Health underscores that "[a] testament to the fairness and reliability of our data, New York, Connecticut, and many other states have adopted FAIR Health's cost information as the guidepost in laws protecting consumers, and for many other purposes." *Id.*

15. The Centers for Medicare & Medicaid Services (CMS) of the Department of Health and Human Services has certified FAIR Health as a Qualified Entity (QE). *Qualified Entity*

Program, *available at*: https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/QEMedicareData (last visited Nov. 4, 2021). FAIR Health participates in the CMS QE Program, "which enables organizations to receive Medicare claims data under Parts A, B, and D for use in evaluating provider performance." *Id.*

16. If all group health plans and issuers began paying $18,668 or less for the base rate for an out-of-network air ambulance transport, effective January 1, 2022, then most of PHI Health, LLC's air bases would experience reductions in revenue for calendar year 2022. My business judgment is that the reductions in revenue would be so great that as many as 33 of PHI Health, LLC's air bases would cease to cover their costs, and it would become necessary for PHI Health, LLC to close or consolidate some or all of those air bases as soon as possible in calendar year 2022. The reductions in revenue and related operational impacts would be even greater if all group health plans and issuers began paying a total of $18,668 or less for an out-of-network air ambulance transport, effective January 1, 2022.

17. The impact of all group health plans and issuers paying $18,668 or less for the base rate for out-of-network air ambulance transports would have a ripple effect throughout the industry because group health plans and issuers would have a compelling economic incentive to terminate or renegotiate any existing network contracts at base rates in excess of $18,668 per transport. Such conduct by group health plans and issuers would lead to additional base closings or consolidations. Again, the impact would be even greater if all group health plans and issuers began paying a total of $18,668 or less for out-of-network air ambulance transports.

18. The narrowing of PHI Health, LLC's operational footprint through the closing or consolidation of air bases would reduce PHI Health, LLC's geographic service area and, by extension, the public's access to air ambulance services provided by PHI Health, LLC.

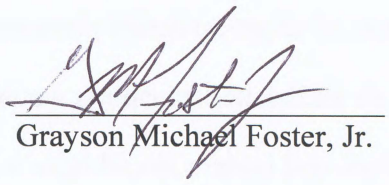
19. The economic and social harms would be irreparable because of the challenges inherent in operating air bases, particularly in rural communities. Once the physical plant of the

air base is shuttered, the aircraft and equipment are relocated or sold. The flight crew is reassigned or released. After these changes are made, they cannot readily be undone. The equipment and crew cannot just be recalled and reassembled by PHI Health, LLC. PHI Health, LLC has to obtain capital, and then deploy the capital together with corporate resources to re-create the air base from scratch, recruit new and highly-trained personnel to work at the air base, and obtain the requisite licenses and regulatory approvals (which, standing alone, can take years). The opening of a new air base requires a substantial investment of capital and resources in the best of times and will undoubtedly become more challenging in an environment where government policy is causing a reduction in the commercial rates paid to air ambulance providers nationwide.

***

I declare under penalty of perjury as set forth in 28 U.S.C. § 1746 that the foregoing is true and correct to the best of my knowledge, information, and belief.

Executed on November 15, 2021, at Phoenix, Arizona.



Grayson Michael Foster, Jr.

Exhibit 6

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

ASSOCIATION OF AIR MEDICAL SERVICES,
909 N. Washington Street, Suite 410
Alexandria, VA 22314,

Plaintiff,

v.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES,
200 Independence Avenue SW
Washington, DC 20201,

XAVIER BECERRA, in his official capacity as Secretary of Health and Human Services,
200 Independence Avenue SW
Washington, DC 20201,

U.S. OFFICE OF PERSONNEL MANAGEMENT,
1900 E Street NW
Washington, DC 20415,

KIRAN AHUJA, in her official capacity as Director of the U.S. Office of Personnel Management,
1900 E Street NW
Washington, DC 20415,

LAURIE BODENHEIMER, in her official capacity as Associate Director, Healthcare and Insurance, in the U.S. Office of Personnel Management,
1900 E Street NW
Washington, DC 20415,

U.S. DEPARTMENT OF LABOR,
200 Constitution Avenue NW
Washington, DC 20210,

MARTIN J. WALSH, in his official capacity as Secretary of Labor,
200 Constitution Avenue NW
Washington, DC 20210,

Civ. No. 1:21-cv-3031

U.S. EMPLOYEE BENEFITS SECURITY ADMINISTRATION,
200 Constitution Avenue NW
Washington, DC 20210,

ALI KHAWAR, in his official capacity as the Acting Assistant Secretary for the Employee Benefits Security Administration,
200 Constitution Avenue NW
Washington, DC 20210

U.S. DEPARTMENT OF THE TREASURY,
1500 Pennsylvania Avenue NW
Washington, DC 20220,

JANET YELLEN, in her official capacity as Secretary of the Treasury,
1500 Pennsylvania Avenue NW
Washington, DC 20220,

LILY L. BATCHELDER, in her official capacity as Assistant Secretary of the Treasury (Tax Policy),
1500 Pennsylvania Avenue NW
Washington, DC 20220,

INTERNAL REVENUE SERVICE,
1111 Constitution Avenue NW,
Washington, DC 20224,

CHARLES RETTIG, in his official capacity as Commissioner of the Internal Revenue Service,
1111 Constitution Avenue NW,
Washington, DC 20224,

and

DOUGLAS W. O'DONNELL, in his official capacity as Deputy Commissioner for Services and Enforcement in the Internal Revenue Service,
1111 Constitution Avenue NW
Washington, DC, 20224,

Defendants.

DECLARATION OF MICHAEL PREISSLER

I, Michael Preissler, allege as follows:

1. I am over the age of eighteen. If called as a witness in this action, I could testify to the facts stated herein.

BACKGROUND

2. I am the Chief Financial Officer at Global Medical Response, Inc. Global Medical Response, Inc. is a for profit provider of air emergency ambulance services. Global Medical Response, Inc., through its subsidiaries, (together "GMR") delivers rotor-wing and fixed-wing air emergency ambulance services from 340 air bases located in 38 states.

3. I have served as Chief Financial Officer at GMR since May, 2008. Prior to serving as Chief Financial Officer, I was the Vice President of Finance.

4. In my role as Chief Financial Officer, I am responsible for the analysis, internal reporting, and projection of the financial performance of GMR's air bases. To fulfill my responsibility, I lead a team of financial personnel that monitors and analyzes the costs of operating GMR's air bases; the health coverage of the individual patients transported by GMR; the anticipated and collected payments by third-party payors such as group health plans, private insurance plans, and government healthcare programs; and the patient liabilities (*e.g.*, coinsurance) and collections after third-party payments. We use the same data to project the future financial performance.

5. I am involved in GMR's contracting with commercial third-party payors such as group health plans and health insurance issuers. GMR generally favors entering into network contracts with commercial third-party payors because such arrangements foster greater financial certainty and administrative efficiency. GMR uses good faith, reasonable efforts to try to procure in-network contracts with commercial third-party payors; however, we are often unable to procure

such contracts because the commercial third-party payors decline to offer or accept rates that align with the cost structure of GMR.

6. To deliver air emergency services, GMR necessarily incurs costs related to air bases, aircraft, maintenance, specialized equipment, training, certifications and licenses, and regulatory compliance. Those costs are fixed, substantial, and generally unavoidable. They are also common to all air emergency ambulance providers (though they may vary somewhat by geography).

7. The revenue that GMR receives for transporting patients covered by commercial third-party payors is integral to GMR's ability to operate because most of GMR's patients are covered through government healthcare programs or uninsured. Government healthcare programs such as Medicare and Medicaid pay take-it-or-leave-it rates that do not cover the costs of transports. Most transports of uninsured patients are conducted on a charitable basis and generate a nominal amount of revenue at best, and unlike hospitals, air emergency operators are not reimbursed for serving the uninsured. GMR must either make up the difference on transports of patients covered by commercial third-party payors, or shutter air bases with payor mixes that yield aggregate revenues below costs.

8. My experience is that the operation and financial performance of every air emergency base is unique in certain respects. Notably, the financial performance of air emergency bases varies based on the overall number of transports, the percentage of the transports that are for patients with commercial health coverage, and the amounts actually paid by commercial third-party payors, regardless of whether GMR has entered into a network contract with the payor. Air emergency bases with lower percentages of transports of patients with commercial health coverage are more financially sensitive to changes in the amounts paid by commercial third-party payors than air emergency bases with higher percentages of such patients. Likewise, air emergency bases that operate in states where the predominant commercial third-party payors decline to offer or

accept rates aligned with costs are more financially sensitive to changes in the amounts paid than air bases in states where the predominant commercial third-party payors are willing to align rates with costs.

9. The analysis of the financial performance of an air emergency base involves a measure of business judgment because the overall number of transports and the payor mix varies weekly, monthly, and yearly. Those variations are outside the control of GMR because first responders (e.g., EMS and police departments) and other providers (e.g., physicians) are the ones that request air ambulance transports. GMR responds when called so long as flight conditions allow it. In some locations, state laws or regulations actually compel GMR to respond as a condition of licensure, so long as flight conditions allow it. The nature and extent of the patient's health coverage have no bearing on whether GMR responds.

10. Consequently, my prospective financial analyses of air emergency bases customarily take into account historical and current data on flight volume, historical and current data on payor mix, applicable legal and regulatory mandates, current market conditions with commercial third-party payors, rate information supplied by third-party healthcare payment databases, and the business judgment that I have developed through years of experience in the industry.

THE NO SURPRISES ACT

11. I am presently evaluating the impact that implementation of the federal No Surprises Act will have on the future financial performance of GMR's air emergency bases. I assume that implementation of the Act under the Interim Final Rules promulgated by the Departments of Health and Human Services, the Treasury, and Labor and the Office of Personnel Management (together, "the Departments") will drive payments by group health plans or issuers to a level at or below the group health plan's or issuer's qualified payment amount (QPA) for an air emergency ambulance transport. I draw that assumption because the group health plan or issuer

will have no rational business reason to enter into a network contract with an air emergency ambulance provider at a rate exceeding the group health plan's or issuer's QPA under the Act. I further assume that the QPA is the group health plan's or issuer's median in-network rate or, absent sufficient information the form of at least three network contracts with air ambulance providers, a rate the group health plan or issuer derives from a third-party database such as FAIR Health.

12. One of the data points that I am considering in my evaluation is the recent report by FAIR Health that from 2017 to 2020, "[t]he average estimated allowed amount [for the base rate for an air ambulance transport] rose 60.8 percent, from $11,608 to $18,668."[1] *Air Ambulance Services in the United States: A Study of Private and Medicare Claims, A FAIR Health White Paper, September 28, 2021*, at p. 2, n.1. These costs "do not include mileage fees." *Id*.

13. FAIR Health states in its report that "[a]n allowed amount is the total fee negotiated between an insurance plan and a provider for an in-network service; the allowed amount includes both the insurer's and the member's share of the total fee. Because payors' contracted network rates are proprietary, FAIR Health employs an imputation methodology to determine benchmarks for allowed amounts. First, FAIR Health calculates the ratios of actual allowed amounts to charges for groups of procedure codes on a regional basis. The resulting ratios are applied to the actual charges for each specific procedure at the local (geozip) level to develop an 'imputed' or 'estimated' allowed amount for each claim line." *Id*. at p. 7, n.12

14. FAIR Health describes itself as "an independent nonprofit that collects data for and manages the nation's largest database of privately billed health insurance claims and is entrusted with Medicare Parts A, B and D claims data for 2013 to the present." FAIR Health – About Us, *available at*: https://www.fairhealth.org/about-us (last visited Oct. 28, 2021). FAIR Health underscores that "[a] testament to the fairness and reliability of our data, New York, Connecticut,

[1] GMR is not making any representation as to the accuracy of FAIR Health's data as GMR believes FAIR Health does not take into consideration sufficient reimbursement information to accurately reflect charges or reimbursement.

and many other states have adopted FAIR Health's cost information as the guidepost in laws protecting consumers, and for many other purposes." *Id*.

15. The Centers for Medicare & Medicaid Services (CMS) of the Department of Health and Human Services has certified FAIR Health as a Qualified Entity (QE). *Qualified Entity Program*, available at: https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/QEMedicareData (last visited Nov. 4, 2021). FAIR Health participates in the CMS QE Program, "which enables organizations to receive Medicare claims data under Parts A, B, and D for use in evaluating provider performance." *Id*.

16. The FAIR Health average estimated allowed amount is a benchmark for QPAs for all group health plans and issuers nationally. If all group health plans and issuers calculate and pay median contracted base rates of approximately $18,668 or less for an out-of-network emergency air ambulance transport, effective January 1, 2022, then most of GMR's air bases would experience reductions in revenue for calendar year 2022. The reductions in revenue and related operational impacts would be greater if all group health plans and issuers began paying a median contracted total rate of approximately $18,668 or less for an out-of-network emergency air ambulance transport, effective January 1, 2022.

17. My business judgment is that group health plans and issuers will use FAIR Health (or similar a third-party database) or a QPA equivalent to FAIR Health to determine payments for up to 10% of GMR's total annual emergency transports for all air bases in calendar year 2022. My business judgment accounts for the factors that I described in Paragraphs 8 through 10, the Departments' assertion that only 25% of air ambulance transports in 2012 and 31% in 2017 were made under traditional in-network contracts, and the historical lack of network contracts for air ambulance services.

18. If group health plans and issuers use the FAIR Health average estimated allowed amount of $18,668 as the base rate when paying for 10% of GMR's total annual transports for all

air bases, then most of GMR's bases would experience reductions in revenue for calendar year 2022. The reductions in revenue will be deeper and more widespread if group health plans and issuers use the FAIR Health average estimated allowed amount of $18,668 as the total rate paid.

***

I declare under penalty of perjury as set forth in 28 U.S.C. § 1746 that the foregoing is true and correct to the best of my knowledge, information, and belief.

Executed on November 15, 2021, at Denver, Colorado.

DocuSigned by:
Michael.Preissler
D558D146A46E4F0...

MICHAEL PREISSLER
CHIEF FINANCIAL OFFICER
GLOBAL MEDICAL RESPONSE

Exhibit 7

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

ASSOCIATION OF AIR MEDICAL SERVICES,
909 N. Washington Street, Suite 410
Alexandria, VA 22314,

Plaintiff,

v.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES,
200 Independence Avenue SW
Washington, DC 20201,

XAVIER BECERRA, in his official capacity as Secretary of Health and Human Services,
200 Independence Avenue SW
Washington, DC 20201,

U.S. OFFICE OF PERSONNEL MANAGEMENT,
1900 E Street NW
Washington, DC 20415,

KIRAN AHUJA, in her official capacity as Director of the U.S. Office of Personnel Management,
1900 E Street NW
Washington, DC 20415,

LAURIE BODENHEIMER, in her official capacity as Associate Director, Healthcare and Insurance, in the U.S. Office of Personnel Management,
1900 E Street NW
Washington, DC 20415,

U.S. DEPARTMENT OF LABOR,
200 Constitution Avenue NW
Washington, DC 20210,

MARTIN J. WALSH, in his official capacity as Secretary of Labor,
200 Constitution Avenue NW
Washington, DC 20210,

Civ. No. 1:21-cv-3031

U.S. EMPLOYEE BENEFITS SECURITY ADMINISTRATION,
200 Constitution Avenue NW
Washington, DC 20210,

ALI KHAWAR, in his official capacity as the Acting Assistant Secretary for the Employee Benefits Security Administration,
200 Constitution Avenue NW
Washington, DC 20210

U.S. DEPARTMENT OF THE TREASURY,
1500 Pennsylvania Avenue NW
Washington, DC 20220,

JANET YELLEN, in her official capacity as Secretary of the Treasury,
1500 Pennsylvania Avenue NW
Washington, DC 20220,

LILY L. BATCHELDER, in her official capacity as Assistant Secretary of the Treasury (Tax Policy),
1500 Pennsylvania Avenue NW
Washington, DC 20220,

INTERNAL REVENUE SERVICE,
1111 Constitution Avenue NW,
Washington, DC 20224,

CHARLES RETTIG, in his official capacity as Commissioner of the Internal Revenue Service,
1111 Constitution Avenue NW,
Washington, DC 20224,

and

DOUGLAS W. O'DONNELL, in his official capacity as Deputy Commissioner for Services and Enforcement in the Internal Revenue Service,
1111 Constitution Avenue NW
Washington, DC, 20224,

Defendants.

DECLARATION OF DAVID PORTUGAL

I, David Portugal, state and allege as follows:

1. I am over the age of eighteen. If called as a witness in this action, I could testify to the facts stated herein.

BACKGROUND

2. I am the Chief Financial Officer at Air Methods Corporation ("AMC"). AMC is a for profit provider of air ambulance services. AMC delivers rotor-wing air ambulance services from 257 air bases located in 42 states. AMC delivers fixed-wing air ambulance services from 27 air bases located in 15 states.

3. I have served as CFO at AMC for one year. Prior to serving as CFO, I was Group Executive for Strategic Resource Development at Newmont Mining Corporation. Prior to serving as Group Executive for Strategic Resource Development, I served as Newmont's Regional Chief Financial Officer for South America..

4. In my role as CFO, I am responsible for the analysis, internal reporting, and projection of the financial performance of AMC's air bases. To fulfill my responsibility, I lead a team of financial personnel that monitors and analyzes the costs of operating AMC's air bases and I am familiar with the health coverage of the individual patients transported by AMC; the anticipated and collected payments by third-party payors such as group health plans, private insurance plans, and government healthcare programs; and the patient liabilities (*e.g.*, coinsurance) and collections after third-party payments. We use the same data to project the future financial performance.

5. I am familiar with AMC's contracting with commercial third-party payors such as group health plans and health insurance issuers. AMC generally favors entering into network contracts with commercial third-party payors because such arrangements foster greater financial

certainty and administrative efficiency. AMC generally uses good faith, reasonable efforts to try to procure in-network contracts with commercial third-party payors. But we are often unable to procure such contracts because the commercial third-party payors decline to offer or accept rates that align with the cost structure of AMC.

6. To deliver services, AMC necessarily incurs costs related to air bases, aircraft, maintenance, specialized equipment, training, certifications and licenses, and regulatory compliance. Those costs are fixed, substantial, and generally unavoidable. They are also common to all air ambulance providers (though they may vary somewhat by geography).

7. The revenue that AMC receives for transporting patients covered by commercial third-party payors is integral to AMC's ability to operate because most of AMC's patients are covered through government healthcare programs or uninsured. Government healthcare programs such as Medicare and Medicaid pay take-it-or-leave-it rates that do not cover the costs of transports. Most transports of uninsured patients are conducted on a charitable basis and generate a nominal amount of revenue at best. AMC must either make up the difference on transports of patients covered by commercial third-party payors, or shutter air bases with payor mixes that yield aggregate revenues below costs.

8. My experience is that the operation and financial performance of every air base is unique in certain respects. Notably, the financial performance of air bases varies based on the overall number of transports, the percentage of the transports that are for patients with commercial health coverage, and the amounts actually paid by commercial third-party payors, regardless of whether AMC has entered into a network contract with the payor. Air bases with lower percentages of transports of patients with commercial health coverage are more financially sensitive to changes in the amounts paid by commercial third-party payors than air bases with higher percentages of such patients. Likewise, air bases that operate in states where the predominant commercial third-party payors decline to offer or accept rates aligned with costs are

more financially sensitive to changes in the amounts paid than air bases in states where the predominant commercial third-party payors are willing to align rates with costs.

9. The analysis of the financial performance of an air base involves a measure of business judgment because the overall number of transports and the payor mix varies weekly, monthly, and yearly. Those variations are outside the control of AMC because first responders (e.g., police departments) and other providers (e.g., physicians) are the ones that dispatch AMC to conduct transports. AMC responds when called so long as flight conditions allow it. In some locations, state laws or regulations actually compel AMC to respond as a condition of licensure, so long as flight conditions allow it. The nature and extent of the patient's health coverage have no bearing on whether AMC responds.

10. Consequently, my prospective financial analyses of air bases customarily take into account historical and current data on flight volume, historical and current data on payor mix, applicable legal and regulatory mandates, current market conditions with commercial third-party payors, rate information supplied by third-party healthcare payment databases, and the business judgment that I have developed through years of experience.

THE NO SURPRISES ACT

11. I am presently evaluating the impact that implementation of the federal No Surprises Act will have on the future financial performance of AMC's air bases. I assume that implementation of the Act under the Interim Final Rules promulgated by the Departments of Health and Human Services, the Treasury, and Labor and the Office of Personnel Management (together, "the Departments") will drive payments by group health plans or issuers to a level at or below the group health plan's or issuer's qualified payment amount (QPA) for an air ambulance transport. I draw that assumption because the group health plan or issuer will have no rational business reason to enter into a network contract with an air ambulance provider at a rate exceeding the group health plan's or issuer's QPA under the Act. I further assume that the QPA is the group

health plan's or issuer's median in-network rate or, absent sufficient information the form of at least three network contracts with air ambulance providers, a rate the group health plan or issuer derives from a third-party database such as FAIR Health.

12. One of the data points that I am considering in my evaluation is the recent report by FAIR Health that from 2017 to 2020, "[t]he average estimated allowed amount [for the base rate for an air ambulance transport] rose 60.8 percent, from $11,608 to $18,668." *Air Ambulance Services in the United States: A Study of Private and Medicare Claims, A FAIR Health White Paper, September 28, 2021*, at p. 2, n.1. These costs "do not include mileage fees." *Id*.

13. FAIR Health states in its report that "[a]n allowed amount is the total fee negotiated between an insurance plan and a provider for an in-network service; the allowed amount includes both the insurer's and the member's share of the total fee. Because payors' contracted network rates are proprietary, FAIR Health employs an imputation methodology to determine benchmarks for allowed amounts. First, FAIR Health calculates the ratios of actual allowed amounts to charges for groups of procedure codes on a regional basis. The resulting ratios are applied to the actual charges for each specific procedure at the local (geozip) level to develop an 'imputed' or 'estimated' allowed amount for each claim line." *Id*. at p. 7, n.12

14. FAIR Health describes itself as "an independent nonprofit that collects data for and manages the nation's largest database of privately billed health insurance claims and is entrusted with Medicare Parts A, B and D claims data for 2013 to the present." FAIR Health – About Us, *available at*: https://www.fairhealth.org/about-us (last visited Oct. 28, 2021). FAIR Health underscores that "[a] testament to the fairness and reliability of our data, New York, Connecticut, and many other states have adopted FAIR Health's cost information as the guidepost in laws protecting consumers, and for many other purposes." *Id*.

15. The Centers for Medicare & Medicaid Services (CMS) of the Department of Health and Human Services has certified FAIR Health as a Qualified AMC (QE). *Qualified AMC*

Program, available at: https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/QEMedicareData (last visited Nov. 4, 2021). FAIR Health participates in the CMS QE Program, "which enables organizations to receive Medicare claims data under Parts A, B, and D for use in evaluating provider performance." *Id*.

16. The FAIR Health average estimated allowed amount is a benchmark for QPAs for all group health plans and issuers nationally. If all group health plans and issuers calculate and pay median contracted base rates of approximately $18,668 or less for an out-of-network air ambulance transport, effective January 1, 2022, then eighty percent of AMC's air bases would experience reductions in revenue for calendar year 2022. The reductions in revenue and related operational impacts would be greater if all group health plans and issuers began paying a median contracted total rate of approximately $18,668 or less for an out-of-network air ambulance transport, effective January 1, 2022.

17. My business judgment is that group health plans and issuers will use FAIR Health (or similar a third-party database) to determine payments for up to seven percent (7%) of AMC's total annual transports in calendar year 2022. My business judgment accounts for the factors that I described in Paragraphs 8 through 10, the Departments' assertion that only 25% of air ambulance transports in 2012 and 31% in 2017 were made under traditional in-network contracts, and the historical lack of network contracts for air ambulance services.

18. If group health plans and issuers use the FAIR Health average estimated allowed amount of $18,668 as the base rate when paying for seven percent (7%) of AMC's total annual transports for each air base, then eighty percent of AMC's bases would experience reductions in revenue for calendar year 2022. The reductions in revenue will be deeper and more widespread if group health plans and issuers use the FAIR Health average estimated allowed amount of $18,668 as the total rate paid.

***

I declare under penalty of perjury as set forth in 28 U.S.C. § 1746 that the foregoing is true and correct to the best of my knowledge, information, and belief.

Executed on November 15, 2021, at Greenwood Village, Colorado.

David Portugal

CIVIL COVER SHEET

JS-44 (Rev. 11/2020 DC)

I. (a) PLAINTIFFS

Association of Air Medical Services

(b) COUNTY OF RESIDENCE OF FIRST LISTED PLAINTIFF 88888
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) ATTORNEYS (FIRM NAME, ADDRESS, AND TELEPHONE NUMBER)

Sarah P. Hogarth
McDermott Will & Emery LLP
500 North Capitol Street NW
Washington, DC 20001
(202) 756-8354

DEFENDANTS

US Dep't of Health and Human Servs.; Xavier Becerra; US Office of Personnel Mgmt.; Kiran Ahuja; Laurie Bodenheimer; US Dep't of Labor; Martin Walsh; US Emp. Benefits Sec. Admin.; Ali Khawar; US Dep't of Treasury; Janet Yellen; Lily Batchelder; Internal Revenue

COUNTY OF RESIDENCE OF FIRST LISTED DEFENDANT
(IN U.S. PLAINTIFF CASES ONLY)
NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED

ATTORNEYS (IF KNOWN)

II. BASIS OF JURISDICTION
(PLACE AN x IN ONE BOX ONLY)

- ○ 1 U.S. Government Plaintiff
- ○ 3 Federal Question (U.S. Government Not a Party)
- ◉ 2 U.S. Government Defendant
- ○ 4 Diversity (Indicate Citizenship of Parties in item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES (PLACE AN x IN ONE BOX FOR PLAINTIFF AND ONE BOX FOR DEFENDANT) **FOR DIVERSITY CASES ONLY!**

	PTF	DFT		PTF	DFT
Citizen of this State	○ 1	○ 1	Incorporated or Principal Place of Business in This State	○ 4	○ 4
Citizen of Another State	○ 2	○ 2	Incorporated and Principal Place of Business in Another State	○ 5	○ 5
Citizen or Subject of a Foreign Country	○ 3	○ 3	Foreign Nation	○ 6	○ 6

IV. CASE ASSIGNMENT AND NATURE OF SUIT

(Place an X in one category, A-N, that best represents your Cause of Action and one in a corresponding Nature of Suit)

○ **A. *Antitrust***

- ☐ 410 Antitrust

○ **B. *Personal Injury/ Malpractice***

- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury
- ☐ 362 Medical Malpractice
- ☐ 365 Product Liability
- ☐ 367 Health Care/Pharmaceutical Personal Injury Product Liability
- ☐ 368 Asbestos Product Liability

◉ **C. *Administrative Agency Review***

- ☐ 151 Medicare Act

Social Security
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

Other Statutes
- ☐ 891 Agricultural Acts
- ☐ 893 Environmental Matters
- ☒ 890 Other Statutory Actions (If Administrative Agency is Involved)

○ **D. *Temporary Restraining Order/Preliminary Injunction***

Any nature of suit from any category may be selected for this category of case assignment.

(If Antitrust, then A governs)

○ **E. *General Civil (Other)*** OR ○ **F. *Pro Se General Civil***

Real Property
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent, Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

Personal Property
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

Bankruptcy
- ☐ 422 Appeal 27 USC 158
- ☐ 423 Withdrawal 28 USC 157

Prisoner Petitions
- ☐ 535 Death Penalty
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Conditions
- ☐ 560 Civil Detainee – Conditions of Confinement

Property Rights
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 835 Patent – Abbreviated New Drug Application
- ☐ 840 Trademark
- ☐ 880 Defend Trade Secrets Act of 2016 (DTSA)

Federal Tax Suits
- ☐ 870 Taxes (US plaintiff or defendant)
- ☐ 871 IRS-Third Party 26 USC 7609

Forfeiture/Penalty
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 690 Other

Other Statutes
- ☐ 375 False Claims Act
- ☐ 376 Qui Tam (31 USC 3729(a))
- ☐ 400 State Reapportionment
- ☐ 430 Banks & Banking
- ☐ 450 Commerce/ICC Rates/etc
- ☐ 460 Deportation
- ☐ 462 Naturalization Application
- ☐ 465 Other Immigration Actions
- ☐ 470 Racketeer Influenced & Corrupt Organization
- ☐ 480 Consumer Credit
- ☐ 485 Telephone Consumer Protection Act (TCPA)
- ☐ 490 Cable/Satellite TV
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 896 Arbitration
- ☐ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ☐ 950 Constitutionality of State Statutes
- ☐ 890 Other Statutory Actions (if not administrative agency review or Privacy Act)

○ **G. *Habeas Corpus/ 2255***	○ **H. *Employment Discrimination***	○ **I. *FOIA/Privacy Act***	○ **J. *Student Loan***
☐ 530 Habeas Corpus – General ☐ 510 Motion/Vacate Sentence ☐ 463 Habeas Corpus – Alien Detainee	☐ 442 Civil Rights – Employment (criteria: race, gender/sex, national origin, discrimination, disability, age, religion, retaliation) *(If pro se, select this deck)*	☐ 895 Freedom of Information Act ☐ 890 Other Statutory Actions (if Privacy Act) *(If pro se, select this deck)*	☐ 152 Recovery of Defaulted Student Loan (excluding veterans)
○ **K. *Labor/ERISA (non-employment)***	○ **L. *Other Civil Rights (non-employment)***	○ **M. *Contract***	○ **N. *Three-Judge Court***
☐ 710 Fair Labor Standards Act ☐ 720 Labor/Mgmt. Relations ☐ 740 Labor Railway Act ☐ 751 Family and Medical Leave Act ☐ 790 Other Labor Litigation ☐ 791 Empl. Ret. Inc. Security Act	☐ 441 Voting (if not Voting Rights Act) ☐ 443 Housing/Accommodations ☐ 440 Other Civil Rights ☐ 445 Americans w/Disabilities – Employment ☐ 446 Americans w/Disabilities – Other ☐ 448 Education	☐ 110 Insurance ☐ 120 Marine ☐ 130 Miller Act ☐ 140 Negotiable Instrument ☐ 150 Recovery of Overpayment & Enforcement of Judgment ☐ 153 Recovery of Overpayment of Veteran's Benefits ☐ 160 Stockholder's Suits ☐ 190 Other Contracts ☐ 195 Contract Product Liability ☐ 196 Franchise	☐ 441 Civil Rights – Voting (if Voting Rights Act)

V. ORIGIN

◉ 1 Original Proceeding ○ 2 Removed from State Court ○ 3 Remanded from Appellate Court ○ 4 Reinstated or Reopened ○ 5 Transferred from another district (specify) ○ 6 Multi-district Litigation ○ 7 Appeal to District Judge from Mag. Judge ○ 8 Multi-district Litigation – Direct File

VI. CAUSE OF ACTION (CITE THE U.S. CIVIL STATUTE UNDER WHICH YOU ARE FILING AND WRITE A BRIEF STATEMENT OF CAUSE.)
Administrative Procedure Act, 5 U.S.C. 702, 706 - arbitrary, capricious, and contrary to law agency action.

VII. REQUESTED IN COMPLAINT ☐ CHECK IF THIS IS A **CLASS ACTION** UNDER F.R.C.P. 23 **DEMAND $** 0 **JURY DEMAND:** Check YES only if demanded in complaint **YES** ☐ **NO** ☒

VIII. RELATED CASE(S) IF ANY (See instruction) **YES** ☐ **NO** ☒ If yes, please complete related case form

DATE: 11/16/2021 **SIGNATURE OF ATTORNEY OF RECORD** /s/ Sarah P. Hogarth

INSTRUCTIONS FOR COMPLETING CIVIL COVER SHEET JS-44
Authority for Civil Cover Sheet

The JS-44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and services of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. Listed below are tips for completing the civil cover sheet. These tips coincide with the Roman Numerals on the cover sheet.

I. COUNTY OF RESIDENCE OF FIRST LISTED PLAINTIFF/DEFENDANT (b) County of residence: Use 11001 to indicate plaintiff if resident of Washington, DC, 88888 if plaintiff is resident of United States but not Washington, DC, and 99999 if plaintiff is outside the United States.

III. CITIZENSHIP OF PRINCIPAL PARTIES: This section is completed only if diversity of citizenship was selected as the Basis of Jurisdiction under Section II.

IV. CASE ASSIGNMENT AND NATURE OF SUIT: The assignment of a judge to your case will depend on the category you select that best represents the primary cause of action found in your complaint. You may select only one category. You must also select one corresponding nature of suit found under the category of the case.

VI. CAUSE OF ACTION: Cite the U.S. Civil Statute under which you are filing and write a brief statement of the primary cause.

VIII. RELATED CASE(S), IF ANY: If you indicated that there is a related case, you must complete a related case form, which may be obtained from the Clerk's Office.

Because of the need for accurate and complete information, you should ensure the accuracy of the information provided prior to signing the form.

AO 440 (Rev. 06/12; DC 3/15) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

District of Columbia

Association of Air Medical Services

Plaintiff(s)

v.

U.S. Department of Health and Human Services, et al.

Defendant(s)

Civil Action No. 1:21-cv-3031

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* U.S. Department of Health and Human Services,
200 Independence Avenue SW
Washington, DC 20201

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are: Sarah P. Hogarth
McDermott Will & Emery LLP
500 North Capitol Street NW
Washington, DC 20001

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

ANGELA D. CAESAR, CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No. 1:21-cv-3031

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____ was received by me on *(date)* _____ .

❒ I personally served the summons on the individual at *(place)* _____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____ , a person of suitable age and discretion who resides there, on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is designated by law to accept service of process on behalf of *(name of organization)* _____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc:

AO 440 (Rev. 06/12; DC 3/15) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

District of Columbia

Association of Air Medical Services

Plaintiff(s)

v.

U.S. Department of Health and Human Services, et al.

Defendant(s)

Civil Action No. 1:21-cv-3031

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* Xavier Becerra, in his official capacity as Secretary of Health and Human Services,
200 Independence Avenue SW
Washington, DC 20201

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are: Sarah P. Hogarth
McDermott Will & Emery LLP
500 North Capitol Street NW
Washington, DC 20001

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

ANGELA D. CAESAR, CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No. 1:21-cv-3031

PROOF OF SERVICE

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❒ I personally served the summons on the individual at *(place)* _____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____ , a person of suitable age and discretion who resides there, on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is designated by law to accept service of process on behalf of *(name of organization)* _____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc:

AO 440 (Rev. 06/12; DC 3/15) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

District of Columbia

Association of Air Medical Services

Plaintiff(s)

v.

U.S. Department of Health and Human Services, et al.

Defendant(s)

Civil Action No. 1:21-cv-3031

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* U.S. Office of Personnel Management
1900 E Street NW
Washington, DC 20415

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are: Sarah P. Hogarth
McDermott Will & Emery LLP
500 North Capitol Street NW
Washington, DC 20001

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

ANGELA D. CAESAR, CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No. 1:21-cv-3031

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

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❒ I personally served the summons on the individual at *(place)* _____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____ , a person of suitable age and discretion who resides there, on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is designated by law to accept service of process on behalf of *(name of organization)* _____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc:

AO 440 (Rev. 06/12; DC 3/15) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

District of Columbia

Association of Air Medical Services,

Plaintiff(s)

v.

U.S. Department of Health and Human Services, et al.

Defendant(s)

Civil Action No. 1:21-cv-3031

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* Kiran Ahuja, in her official capacity as Director of the U.S. Office of Personnel Management
1900 E Street NW
Washington, DC 20415

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are: Sarah P. Hogarth
McDermott Will & Emery LLP
500 North Capitol Street NW
Washington, DC 20001

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

ANGELA D. CAESAR, CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No. 1:21-cv-3031

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____ was received by me on *(date)* _____ .

❒ I personally served the summons on the individual at *(place)* _____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____ , a person of suitable age and discretion who resides there, on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is designated by law to accept service of process on behalf of *(name of organization)* _____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc:

AO 440 (Rev. 06/12; DC 3/15) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

District of Columbia

Association of Air Medical Services

Plaintiff(s)

v.

U.S. Department of Health and Human Services, et al.

Defendant(s)

Civil Action No. 1:21-cv-3031

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* Laurie Bodenheimer, in her official capacity as Associate Director, Healthcare and Insurance, in the Office of Personnel Management,
1900 E Street NW
Washington, DC 20415

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are: Sarah P. Hogarth
McDermott Will & Emery LLP
500 North Capitol Street NW
Washington, DC 20001

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

ANGELA D. CAESAR, CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No. 1:21-cv-3031

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____ was received by me on *(date)* _____ .

❒ I personally served the summons on the individual at *(place)* _____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____ , a person of suitable age and discretion who resides there, on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is designated by law to accept service of process on behalf of *(name of organization)* _____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc:

AO 440 (Rev. 06/12; DC 3/15) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

District of Columbia

Association of Air Medical Services

Plaintiff(s)

v.

U.S. Department of Health and Human Services, et al.

Defendant(s)

Civil Action No. 1:21-cv-3031

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* U.S. Department of Labor
200 Constitution Avenue NW
Washington, DC 20210

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are: Sarah P. Hogarth
McDermott Will & Emery LLP
500 North Capitol Street NW
Washington, DC 20001

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

ANGELA D. CAESAR, CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No. 1:21-cv-3031

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____ was received by me on *(date)* _____ .

❒ I personally served the summons on the individual at *(place)* _____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____ , a person of suitable age and discretion who resides there, on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is designated by law to accept service of process on behalf of *(name of organization)* _____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc:

AO 440 (Rev. 06/12; DC 3/15) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

District of Columbia

Association of Air Medical Services

Plaintiff(s)

v.

U.S. Department of Health and Human Services, et al.

Defendant(s)

Civil Action No. 1:21-cv-3031

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* Martin J. Walsh, in his official capacity as Secretary of Labor,
200 Constitution Avenue NW
Washington, DC 20210

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are: Sarah P. Hogarth
McDermott Will & Emery LLP
500 North Capitol Street NW
Washington, DC 20001

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

ANGELA D. CAESAR, CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No. 1:21-cv-3031

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____ was received by me on *(date)* _____ .

❒ I personally served the summons on the individual at *(place)* _____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____ , a person of suitable age and discretion who resides there, on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is designated by law to accept service of process on behalf of *(name of organization)* _____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc:

AO 440 (Rev. 06/12; DC 3/15) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

District of Columbia

Association of Air Medical Services

Plaintiff(s)

v.

U.S. Department of Health and Human Services, et al.

Defendant(s)

Civil Action No. 1:21-cv-3031

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* U.S. Employee Benefits Security Administration
200 Constitution Avenue NW
Washington, DC 20210

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are: Sarah P. Hogarth
McDermott Will & Emery LLP
500 North Capitol Street NW
Washington, DC 20001

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

ANGELA D. CAESAR, CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No. 1:21-cv-3031

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____ was received by me on *(date)* _____ .

❒ I personally served the summons on the individual at *(place)* _____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____ , a person of suitable age and discretion who resides there, on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is designated by law to accept service of process on behalf of *(name of organization)* _____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc:

AO 440 (Rev. 06/12; DC 3/15) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

District of Columbia

Association of Air Medical Services

Plaintiff(s)

v.

U.S. Department of Health and Human Services, et al.

Defendant(s)

Civil Action No. 1:21-cv-3031

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* Ali Khawar, in his official capacity as the Acting Assistant Secretary for the Employee Benefits Security Administration,
200 Constitution Avenue NW
Washington, DC 20210

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are: Sarah P. Hogarth
McDermott Will & Emery LLP
500 North Capitol Street NW
Washington, DC 20001

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

ANGELA D. CAESAR, CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No. 1:21-cv-3031

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____ was received by me on *(date)* _____ .

❒ I personally served the summons on the individual at *(place)* _____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____ , a person of suitable age and discretion who resides there, on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is designated by law to accept service of process on behalf of *(name of organization)* _____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc:

AO 440 (Rev. 06/12; DC 3/15) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

District of Columbia

Association of Air Medical Services

Plaintiff(s)

v.

U.S. Department of Health and Human Services, et al.

Defendant(s)

Civil Action No. 1:21-cv-3031

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* U.S. Department of the Treasury
1500 Pennsylvania Avenue NW
Washington, DC 20220

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are: Sarah P. Hogarth
McDermott Will & Emery LLP
500 North Capitol Street NW
Washington, DC 20001

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

ANGELA D. CAESAR, CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No. 1:21-cv-3031

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____ was received by me on *(date)* _____ .

❒ I personally served the summons on the individual at *(place)* _____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____ , a person of suitable age and discretion who resides there, on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is designated by law to accept service of process on behalf of *(name of organization)* _____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc:

AO 440 (Rev. 06/12; DC 3/15) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

District of Columbia

Association of Air Medical Services

Plaintiff(s)

v.

U.S. Department of Health and Human Services, et al.

Defendant(s)

Civil Action No. 1:21-cv-3031

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* Janet Yellen, in her official capacity as Secretary of the Treasury,
1500 Pennsylvania Avenue NW
Washington, DC 20220

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are: Sarah P. Hogarth
McDermott Will & Emery LLP
500 North Capitol Street NW
Washington, DC 20001

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

ANGELA D. CAESAR, CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No. 1:21-cv-3031

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____ was received by me on *(date)* _____ .

❒ I personally served the summons on the individual at *(place)* _____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____ , a person of suitable age and discretion who resides there, on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is designated by law to accept service of process on behalf of *(name of organization)* _____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc:

AO 440 (Rev. 06/12; DC 3/15) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

District of Columbia

Association of Air Medical Services

Plaintiff(s)

v.

U.S. Department of Health and Human Services, et al.

Defendant(s)

Civil Action No. 1:21-cv-3031

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* Lily L. Batchelder, in her official capacity as Assistant Secretary of the Treasury (Tax Policy),
1500 Pennsylvania Avenue NW
Washington, DC 20220

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are: Sarah P. Hogarth
McDermott Will & Emery LLP
500 North Capitol Street NW
Washington, DC 20001

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

ANGELA D. CAESAR, CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No. 1:21-cv-3031

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____ was received by me on *(date)* _____ .

❒ I personally served the summons on the individual at *(place)* _____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____ , a person of suitable age and discretion who resides there, on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is designated by law to accept service of process on behalf of *(name of organization)* _____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc:

AO 440 (Rev. 06/12; DC 3/15) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

District of Columbia

Association of Air Medical Services

Plaintiff(s)

v.

U.S. Department of Health and Human Services, et al.

Defendant(s)

Civil Action No. 1:21-cv-3031

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* Internal Revenue Service
1111 Constitution Avenue NW,
Washington, DC 20224

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are: Sarah P. Hogarth
McDermott Will & Emery LLP
500 North Capitol Street NW
Washington, DC 20001

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

ANGELA D. CAESAR, CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No. 1:21-cv-3031

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____ was received by me on *(date)* _____ .

❒ I personally served the summons on the individual at *(place)* _____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____ , a person of suitable age and discretion who resides there, on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is designated by law to accept service of process on behalf of *(name of organization)* _____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc:

AO 440 (Rev. 06/12; DC 3/15) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

District of Columbia

Association of Air Medical Services

Plaintiff(s)

v.

U.S. Department of Health and Human Services, et al.

Defendant(s)

Civil Action No. 1:21-cv-3031

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* Charles Rettig, in his official capacity as Commissioner of the Internal Revenue Service,
1111 Constitution Avenue NW
Washington, DC 20224

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are: Sarah P. Hogarth
McDermott Will & Emery LLP
500 North Capitol Street NW
Washington, DC 20001

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

ANGELA D. CAESAR, CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No. 1:21-cv-3031

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____ was received by me on *(date)* _____ .

❒ I personally served the summons on the individual at *(place)* _____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____ , a person of suitable age and discretion who resides there, on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is designated by law to accept service of process on behalf of *(name of organization)* _____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc:

AO 440 (Rev. 06/12; DC 3/15) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

District of Columbia

Association of Air Medical Services

Plaintiff(s)

v.

U.S. Department of Health and Human Services, et al.

Defendant(s)

Civil Action No. 1:21-cv-3031

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* Douglas W. O'Donnell, in his official capacity as Deputy Commissioner for Services and Enforcement in the Internal Revenue Service,
1111 Constitution Avenue NW
Washington, DC 20224

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are: Sarah P. Hogarth
McDermott Will & Emery LLP
500 North Capitol Street NW
Washington, DC 20001

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

ANGELA D. CAESAR, CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No. 1:21-cv-3031

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____ was received by me on *(date)* _____ .

❒ I personally served the summons on the individual at *(place)* _____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____ , a person of suitable age and discretion who resides there, on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is designated by law to accept service of process on behalf of *(name of organization)* _____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc: