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Requirements Related to Surprise Billing; Part I (CMS-9909-IFC); Summary of Interim Final Rule with Comment

On July 13, 2021, the Departments of Treasury, Labor, and Health and Human Services (the Departments) and the Office of Personnel Management (OPM) published in the Federal Register (86 *FR* 36872) interim final rules with a comment period (IFC). The IFC amends and adds to existing regulations to implement provisions of the No Surprises Act. The No Surprises Act, enacted as part of the Consolidated Appropriations Act, 2021 (CAA),[1] established protections for enrollees of health plans 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 the IFC, the three Departments codify largely parallel provisions implementing the requirements of the No Surprises Act on group health plans and health insurance issuers offering group or individual health insurance coverage. In addition, the Department of Health and Human Services (HHS) codifies rules applicable to health care providers and facilities including emergency departments of hospitals, independent freestanding emergency departments, and air ambulance providers. OPM specifies how certain provisions apply to issuers participating in the Federal Employees Health Benefits Program. Finally, the IFC recodifies patient protections regarding choice of health care professionals and extends the applicability of those protections to grandfathered health plans.

Future rules will address the Independent Dispute Resolution process, transparency requirements, patient-provider dispute resolution, and price comparison tools. The rule is accompanied by a model disclosure notice as well as model notice and consent documents.[2] **Comments are due September 7, 2021.**

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[1] P.L. 116-260
[2] CMS-10780 | CMS

I. Background

Under the Patient Protection and Affordable Care Act (ACA), enacted in 2010, non-grandfathered group or individual health plan issuers that cover emergency services in an emergency department of a hospital are required to make those services available without prior authorization and without regard to whether the provider of emergency services is an in-network provider. Under that requirement, plans and issuers may not impose any limitation on benefits for out-of-network emergency services that is more restrictive than the requirements that apply to in-network emergency services. The ACA did not, however, prohibit or limit the practice of balance billing. As a result, providers of those services who do not participate in a plan's or insurer's network may bill patients for amounts in excess of amounts permitted as payment by the enrollee's plan or issuer – amounts that are often considerably more than the amount the plan or issuer has set as the enrollee's required cost sharing for the services.

The No Surprises Act expands on the ACA protections in the following ways:

- With respect to emergency services, certain non-emergency services, and air-ambulance services, balance billing is prohibited, and cost-sharing is subject to specific limitations.
- The definition of emergency services is expanded to include-post stabilization services. For those post-stabilization services, under certain conditions and with the enrollee's notice and consent, the limitations on balance billing and cost-sharing may be waived.
- With respect to non-emergency services furnished by nonparticipating providers at certain participating health care facilities, under certain conditions and with the enrollee's notice and consent, the limitations on balance billing and cost-sharing may be waived.

- The expanded protections apply to all health plans or coverage offered in the individual and group markets for insurance whether or not the plan is grandfathered and apply to coverage offered under the FEHB program.

In addition to the provisions that apply specifically to health insurance and coverage, the No Surprises Act also includes provisions that apply specifically to health care providers, facilities and providers of air ambulance services. It imposes parallel limitations on cost-sharing and prohibitions on balance billing. In addition, there are requirements related to disclosures about balance billing protections and the establishment of a complaints process with respect to violations of the protections against balance billing and out-of-network cost sharing.

The statutory ACA protections as well as the No Surprises Act provisions are in Title XXVII of the Public Health Service Act (PHSA). The ACA provisions are incorporated into section 9815 of the Internal Revenue Code and section 715 of ERISA; the No Surprises Act provisions are codified in section 9816 of the Internal Revenue Code and section 716 of ERISA. The Act sunsets the original ACA protections and imposes the expanded No Surprises Act for plan years that begin on or after January 1, 2022.

The Departments review the concerns related to surprise billing which preceded the passage of the No Surprises Act. A surprise balance bill is one that comes from a health care provider or facility when a covered individual seeks care at a facility that is in their health plan's network, but one or more of their treating providers at the facility is not. It can also happen in an emergency, when a person is taken to a facility that is not in their health plan network or when they are transported in an emergency by an air ambulance service provider that is not in their network.

The Departments cite analyses describing and examining surprise billing. One analysis indicates that surprise bills often are many times the size of the amounts that in-network individuals would pay for the same services. Other analyses suggest that providers sometimes use balance billing to pressure issuers into paying higher in-network rates, and that the surprise billing problem has been growing. They describe the problems that result for enrollees of health plans – including financial hardship, enduring medical debt, and confusion – challenges that are exacerbated for individuals in underserved communities. Balance billed amounts often do not count towards a person's deductible or other cost-sharing charges required by their coverage.

Some states have enacted laws to reduce or eliminate balance billing, but these efforts have created a patchwork of consumer protections. State balance billing protections typically do not apply to certain employment-based coverage, as federal law generally preempts state laws that regulate self-insured group health plans sponsored by private employers. Further, states have limited power to address surprise bills that involve an out-of-state provider.

The IFC implements 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; (2) prohibit nonparticipating providers, health care facilities, and providers of air ambulance services from balance billing enrollees unless certain notice and consent requirements are satisfied; (3) require certain health care facilities and providers to provide disclosures of federal and state patient protections against balance billing; and (4) set forth a complaints process with respect to violations of the protections against balance billing and out-of-network cost sharing.

Future rules will address other provisions of the No Surprises Act including the Independent Dispute Resolution process, transparency provisions, patient-provider dispute resolution, and price comparison tools. The Departments note that while most provisions of the No Surprises Act become effective for plan years starting on or after January 1, 2022, some rulemaking may be completed after that date. To the extent that rulemaking occurs after the effective dates, the Departments intend to apply a prospective applicability date with adequate time for impacted parties to comply with new requirements. They note that even without rulemaking in advance of the effective dates, plans and issuers are expected to make a good faith effort to implement the requirements of the statute upon its effective date.

II. Surprise Billing Protections

The IFC establishes rules to protect individuals from surprise medical bills for emergency services, air ambulance services furnished by nonparticipating providers, and non-emergency services furnished by nonparticipating providers at participating facilities in certain circumstances. Largely parallel rules are codified in Department of Treasury regulations at 26 CFR Part 54, paragraphs 5-7; Department of Labor regulations at 29 CFR 2590.716 and 2590.717; and Department of HHS at 45 CFR parts 144 and 147. In addition, HHS regulations at part 149 codify requirements of health care providers, facilities and providers of air ambulance services.

Under the regulations,

- If a group health plan or an issuer of individual or group health coverage offers coverage of emergency services, then they must 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.
- If a group health plan or issuer of group or individual coverage covers items or services performed by nonparticipating providers at participating facilities, if notice and consent has not been provided and received, then the plan or issuer must not impose cost sharing that is greater than the amounts that would apply if the items or services had been furnished by a participating provider.
- If a group health plan or issuer of group or individual coverage covers air ambulance services performed by nonparticipating providers, then the plan or issuer must not impose cost sharing that is greater than the amounts that would apply if the items or services had been furnished by a participating provider.

Emergency services are defined to 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, the IFC limits cost sharing for out-of-network services to in-network levels, requires cost sharing to count toward any in-network deductibles and out-of-pocket maximums, and prohibits balance billing.

A. Definitions

In each of 26 CFR §549816-3T; 29 CFR §2590.716-3; and 45 CFR 149.30 the IFC includes a series of definitions of terms including for the term "physician or health care provider." The definitions codified in these sections are described in their context and are described in this summary above and below. The Departments note that they have defined "physician or health care provider" exclusive of air ambulance providers because some of the No Surprises Act requirements of health care providers do not apply to air ambulance providers. To clearly distinguish where requirements do and do not apply to air ambulance providers, the regulations will identify air ambulance providers separately from all other health care providers.

B. Preventing Surprise Medical Bills

1. Scope of the New Surprise Billing Protections

i. Emergency Services

The Departments state that the terms "emergency medical condition," "emergency services," and "to stabilize" generally have the meanings given to them under the Emergency Medical Treatment and Labor Act (EMTALA). The No Surprises Act broadens the definition of emergency services to include those provided at an independent freestanding emergency department. They note that a freestanding emergency department is intended to include any health care facility that is geographically separate and distinct from a hospital and is licensed by a state to provide emergency services.

The Departments discuss the definition of "emergency medical condition" and address current concerns about some plans and issuers determining whether an episode of care involved an emergency medical condition based solely on the final diagnosis without regard to an individual's presenting symptoms or any additional review. They explicitly state that these practices are inconsistent with the emergency services requirements of the No Surprises Act as well as the ACA. They note that determining if the prudent layperson standard is met must be made on a case-by-case basis before an initial denial of an emergency services claim.

The Departments describe how a determination of a prudent layperson standard is met and codify that coverage for an emergency medical condition cannot be limited solely on the basis of diagnosis codes. They state that such a determination may only: be based on all pertinent

documents; be focused on presenting symptoms; and be based on whether a layperson (as opposed to a medical professional) would reasonably consider the situation to be an emergency. Plans may not:

- Restrict coverage of emergency services by imposing a time limit on the onset of symptoms and when the person presented in the emergency department;
- Restrict coverage of an emergency service because the patient did not experience a sudden onset of the condition; or
- Restrict access to emergency services based on a general plan exclusion – for example by denying coverage of emergency services to a pregnant woman because the plan excludes coverage of maternity care.

ii. Post-Stabilization Services

The No Surprises Act defines emergency services to include any additional items and services that are covered and furnished by a nonparticipating provider or nonparticipating emergency facility 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 "post-stabilization services" are considered emergency services subject to surprise billing protections unless certain conditions are met. Those conditions, codified in HHS regulations 45 CFR 149.410(b), are:

- The enrollee is able to travel using nonmedical transportation within a reasonable distance;
- The provider or facility providing the services satisfies notice and consent requirements (The notice and consent requirements are further described below and are codified in 410.420(c) through (g).)
- The enrollee is in a condition to receive the information; and
- The provider or facility satisfies any other requirements imposed under state law.

The Departments note that the ability to travel must take into account an individual's specific medical condition and be based on all relevant facts and circumstances including those related to underserved areas or geographic isolation. For example, that includes the enrollee's ability to pay for transportation, the availability and safety of public transport, etc. **The Departments seek comment on the definition of "reasonable travel distance" and whether standards are needed to describe an unreasonable travel burden.**

Likewise, an individual must be in a condition to receive and satisfy the notice and consent requirements. The Departments clarify that the attending physician or treating provider would make this determination taking into account all relevant facts and circumstances including the patient's state of mind and emotional state; whether they are impaired by alcohol, drugs or prescribed medications; or displaying symptoms of a mental or behavioral health disorder. Providers should also take into account cultural and contextual factors that could affect informed decision-making such as lack of trust or historical inequities.

The Departments solicit comments on whether there are any additional conditions that should be included the definition of emergency services. The Departments also solicit

comments on what guidelines may be needed to determine when an individual is in a condition to receive the written notice and provide consent.

iii. Non-Emergency Services

Unless notice and consent requirements have been met, the surprise billing protections apply to non-emergency services performed by nonparticipating providers at participating health facilities. The provisions apply to the extent that the plan or coverage covers benefits for those items or services. Requirements applicable in the case of non-emergency services are codified in 26 CFR 54.9816-5T; 29 CFR 2590.716-5; and 45 CFR 149.420.

iv. Health Care Facilities

With respect to non-emergency services and consistent with the No Surprises Act, a participating health care facility is defined as a health care facility that has a contractual relationship directly or indirectly with a group health plan or health insurance issuer. The IFC specifies that this includes where there is a single case agreement between a facility and the plan or issuer to address unique situations in which an enrollee requires services that are typically out-of-network services.

A health care facility in this context includes a hospital (defined in 1861(e) of the Social Security Act (SSA)), a hospital outpatient department, a critical access hospital (defined in 1861(mm)(1) of the SSA), or an ambulatory surgical center (described in section 1833(i)(1)(A) of the SSA).

The Departments may designate additional facilities as health care facilities for this purpose and solicit comment on other appropriate facilities to include – including, in particular, those where surprise bills frequently arise and whether urgent care centers or retail clinics should be included. They are interested in the degree to which individuals use urgent care centers and independent freestanding emergency departments similarly or differently, whether plans and issuers contract separately with urgent care centers and their providers, how often nonparticipating providers furnish services at urgent care centers, and potential definitions for the term urgent care center.

v. Items and Services within the Scope of a Visit

The Departments clarify that a visit to a participating health care facility includes the furnishing of equipment and devices, telemedicine services, imaging services, laboratory services, and preoperative and postoperative services. Examples provided include laboratory services for a sample collected during an individual's hospital visit and sent to an off-site laboratory, and a consultation with a specialist via telemedicine during a visit to a participating hospital.

The Departments solicit comments regarding other items and services that would be appropriate to include within the scope of a visit.

vi. Air Ambulance Services

Under the IFC, surprise billing protections apply where a plan or coverage includes benefits for air ambulance services and has a network of participating providers whether or not any air ambulance providers are included in that network.

2. Determination of the Cost-Sharing Amount and Payment Amount

i. In General

Under the No Surprises Act,

- If a plan or issuer covers services in an emergency department of a hospital or an independent freestanding emergency department, the cost-sharing requirement for such services performed by a nonparticipating provider or nonparticipating emergency facility cannot be greater than the requirement that would apply if the services were provided by a participating provider or a participating emergency facility;
- If a plan or issuer covers 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 the notice and consent requirement, 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; and
- If a plan or issuer covers air ambulance services, the plan or issuer must cover such services from a nonparticipating provider in such a manner that the cost-sharing requirement is the same that would apply if such services were provided by a participating provider.

Where a plan or issuer does not have an established cost-sharing requirement that specifically applies to participating providers, the cost-sharing amount under the No Surprises Act must be calculated using the generally applicable cost-sharing requirement for the item or service under the plan or coverage.

Plans and issuers are also required to count the cost-sharing amounts for the impacted items or services toward any in-network deductible or out-of-pocket maximums under the plan or coverage.

ii. Cost-Sharing Amount

The cost-sharing amounts for protected items or services (except for air ambulance services) must be calculated as if the total amount that would have been charged for the services is equal to the "recognized amount." The recognized amount is defined as: (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 qualified payment amount (QPA), which

the IFC defines as the median contracted rate of the plan or issuer for the item or service in the geographic region.

The Departments state that by requiring that payment be based on the recognized amount, provider-payer disputes will be limited.

With respect to air ambulance services, there is no recognized amount – instead the IFC requires that coinsurance and deductible for air ambulance services provided by a nonparticipating provider be based on the lesser of the QPA or the billed amount. There are no All-Payer Model agreements that impact air ambulance services and the Departments are unaware of any specified state laws that apply.

iii. Out-of-Network Rate

The No Surprises Act and the IFC establish limits on the total amount that must be paid by a plan or issuer for protected items or services (the out-of-network rate). Similar to the limitations applicable for calculating cost-sharing amounts, the out-of-network rate must be equal to one of the following amounts less any cost sharing from the enrollee: (1) an amount determined under an All-Payer Model Agreement; (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.

The Departments address the possibility that under these rules, a plan or issuer may be required to make a payment to a provider in advance of an enrollee meeting their deductible. This could occur because the calculation for the cost-sharing responsibility for protected services is based on a different amount than the out-of-network rate. They provide the following example of this possibility:

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

While such a payment might otherwise cause a high deductible plan to lose its status as a high-deductible plan, the Departments note that the No Surprises Act included a provision establishing that a plan will not fail to be treated as a high-deductible health plan as a result of providing benefits in accordance with the No Surprises Act.[3]

iv. Specified State Law

Under the No Surprises Act and the IFC, the permitted cost-sharing payment amounts and out-of-network rates applicable to protected services may be based on a state law that specifies a method for determining those amounts. The IFC describes this to mean that there is a state law that applies (1) to the plan, issuer or coverage involved; (2) to the nonparticipating provider, air ambulance provider or emergency facility involved; and (3) to the item or service involved. Otherwise, the federal recognized amount or out-of-network rate will be determined based on the No Surprises Act statute and regulations. For example, if a state surprise billing law applies only to health maintenance organizations, the federal law and regulations for determining the recognized amount and out-of-network rates would apply with respect to other types of health plans and issuers.

The Departments specify that the state law could apply with respect to plans or issuers that are permitted to opt in to the state protections. The Departments note that because of restrictions in the federal Airline Deregulation Act of 1978, there are not state laws that would apply with respect to determining the payment amounts for air ambulance services.

The Departments seek comment on whether flexibility should be permitted to opt in to a state's program of regulatory protections against surprise billing or whether such flexibility would result in providers and facilities selectively opting in to state programs that favor their own payments. In addition, the Departments seek comments specifically from issuers, providers, or facilities located in underserved or rural communities, or areas where there are shortages of providers.

(a) State Law Interaction with ERISA. The Departments describe the Employee Retirement Income Security Act of 1974's (ERISA) general preemption of state laws that "relate" to employee benefit plans and its "savings clause" which permits state laws that regulate the business of insurance. Under those provisions and as indicated by the conference report accompanying the Health Insurance Portability and Accountability Act of 1996 (which established a series of federal insurance laws), ERISA's preemption of state laws is intended to be applied narrowly leaving states with significant latitude to impose requirements on issuers that are more restrictive than federal law. State laws must not, however, prevent the application of ERISA requirements. States are also permitted to allow self-insured plans sponsored by private employers to opt in to a state program including to voluntarily opt in to a state law that provides a method for determining the cost-sharing amount or total amount payable under a state's surprise billing protections.

[3] See section 223(c)(2)(F) of the Internal Revenue Code of 1986 as added by The No Surprises Act.

Under the IFC, a self-insured plan that opts in to a state law must prominently display in its plan materials on coverage for out-of-network services, a statement that the plan has opted in to a specified state law; identify the relevant state; and provide 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 Departments provide several examples, duplicated below, illustrating how state laws may or may not apply (assuming that there is no applicable All-Payer Model Agreement).

Example 1.
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.
Conclusion. In this Example 1, State A's law would apply to determine the recognized amount and the out-of-network rate.
Example 2.
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.
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.
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.
Conclusion. In this Example 3, State A's law would apply to determine the cost-sharing amount and out-of-network rate for the emergency services, as defined under State A's law. State A's law would not apply for purposes of determining the cost-sharing amount and out-of-network rate for the post-stabilization services. Instead,

the lesser of the QPA or billed amount would apply to determine the recognized amount, and either an amount determined through agreement between the hospital and issuer or an amount determined by an IDR entity would apply to determine the out-of-network rate, with respect to post-stabilization services.

Example 4.

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.

Conclusion. In this example, State A's law would apply to determine the recognized amount and the out-of-network rate.

The Departments expect that it would be uncommon for laws of more than one state to each apply to the same health insurance issuer, but seek comment on the need for and ways to resolve a question of which state law would apply if such a question should arise. The Departments also seek comment on how states have handled such questions prior to the enactment of the No Surprises Act, where these types of conflicts exist.

The Departments further clarify that they interpret the No Surprises Act provision that applies state surprise billing laws for determining the total amount of payment broadly. As such, the IFC interprets state laws for setting payment to include state laws that set a formula for that amount; that set a predetermined amount; and that establish an arbitration or negotiation process for establishing the amount. In addition, they believe that Congress did not intend to preempt other provisions in state balance billing laws – including for example, state laws that apply balance billing protections beyond those provided under the No Surprises Act.

v. All-Payer Model Agreements

In states with an All-Payer Model Agreement, the rate under the All-Payer Model Agreement would apply for determining the recognized amount (for calculating cost-sharing) and the out-of-network rate. To account for the variation in All-Payer programs, however, the Departments clarify that for an All-Payer Model Agreement to be used to determine the recognized amount or out-of-network rates, the Agreement must apply (1) to the coverage involved; (2) to the nonparticipating provider or nonparticipating emergency facility involved; and (3) to the item or service involved.

These conditions are necessary where an All-Payer Model Agreement is only in place in certain geographic areas of a state, applies to only certain providers or provider types, or only applies to certain types of services. In addition, where providers voluntarily participate in an agreement,

where both the provider or facility and plan or issuer participate, the All-Payer Model Agreement rates would apply. Where one or the other is not participating, the federal laws and regulations would apply.

vi. Calculating Median Contracted Rates

The No Surprises Act directs the Departments to establish a methodology for determining the QPA and defines the QPA as the median of the contracted rates of 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 where it is furnished, increased for inflation. Cost-sharing maximums for protected services are based on the lesser of the billed charge or the QPA (in a state without an All-Payer Model Agreement) and IDR entities must consider the QPA as part of the IDR process.

The median contracted rate is determined by a plan sponsor for all of their group or individual health coverage offered within the same insurance market. The statute specifies using an alternative methodology where a plan or issuer has insufficient information to calculate a median contracted rate, but the Departments see such approaches as only being used in limited circumstances and have established an approach for determining the QPA that they believe will minimize the need for alternative methodologies. (Alternate methodologies are described in more detail below.)

(a) Median Contracted Rate. Under the IFC, the median contracted rate is calculated by arranging in order from least to greatest, the contracted rates of all plans of the plan sponsor for the same or similar item or services provided by a provider in the same or similar specialty or facility type and within the same geographic region and selecting the middle number. If there are an even number of rates, median contracted rate is the average of the two middle rates.

The *contracted rate* is the total amount (including cost sharing) that the health plan or issuer has contractually agreed to pay a participating provider, facility, or provider of air ambulance services. Each contracted rate is a single data point. Where a plan or issuer rents a provider network, the rates of the entity responsible for managing the network would be treated as the plan or issuer's contracted rates for this purpose. A contracted rate would not include a single case agreement or other arrangement where a plan or issuer has a special agreement with a provider or facility that is not otherwise contracted to participate in the network to provide services under unique circumstances.

The term "*Insurance Market*" for this purpose is one of the following: the individual market, the small group market, or the large group market. Those terms are defined in section 2791(e) of the Public Health Service Act. Small and large group markets include self-insured group health plans some of which may require a third-party administrator to calculate the QPA on their behalf. The contracted rate will not include rates negotiated under limited types of health coverage such as excepted benefits, short-term limited-duration insurance, health reimbursement accounts and

other account-based plans nor under Medicare Advantage or Medicaid managed care plans. **The Departments seek comment on whether any contractual or other issue may prevent an entity, such as a third-party administrator, from using contracted rates from the 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 administering entities for compliance with these requirements**.

The *same or similar item or service* is meant to denote an item or service billed under the same service code or a comparable code under a different procedural code system. When modifiers to the code are applied to adjust payment rates, those modified rates must be included as a separate rate. Modifiers that do not cause rates to vary do not need to be taken into account.

A *Provider in the Same or Similar Specialty* is identified to be consistent with the plan or issuer's usual business practice. Plans or issuers need only calculate median contracted rates separately by provider specialty only where their contracts vary contracted rates based on provider specialty. The Departments state that this gives plans necessary flexibility to calculate the median contracted rates based on their own contracting practices. Air ambulance providers are all considered to be a single provider specialty for these purposes, however.

Facility of Same or Similar Facility Type. The median contracted rate is calculated separately only when contracted rates for emergency services vary based on the type of facility when the type of facility is an emergency department of a hospital versus a freestanding emergency department. Separate rates would not, however, be calculated when rates vary by other characteristic of facilities – for example teaching hospitals or academic medical centers.

Geographic Regions are defined as each metropolitan statistical area (MSA) within a state and all other areas within a state. 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 could consider all MSAs in the state to be a single region. For air ambulance services, a geographic region means one region consisting of all MSAs within a state and one region consisting of all other portions of the state.

Non-Fee-for-Service (FFS) Contractual Arrangements. The No Surprises Act directs the methodology to take into account payments for items or services that are not paid on a FFS basis. The Departments state that plans or issuers typically have an internal methodology used to value claims made on a capitated basis – sometimes for calculating an individual's cost sharing, for submitting data for risk adjustment purposes, or for meeting transparency reporting requirements. Under the IFC, such an underlying fee schedule would be used to calculate the median contracted rate. Where capitated or bundled rates are reconciled retrospectively or value-based adjustments are made that change a net payment amount, those amounts are disregarded for the purpose of calculating the median contracted rate. Examples of such after the fact

adjustments include risk sharing, bonus, penalty, incentive-based and retrospective payments or payment adjustments.

The Departments considered but rejected alternative approaches – such as permitting median contracted rates for service bundles, or excluding non-fee-for services contracts from the calculation of the median contracted rate.

(b) Indexing. The No Surprises Act provides that the median contracted rate determined as of January 31, 2019 is indexed using the consumer price index for all urban consumers (CPI-U) for each of 2019, 2020, and 2021 to calculate the QPA for 2022. Thereafter, the amount is indexed annually using the CPI-U for the prior year. To ensure that all plans and issuers are adjusting the amounts in a uniform manner, the IFC requires all plans and issuers to use the percentage increase for any year based on the CPI-U published by the Bureau of Labor Statistics. 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. The IFC provides for special rules for when a plan or issuer determines the reimbursement level for services by multiplying a contracted rate by another unit – such as time or mileage. In this case, the QPA is calculated by determining the median contracted rate, indexing that amount in accordance with the above described indexing rules, and then applying the multipliers.

Anesthesia Services are generally reimbursed at an amount that is determined by multiplying a negotiated rate for an anesthesia conversion factor by a base unit for the anesthesia service code, a time unit and a physical status modifier unit. To calculate the QPA for anesthesia services for 2022, the IFC requires the plan or issuer to first index the median contracted rate for the anesthesia conversion factor for the item or service by the CPI-U, using the methodology described above. This amount, referred to as the indexed median contract rate, is then multiplied 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.

Air Ambulance Services are generally reimbursed at an amount using air mileage service codes and reimbursement levels that reflect the number of miles a person is transported by the air ambulance. To calculate the QPA for the portion of air ambulance services billed using the air mileage service codes for 2022, the plan or issuer must first index the median contracted rate using the methodology described above. This amount, referred to as the indexed median air mileage rate, must then be multiplied by the number of loaded miles provided to the participant, beneficiary, or enrollee.

(d) Cases with Insufficient Information. The No Surprises Act requires there to be an alternative approach for determining the QPA in cases where a plan or issuer lacks sufficient information to calculate the median contracted rates for 2019.

The IFC defines sufficient information to be when a plan or issuer has at least three contracted rates on January 31, 2019.

Where a plan or issuer initially does not have sufficient information but later gains sufficient information, the plan or issuer must calculate the QPA using the median contracted rate for the first sufficient plan year. The IFC defines the first sufficient plan year as: (1) in the case of an item or service for which a plan or issuer does not have sufficient information 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.

Where contracted rates for a year after 2019 are used to calculate the median contracted rate, a plan or issuer will be considered to have sufficient information if, with respect to that year: (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 IFC methodology; 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 Departments note that the 25 percent minimum claims volume requirement is intended to ensure that those network contracts represent a reasonable proportion of a plan or issuer's total claims and therefore are not designed to manipulate the QPA.

Eligible Information. Where a plan or issuer does not have "sufficient information" the statute permits them to use a database to calculate the QPA as long as the database does not have conflicts of interest and has sufficient information for the relevant services in the geographic area. The IFC establishes the following standards for those databases. State all-payer claims databases are permitted to be used. Other third-party databases may be used if: (1) the database or the organization maintaining the database 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, any such entity. Examples of this condition are provided. A controlled group is described as a group of two or more persons who are treated as a single employer under the Internal Revenue Code. (2) The database has sufficient information. The Departments do not

further define this condition in order to provide flexibility **but seek comment on how to define when a database has sufficient information**. (3) The database provides sufficient information to distinguish commercial payment rates versus payments by public payers.

If the conditions are met, the QPA would be calculated following the same methodology as applicable to a plan or issuer's own rate information.

When a plan or issuer uses an eligible database for calculating the median contracted rate for an item or service, it must rely on that database through the last day of the calendar year. This consistency requirement ensures that a plan or issuer is not changing the database to manipulate the QPA. **The Departments seek comment on whether additional regulations or guidance are needed to ensure compliance and prevent abuse.**

New Plans and Coverage. The statute also requires a methodology for calculating the QPA for the first time when a plan or issuer did not offer any coverage in a geographic region in 2019. Under the IFC, if the plan or issuer has provider contracts for 2019 under other existing coverage that provides sufficient information, they must use that information to calculate the QPA and do not need to use the special methodology described below. If the plan or issuer had no provider contracts for 2019 that offer sufficient information, they would use the rules applicable to those without sufficient information – including the use of eligible databases.

For each subsequent year, the QPA calculated for 2019 will be increased by the CPI-U as described above. They would not switch to their own data; however, the **Departments seek comment on whether they should permit new plans and coverage to transition to calculating a QPA based on data from a first sufficient information year.**

New Service Codes. When new service codes are created or substantially revised after 2019, the IFC requires plans or issuers to calculate median contracted rates using a reasonably related service code. They would calculate a "relativity ratio" which is the ratio of the rate that the plan or issuer reimburses for the new item or service compared to the reasonably related item or service. The ratio would be applied to the QPA for the item or services billed under the related service code. Where Medicare has established a payment rate for the new service code, the Medicare payment rates may be used to approximate the relative cost of the two different but reasonably related services codes.

Once a plan or issuer has sufficient information to calculate a QPA for a new service code, it would switch to using that data.

The Departments seek information on alternate approaches for determining the QPA for new service codes, or whether additional guidance is needed for applying the methodology described in the IFC.

(e) Information to be Shared about the QPA. The No Surprises Act requires the Departments to specify the information about the QPA that a plan or issuer must share with a nonparticipating provider or emergency facility. Providers, emergency facilities, and air ambulance providers will need the information on the QPA to inform the negotiation process, and IDR entities will need the information because they are required to consider the QPA in selecting the offers submitted by the impacted parties.

The IFC establishes that the following information must be provided by a plan or issuer in writing or electronically to a nonparticipating provider, emergency facility, or provider of air ambulance services, as applicable, when the QPA serves as the recognized amount:

- The QPA for each item or service involved;
- A statement certifying that the QPA applies for purposes of the recognized amount and each QPA was determined in compliance with the methodology described in the IFC; and
- A statement that if the provider or facility wishes to initiate a 30-day open negotiation period, they may do so and if at the end of the period there is no agreement, the IDR process may be initiated within 4 days of the end of the open negotiation period.

In addition, at the request of the provider or facility, a plan or issuer must provide, in a timely manner, information about the calculation of the QPA and a statement, if applicable, that the contracted rates include risk sharing, bonus, or other incentive-based payments that were excluded for the purpose of calculating the QPA. **The Departments seek comment on what additional information a plan or issuer should be required to share with a provider or facility about the QPA, and 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 Department describe each of their existing jurisdictions for enforcement of federal requirements on health coverage through insurance, under employment-based plans, non-federal government plans, FEHB program, and church plans – including where states have jurisdiction but fail to substantially enforce a requirement of insurance issuers. They note that they will use existing processes to ensure compliance under the No Surprises Act.

The Departments seek comment on whether there are considerations that are not sufficiently accounted for with respect to calculating the median contracted rate; the impact of the methodology on cost sharing, payment amounts, and provider networks; whether additional rulemaking or guidance is needed; and the impact of large consolidated systems on contracted rates and the QPA.

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

Under the No Surprises Act, where there is no specified state law or All-Payer Model Agreement, the out-of-network rate is determined either through agreement between a provider or facility and a plan or issuer or through the IDR process.

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

Under the IFC, there are several procedural requirements to ensure a timely dispute resolution. Plans or issuers must send an initial notice of denial of payment or initial payment no later than 30 calendar days after a nonparticipating provider or facility submits a bill for the protected services. The Departments interpret this timeline as beginning when a nonparticipating provider or facility submits a clean claim. The Departments encourage providers and facilities to include on the claims whether the surprise billing protections apply. **The Departments seek recommendations on how HIPAA standard transactions to submit claims could be modified to accommodate the submission of information on whether the surprise billing protections apply, whether the item or service was furnished at a participating facility and whether the requirements for notice and consent were met. They also solicit comment on any additional standards that are necessary to prevent abusive claims payment practices.**

The 30-day timeline does not apply with respect to post-stabilization services and out-of-network nonemergency services where the provider or facility provided notice and received consent from the enrollee for the out-of-network services. The Departments emphasize the importance for providers to meet their timelines (described further below) for informing plans or issuers about whether notice and consent requirements were met.

The Departments discuss the statutory requirement that plans and issuers make an "initial payment" (or notice of denial) no later than 30 calendar days after the bill for such services is transmitted by such provider. They interpret an initial payment to be the intended payment in full prior to the start of an open negotiation period rather than some type of payment installment. The IFC does not establish minimum standards for this amount but notes that some state laws do. **They seek comment on whether a minimum payment amount, rate or payment methodology for the initial payment should be established in future rulemaking.**

The Departments summarize timelines in long-established regulations that are applicable to benefits determinations and appeals and note that the timelines for processes under the No Surprises Act do not necessarily align with the timelines with respect to benefits determinations and appeals. There is however, significant distinction between the process for determinations and appeals and the processes that apply when an initial payment is less than the billed amount for a claim related to items and services protected by the No Surprises Act. They provide the following to clarify when claims disputes would be resolved through the open negotiation and IDR processes: (1) when the adjudication of a claim results in a decision that does not affect the amount the 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 enrollee.

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

The No Surprises Act requires, and the IFC establishes, a process for the Departments to receive complaints regarding violations of the QPA requirements by plans and issuers. The IFC extends the process beyond QPA requirements to all of the consumer protections and balance billing requirements of the No Surprises Act. In addition, the statute directs HHS to establish a process to receive consumer complaints regarding violations of the Act by providers, facilities, and providers of air ambulance services. That process is described further below.

Under the IFC complaint process, a complaint is defined as a written or oral communication claiming a potential violation by a plan or issuer, or by a provider, facility, or provider of air ambulance services. The complaint must include a statement with information about the potential violation sufficient to identify the parties involved and the action or inaction that is the subject of the complaint. It may include information about timing and the state where the violation occurred. **The Departments decline to establish a timeline for filing a complaint but seek comment on whether such time period should be established and how long the period should be.**

With respect to the HHS complaint process, the statute directs HHS to respond to complaints related to balance billing 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 and establishes in the IFC that the Departments will respond to complainants no later than 60 business days after the complaint is received. HHS will respond to a complaint regarding a health care provider, facility, or provider of air ambulance services no later than 60 business days after the complaint is received.

The oral or written response will acknowledge receipt, notify the complainant of their rights and obligations, and describe the next steps of the process. The Departments may request additional information including an explanation of benefits, processed claims, information about the health care provider, facility, or air ambulance service provider involved; information about the plan or issuer covering the individual; information about whether the service was an emergency or non-emergency service; the summary plan description, policy, certificate, contract of insurance; or any other information the Departments may need to make a determination of facts for an investigation. HHS may require similar information to process complaints regarding health care providers, facilities, or providers of air ambulance services.

Next steps in the complaint process may include referring the complainant to another state or federal resolution process or regulatory authority with jurisdiction, or initiating an investigation.

In order to provide a seamless experience for the filing of complaints, the Departments will create a single system to intake all complaints related to the No Surprises Act. They intend to release additional guidance and **seek feedback on ways to ensure customers are aware of and know how to access the system. Comments are also sought on barriers to the complaint**

process that might be experienced by individuals in underserved, minority, or rural areas or by those impacted by poverty or inequities.

C. Choice of Health Care Professionals

Under the Public Health Service Act, individuals must be ensured choice of a health care professional under certain circumstances. If a plan or issuer requires or provides for designation of a 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.

The No Surprises Act extends these protections to apply to a grandfathered health plan in addition to non-grandfathered plans offered in the group or individual health insurance markets as under prior law. Under the IFC, the rules are applied to grandfathered plans, "grandmothered" plans, and to FEHB plans.[4]

Because the rules are substantively the same as under prior law, substantive changes beyond those impacting applicability were not needed, although the IFC makes minor technical edits to the original provisions for clarity.

D. Applicability

The IFC generally applies to group health plans and health insurance issuers offering group or individual health insurance coverage with respect to plan years (in the individual market, policy years) beginning on or after January 1, 2022. The term "group health plan" includes both insured and self-insured group health plans including those subject to ERISA, non-federal governmental plans (such as plans sponsored by states and local governments) subject to the PHSA, and church plans subject to the Internal Revenue Code. Individual health insurance coverage includes coverage offered in the individual market, through or outside of an Exchange, and includes student health insurance. FEHB carriers are also required to comply.

The rules do not apply to health reimbursement arrangements or other account-based plans, coverage consisting solely of excepted benefits, short-term limited duration insurance, or retiree-only plans.

The rules apply to traditional indemnity plans that do not have networks of providers or facilities although the Departments acknowledge that some of the provisions will not be relevant for coverage that does not use networks. **They seek comment as to whether there are other plan types with unique benefit designs should be exempt from some or all of the IFC rules.**

[4] The term "grandmothered" plans refers to certain non-grandfathered health insurance coverage in the individual and small groups markets with respect to which CMS has announced it will not take enforcement action with respect to certain market requirements and patient protections. See 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.

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

A. Preventing Surprise Medical Bills, In General

The No Surprises Act added provisions applying balance billing prohibitions to health care providers and facilities that are parallel to the requirements of group health plans and health insurance issuers. New Part E of Title XXVII of the PHSA prohibits nonparticipating providers, facilities, and providers of air ambulance services from billing or holding liable individuals for an amount that exceeds in-network cost sharing 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.

With respect to post-stabilization services provided by nonparticipating emergency facilities or providers and non-emergency services furnished by nonparticipating providers at participating facilities, the prohibitions on balance billing do not apply if notice is provided and consent to waive those protections is obtained.

Nonparticipating providers must take steps to determine whether a given item or service is subject to the balance billing provisions and to communicate with plans and issuers when the limitations do not apply because notice has been provided and consent received. HHS is able to impose civil money penalties on facilities and providers that violate the balance billing prohibitions and requirements.

HHS notes that nonparticipating providers and nonparticipating emergency facilities may need to refrain from billing an individual directly, even in cases that are not subject to these requirements if, for example, the provider does 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. However, HHS will, consistent with the statute, waive the application of penalties where a provider, facility, or air ambulance provider does not knowingly violate the provisions and, within 30 days of such violation, withdraws the bill.

B. Notice and Consent Exception to Prohibition on Balance Billing

Under the No Surprises Act, if an individual is provided notice and gives consent for the out-of-network non-emergency and post-stabilization services, the limitations on cost sharing and prohibitions on balance billing do not apply. HHS establishes the requirements related to the notice and consent exception at 45 CFR 149.410 (describing the requirements for post-stabilization services) and §149.420 (describing the requirements for non-emergency services).

HHS notes that it sought to strike a balance between permitting a provider to refuse to treat an individual who will not accept their charges and ensuring the individual is not being pressured

into waiving their protections. Further, HHS states that it is important to not create a barrier for individuals to obtain out-of-network care when they have knowingly sought it out.

1. Standards for Notice

Written notice must be provided and be in enough detail to ensure that individuals knowingly accept the provider's out-of-network charges. HHS will provide in guidance a standard notice document that will contain the elements required by statute. Providers and facilities will need to tailor the document to each individual case by identifying the provider or facility and adding their good faith estimated cost for the item or service.

The notice must be provided with the notice and consent documents separate from other documents, within required timeframes, and they must meet language access requirements. An individual may choose to receive them electronically and a participating health facility may provide the information on behalf of a nonparticipating provider.

Authorized Representatives. The notice may be provided to an individual's authorized representative who is described as an individual authorized under state law to provide consent on behalf of the enrollee. The authorized representative may not be a provider affiliated with the facility or an employee of the facility unless they are a family member. **HHS seeks comment on how to define "family member" for this purpose.**

Timing of Notice. The No Surprises Act and the IFC specify that:

- If an individual schedules an appointment for items or services protected under the No Surprises Act 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, the IFC adds 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 addresses concerns that an individual provided notice immediately before a procedure may feel compelled to consent to receive care. **HHS seeks comment on this approach, whether the time period should be longer or shorter, and whether the requirements could impede access to urgently needed care.** HHS notes, however, that to the extent a provider is concerned that the 3 hours' prior requirement will result in a delay in care that would be 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.

Content of Notice. The notice must state that the provider or facility is a nonparticipating provider or facility. It must also include a good faith estimate of the amount that a nonparticipating provider or facility may charge for the needed items or services including those

items reasonably expected to be provided by the nonparticipating facility or nonparticipating providers as part of the visit. HHS notes that individuals cannot waive balance billing protections for unforeseen, urgent medical needs that arise.

Good faith estimates need not include items or services furnished by other providers at the facility.

Multiple nonparticipating providers may provide a single notice so long as: (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 aware that nonparticipating providers and nonparticipating emergency facilities generally will not be able to calculate an individual's final out-of-pocket costs under an individual's plan or coverage and therefore the IFC requires a good faith estimate that reflects the amount the provider or facility expects to charge for the items or services, even if the provider or facility intends to bill the plan or coverage directly.

The notice must also indicate whether prior authorization or other medical management limitations may apply. Again, HHS recognizes that nonparticipating providers or facilities are not likely to have this information about a specific plan with which they do have a contract. Therefore, a general statement would satisfy this requirement. **HHS seeks comment on whether more specific information should be required and the barriers or burdens that would be involved.**

The notice must state clearly that the individual is not required to consent to receiving care from the nonparticipating provider or emergency facility, must include a list of any participating providers at the participating emergency facility who are able to furnish the items or services, and state that they may be referred to such providers.

Standards for Consent. Consent must be provided voluntarily and must be made using the standard consent document that HHS specifies in guidance. It must be signed by the individual (or their representative) giving consent, and they must be given a copy of the signed notice and consent documents either in person, by mail or email as selected by the individual.

Notice and consent documents must meet applicable language access requirements and state that by signing the consent document, the individual agrees to be treated by a nonparticipating provider or emergency facility and that they may be subject to balance billing and to cost-sharing requirements applicable to out-of-network services.

By signing the consent forms, the individual is not waiving surprise billing protections for other items or services provided by providers or facilities that are not named on the consent form.

The consent documents must include the date the notice was received, the date when the individual signed, and the time when the individual signed. Consent may be revoked by notifying the provider or facility in writing prior to the furnishing of items or services.

Language Access. Under the statute and the IFC, the notice must be made available in any of the 15 most common languages in the geographic region. The geographic region under the IFC is the state; however, the provider or facility may choose to provide the notice in the 15 most common languages in its geographic region. If the individuals' preferred language is not among the most common 15 languages, consent cannot be provided unless the provider or facility furnishes the individual with a qualified interpreter. **HHS seeks comments on the use of metropolitan statistical areas, hospital service areas, hospital referral regions and public use microdata areas, as well as other standards that could be used 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.**

HHS reminds readers that providers and facilities are required to comply with other applicable state and federal laws regarding language access and that recipients of federal financial assistance must comply with federal civil rights laws that prohibit discrimination including section 1557 of the ACA, title VI of the Civil Rights Act of 1964, section 504 of the Rehabilitation Act of 1973, and the Americans with Disabilities Act of 1990.

HHS seeks comments on how best to balance between making documents user friendly while ensuring they are consistent with federal rules; how to support individuals with low health literacy; and how to make sure documents are understandable and accurate.

2. Exceptions to the Availability of Notice and Consent

Under certain circumstances, notice and consent exceptions to the No Surprises Act requirements are not available:

- Except for post-stabilization services, notice and consent exceptions may never apply to emergency services.
- With respect to non-emergency services, notice and consent exceptions are not available for ancillary services which include items and services related to emergency medicine, anesthesiology, pathology, radiology, and neonatology; 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, when there is no participating provider who can furnish the item or service at the facility.
- As noted above, the notice and consent exceptions may not apply to items or services furnished as a result of unforeseen, urgent medical needs that arise when being treated by a nonparticipating provider even when they have satisfied the notice and consent criteria.
- In the IFC, HHS extends this last rule to apply to unforeseen, urgent medical needs that arise during post-stabilization services. Under those circumstances, the notice and consent exception is not available even when the criteria had been met for the post-stabilization services.

The statute permits HHS to expand the definition of ancillary services and seeks comment on whether additional services should be made ineligible for the notice and comment exception – in particular services for which individuals have little control over the provider furnishing the services; the types of services for which surprise bills are most common; and the criteria HHS should use for adding to the list of services ineligible for the notice and consent exception.

3. Retention of Documents

The IFC, consistent with statutory requirements, requires nonparticipating emergency facilities, participating health care facilities, and nonparticipating providers to retain written notice and consent documents for at least 7 years after the date that the item or service was furnished.

4. Requirements to Notify the Plan or Issuer

The No Surprises Act and the IFC require nonparticipating providers and facilities to notify the plan or issuer as to whether balance billing and in-network cost sharing protections apply. If notice and consent has been provided, the nonparticipating provider or facility must provide to the plan or issuer a copy of the signed notice and consent documents.

- With respect to non-emergency services, 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. In instances where the nonparticipating provider bills the enrollee directly (where permitted), 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.
- 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 for notice and consent are met with respect to each of the items and services for which the bill is submitted.

HHS seeks comment on whether additional rulemaking is necessary to ensure timely notification of plans and issuers; whether timely should be defined; what processes would be most efficient; and the barriers or burdens for providers or facilities to provide copies of the signed written notice and consent document.

C. Provider and Facility Disclosure Requirements

The No Surprises Act and the IFC require health care providers and facilities to make publicly available, post on a public website, and provide to enrollees a notice about the balance billing requirements (in 45 CFR 149.430) and how to contact state or federal agencies in the case of a potential violation. HHS has issued a model disclosure notice that providers and facilities may use but are not required to do so.[5]

[55] CMS-10780 | CMS

HHS notes that the disclosure requirements do not apply to providers of air ambulance services. HHS, however, encourages those providers to make clear and understandable information about the requirements and prohibitions on balance billing for air ambulance services.

Content of Disclosures. Disclosures must include a clear and understandable statement that:

- Explains the requirements and prohibitions related to prohibitions on balance billing;
- Describes any applicable state law requirements regarding the amounts a provider or facility may charge an enrollee and any applicable cost sharing. HHS encourages states to develop model language to assist providers and facilities to fulfil this requirement; and
- Provides contact information for appropriate state and federal agencies in the event of a potential violation.

HHS encourages providers and facilities to use plain language for the notices and to consider user testing. In addition, the notices must comply with applicable federal civil rights laws, including to provide meaningful access for individuals with limited English proficiency and to communicate with individuals with disabilities.

Methods of Disclosure. To satisfy the requirement to post the disclosure on a public website, the disclosure or link to the disclosure must be searchable on the provider or facility's public website. The website must be accessible free of charge and without passwords or other credentials and without having to submit personal identifying information. A provider or facility without their own website is not required to make the disclosure available on a public website.

Providers and facilities must display the required disclosure on a sign posted prominently at the location of the provider or facility. Disclosures for individuals who are enrollees of a health plan offered by a health insurance issuer must be only one page, in font no smaller than 12-point, and may be provided through mail or email as selected by the enrollee.

*Timing of Disclosure to Individuals***.** The IFC requires a provider or facility to provide the notice to 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). 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 notes that providers and facilities have the flexibility to provide the notice earlier than those timelines.

HHS seeks comment on the timing requirement. It had considered requiring annual disclosures or only requiring disclosures when a patient schedules a service, but rejected those timelines to ensure the disclosure was provided at the point that the individual could potentially experience a violation of the No Surprises Act.

Exceptions. The IFC provides for two exceptions to the general requirements to provide disclosures:

- Health care providers are not required to make the disclosures if they do not furnish items or services at a health care facility, or in connection with visits at health facilities.

- 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 disclosure is required only to individuals who are enrollees of a group health plan or group or individual health insurance coverage offered by a health insurance issuer. The requirement applies to enrollees of a FEHB plan, as well.

Special Rule to Prevent Unnecessary Duplication. HHS notes that it could cause confusion for an enrollee to receive two disclosure notices – one from a provider and another from a facility. To streamline the requirement, reduce burden on providers, and reduce confusion among enrollees, the IFC permits a provider to be considered to have satisfied the disclosure requirement if the facility provides the disclosure pursuant to a written agreement between the two. The provider and facility's contract could meet the "written agreement" requirement. Providers and facilities would continue to each independently be required to make the required disclosure available on a public website.

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

The No Surprises Act directs HHS to establish a process for receiving consumer complaints from health care providers and facilities and to respond to such complaints within 60 days. The IFC establishes this HHS-only complaint process, which is parallel to the process described earlier for the Departments' complaint process for plans and issuers.

E. Catastrophic Plans

As noted above, because a catastrophic plan may be required under the No Surprises Act to make a payment to a provider or facility prior to the enrollee meeting the annual limitation on cost sharing, it would not satisfy the definition of a catastrophic plan under section 1302(e) of the ACA. In response, the IFC amends 45 CFR 156.155 to specify that a catastrophic plan must provide benefits that meet the requirements of the No Surprises Act and in doing so will not fail to be treated as a catastrophic plan.

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

A. Conforming Changes to the Federal Employees Health Benefits Program

The No Surprises Act added a new section 8902(p) of title 5, United States Code (relating to the Federal Employees Health Benefits Program (FEHB Program)) to 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. A new section 890.114 is added to subpart A of title 5, Code of Federal Regulations, to implement the law with respect to the FEHB Program.

OPM notes that the Departments' IFC generally applies to FEHB carriers' compliance with the No Surprises Act except where differences may be required for clarification or application to the FEHB Program. All FEHB carriers offer fully-insured health benefits plans subject to contract terms with the federal government; no health benefits plan is self-insured by OPM or the federal government. **OPM seeks comment on whether there should be any additional considerations in the application of the IFC in the context of the FEHB Program.**

B. Preemption and OPM Enforcement

Section 8902(m) of title 5, United States Code (U.S.C.) dictates that FEHB contract terms preempt state law with respect to coverage or benefits (and payment of benefits) which renders state law inapplicable for determining recognized amounts and out-of-network rates under 26 CFR part 54, 29 CFR part 2590, and 45 CFR part 149. However, OPM and carriers may agree to a FEHB contract term that applies state law to determine the total amount payable. Thus, the FEHB contract term would govern the methodology for determining recognized amounts and out-of-network rates. In the absence of such a contract term, the lesser of the billed amount or the QPA will serve as the recognized amount under the FEHB plan.

OPM authorities under 5 U.S.C. 8901 et seq and implementing regulations will govern enforcement of the IFC with respect to FEHB carriers.

C. Definitions

Generally, the defined terms under the IFC align with OPM's enforcement of section 8902(p) of title 5, U.S.C. However, for purposes of FEHB Program enforcement, the terms "health benefits plan," "carrier," and "enrollee or covered individual" will be used in lieu of the terms "group health plan or plan," "health insurance issuer or issuer," and "participant, beneficiary, or enrollee" respectively.

D. Complaints

When a complaint challenges a FEHB carrier's action or inaction with respect to the surprise billing provisions, OPM will coordinate with the Departments to resolve the complaint. OPM notes that this coordination will include ensuring that complaints appropriate for OPM resolution under the FEHB statute, regulations or contractual authorities are in fact referred to OPM.

E. Jurisdiction of Courts

Section 8912 of title 5, U.S.C. provides that the federal district courts have original jurisdiction, concurrent with the United States Court of Federal Claims, over civil actions or claims against the United States under the FEHB Program. The No Surprises Act included a requirement that a suit for equitable relief under new section 8902(p) of title 5, U.S.C. must be brought against OPM by December 31st of the third year after the year in which the disputed services were rendered. **OPM seeks comment on amendments to its court review regulations.**

F. Applicability

OPM will not apply the IFC to health benefits plans that are retiree-only plans.

It seeks comments on the appropriate manner in which to apply—

1) **The provisions of the No Surprises Act[6] relating to preventing surprise medical bills, preventing surprise air ambulance bills, and ensuring the choice of health care professionals to FEHB carriers; and**
2) **Requirements of the IFC on health care providers, facilities, and providers of air ambulance services (including under sections 2799B–1, 2799B–2, 2799B–3, and 2799B–5 of the PHS Act) with respect to covered individuals in a FEHB plan.**

V. Waiver of Proposed Rulemaking

Provisions of the No Surprises Act authorized the Secretaries to promulgate interim final rules as necessary or appropriate. Additionally, section 553(b) of the Administrative Procedures Act (5 U.S.C. 553(b)) authorizes an agency to waive traditional advance notice and comment rulemaking procedures if the agency finds good cause that notice and comment rulemaking procedures are impracticable, unnecessary, or contrary to the public interest and incorporates a statement of its finding and its reasons in the rule issued.

The Secretaries and the Director of OPM have determined that it would be impractical and contrary to the public interest to delay putting the provisions in the IFC in place until after a full notice and comment process has been completed. The following rationale are included in the interim final rule:

- There is a short period of time between enactment of the law (December 27, 2020) and the application of its requirements on affected parties (plan years beginning on or after January 1, 2022).
- The law and regulations require plans and issuers to make significant changes in the manner that they pay for items and services subject to cost-sharing and balance billing protections, including claims processing changes.
- Plans and issuers must account for these changes in setting premium or contribution rates; interim final rules permit them to take into account finalized regulations in determining rates and plan offerings.
- Health care facilities and providers, as well as air ambulance providers, must implement the requirements relating to authorized balanced billing for items and services, including notice and consent procedures and requirements for public disclosure of policies.
- Critical protections for participants, beneficiaries and enrollees against balance billing must not be delayed beyond the effective date stated in the No Surprises Act.

[6] See 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.

- States require time to assess the enforcement requirements established under the Act; those states that opt to enforce the requirements may have to update their statutes or regulations.
- The No Surprises Act required the Secretaries to issue rulemaking by July 1, 2021 with respect to the QPA methodology as well as related issues; completion of full advance notice and comment rulemaking by that date would not have been feasible.

VI. Economic Impact and Paperwork Burden

The Departments and OPM have examined the effects of the IFC pursuant to Executive Order 13563, Executive Order 12866, the Regulatory Flexibility Act and other authorities. They have determined that the IFC is "economically significant" within the meaning of Executive Order 12866 because they are likely to have economic impacts of $100 million or more in any one year. Accordingly, the Departments provide an assessment of the potential costs, benefits, and transfers associated with these rules, and they note that they are unable to quantify all of the benefits and costs. **Comments are invited on the estimates and non-quantified impacts.**

Table 1 (Accounting Statement) summarizes the non-quantified and quantitative impacts and estimated direct monetary costs and transfers that would result from the IFC.

The Departments estimate that plans, issuers, health care providers, facilities, and providers of air ambulance services will incur significant costs to comply with the requirements of the IFC.

A. Costs

Plans and Issuers

Plans and issuers will incur significant costs to calculate the recognized amount and applicable cost-sharing amount; for self-insured group health plans, the Departments assume the costs will be incurred by third party administrators (TPAs). One-time costs of roughly $4,958 million (approximately $2.8 million on average for each of the 1,758 plans or TPAs) are estimated to make the necessary information technology system changes in 2021; aggregate estimated ongoing operational costs are $2,047 million in 2022 and $724 million annually from 2023 onwards. Additional one-time costs in 2021 related to revising standard operating procedures and training of staff are estimated to be $12.1 million. Starting in 2022, the Departments estimate annual costs of $55.4 million to issuers and TPAs to share information related to QPA.

The Departments estimate the following aggregate costs to plans and issuers to provide disclosures on patient protections to participants, beneficiaries and enrollees: initial one-time costs of approximately $699,245 in 2021 to review the model notice, and modify it as needed, and starting in 2022 annual costs of roughly $23.4 million to provide disclosures. Self-insured plans opting in to state law to include disclosures in plan documents are estimated to incur 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 are estimated at $4.5 million in 2022.

Health Care Providers

Health care facilities and emergency facilities are estimated in the aggregate to incur one-time costs of $117.2 million in 2021 to revise standard operating procedures and provide training to staff, and providers of air ambulance services will incur one-time costs of $517,086 in 2021 for those purposes.

It is estimated that nonparticipating providers and nonparticipating emergency facilities will incur one-time costs of approximately $22.6 million in 2021 and ongoing costs of $117.2 million annually starting in 2022 to comply with requirements related to notice and consent, recordkeeping, and notice to plans and issuers.

Costs to health care providers and facilities to provide disclosures on patient protections against balance billing are estimated to be one-time costs of approximately $6.8 million in 2021 and $2.5 million annually starting in 2022, and costs to health care facilities to enter into agreements for the facilities to provide the disclosure on patient protection on behalf of the providers are estimated to be one-time costs of approximately $6.4 million in 2021.

The Departments estimate costs to individuals and providers to submit complaints related to surprise bills of approximately $97,452 annually starting in 2022.

Individuals

Starting in 2022, the annual cost to individuals to read and understand notices from nonparticipating providers and nonparticipating emergency facilities is estimated to be approximately $99.1 million. As noted above, the estimated costs to individuals and providers to submit complaints related to surprise bills are approximately $97,452 annually starting in 2022.

Federal and State Government

The federal government will incur costs to establish and operate a complaint system, and to expand existing systems, of roughly $19 million in 2021. It is estimated to incur ongoing costs to process complaints of roughly $1.6 million in 2021, $9.9 million in 2022, $10.1 million in 2023 and $10.3 million in 2024 and subsequent years.

States that develop state-specific language for patient disclosures to be provided by health care providers and facilities would incur in the aggregate one-time costs of approximately $10,732 in 2021.

B. Benefits

The No Surprises Act and the IFC 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 not be permitted

balance bill an individual for emergency services, and they may only balance bill 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, all relevant civil rights protections will be upheld and communication with consumers will be accessible, in a language that is understandable, and at an appropriate literacy level; this will help to effectively confer these protections to minority and underserved communities. The protection for the amount of cost-sharing that may be charged, and the counting of cost-sharing paid toward any in-network deductible or in network out-of-pocket maximum, will also benefit participants, beneficiaries, or enrollees.

The Departments also note that these consumer protections will reduce financial anxiety, including anxiety associated with medical debt, for individuals with health coverage, due to a reduction in surprise bills. It is also believed that access to care will be increased for individuals with health coverage that may have otherwise forgone or neglected needed treatment due to high out-of-pocket expenses, and there may be better health outcomes as a result. The Departments also see the potential for 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.

C. Transfers

Because the IFC will result in lower out-of-pocket spending by individuals, plans and issuers will now have to pay for some expenses for items and services provided by nonparticipating facilities and providers (including air ambulance providers). The Departments believe that these situations will result in transfers from plans and issuers to individuals. There is also the potential for the 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.

As noted previously, the IFC is the first of several rules necessary to implement the No Surprises Act as well as the transparency provisions of title II of Division BB of the CAA. Additional regulations, including those to implement the federal IDR process, will have an effect on the economic impact, including the impact on premiums. A more detailed impact statement will be provided in future rulemaking which will include information on the following:

- 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 the IFC.

D. Alternatives Considered

The Departments considered alternative approaches for a number of policies under the IFC, including the following.

Methodology for Calculating the QPA

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; however, it was determined that this approach would not result in a pure median of contracted rates. There is also the concern that this might put upward pressure on the QPA by giving greater weight to contracts of larger provider groups and facilities.

Another policy considered was to require plans and issuers to calculate separate median contracted rates for facilities based on the characteristics of facilities (e.g., 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 declined to take this approach fearing that it would result in higher median contracted rates for facilities with higher operating costs that is not contemplated in the definition of QPA in the No Surprises Act. However, because payment amounts for facility charges may vary depending on whether an emergency facility is connected with a hospital, the final policy permits 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.

The Departments considered but declined to use rating areas to define geographic regions because a plan or issuer would have to calculate separate median contracted rates for a large number of geographic regions and because there may be a large number of geographic regions without sufficient information and large numbers of geographic regions in which the median contracted rate is influenced by outliers.

Definition of Health Care Facility. The Departments considered whether to expand the definition of health care facility (for example by including urgent care centers) but declined to do so because they believe that the facilities at which balance billing is currently most frequent are included in the current definition. It was also considered whether to exclude facilities that had only single case agreements in place with a plan or issuer; however, this alternative was rejected due to concerns about harm to participants, beneficiaries or enrollees.

Applicability of State Law. 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; they interpret the No Surprises Act as creating a floor regarding individuals' ability to waive balance billing protections. It was 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; they conclude that such deference to state law is consistent with the No Surprises Act.

Notice and Consent Exception to Prohibition on Balance Billing. The Departments considered 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. These are viewed as critical factors in determining whether an individual can provide informed consent. With respect to language access requirements, while the IFC uses the state as a geographic region, other regions were considered such as MSAs, hospital service areas (HSAs), hospital referral regions (HRRs), and public use microdata areas (PUMAs), applied based on where the applicable facility is located. HHS believes use of the state would reduce provider and facility burden and provide flexibility with respect to facilities that serve populations that cross state borders.

Provider Disclosure Requirements Regarding Patient Protections against Balance Billing. The IFC limits the disclosure requirement under section 2799B-3 of the PHS Act to certain providers and facilities, and with respect to certain individuals, and they 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. While HHS considered broadening the scope of the disclosure requirement, it believes that it would significantly increase administrative burden and cost on providers and could under certain circumstances cause consumer confusion.

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

HHS solicits public comment on its collection of information before its submission to OMB for review and approval, including the need for the information collection, the accuracy of its estimates, the quality of information collected, and recommendations to minimize the collection burden. Table 15 of the IFC provides a summary of the annual burden estimates for information collection requirements.

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

HHS estimates that the total annual burden for all issuers and TPAs for providing the initial and additional information related to QPAs will be 1,478,316 hours, with an equivalent cost of $55,436,853. The assumption is that issuers and TPAs will need to calculate the QPA for two-thirds of claims involving nonparticipating providers or nonparticipating emergency facilities. Using 2018 data for emergency department visits and 2016 data for facility visits for surgical and nonsurgical procedures for individuals with group health or individual market coverage, plans and issuers will have 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 further assume that 50 percent of those claims will result in requests to provide additional information.

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. DOL and the Treasury Department will each account for 25 percent of the burden or 369,579 burden hours with an equivalent cost of approximately $13,859,214.

The Departments seek comment on these burden estimates.

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

Because the Departments' existing enforcement procedures will apply with respect to audit requirements, this collection is exempt from the PRA.

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

HHS estimates that roughly 84 self-insured non-federal governmental plans in New Jersey, Nevada, Virginia and Washington will opt-in and incur the one-time burden and cost to include the disclosure in their plan documents in 2022. The estimated total annual burden for all 84 plans will be approximately 126 hours with an equivalent cost of approximately $8,783. The estimated cost to deliver printed disclosures to two-thirds of the estimated 11,956 policyholders is approximately $197. The total one-time cost for all plans, incurred in 2022, is estimated to be approximately $8,981.

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

HHS estimates that, on average, there will be 3,600 balance billing complaints against providers, facilities, providers of air ambulance services, plans, and issuers submitted annually. The total burden on complainants is estimated to be 1,800 hours, with an equivalent annual cost of approximately $97,452. As the Departments share jurisdiction, HHS will account for 50 percent of the burden, approximately 900 burden hours with an equivalent cost of approximately $48,726. DOL and the Treasury Department will each account for 25 percent of the burden or 450 burden hours with an equivalent cost of approximately $24,363.

5. ICRs Regarding Notice of Right to Designate a Primary Care Provider (45 CFR 149.310(a)(4))

To satisfy the patient protection disclosure requirement, state and local government plans and issuers in the individual market must notify policy holders of their plans' policy in regards to designating a primary care physician and for obstetrical or gynecological visits; there will be a one-time burden and cost to incorporate the notice in plan documents. HHS estimates that in 2022, 5,450 grandfathered non-federal governmental plans and individual market policies must comply with this notice requirement; however, the estimate is considered an overestimate of the number of affected entities because 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. 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. The estimated cost to deliver printed notices in 2022 to roughly two-thirds of the

estimated policyholders is approximately $15,461. To account for this burden, HHS will revise the burden currently approved under OMB Control Number 0938-1094.

6. 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))

HHS assumes that of 17,647 health care facilities and emergency departments, 16,992 will incur burden to develop the notice and consent documents. HHS also assumes that the facilities will provide the notice and receive consent on behalf of nonparticipating providers, as well as retain records and notify plans. The total one-time first-year burden to develop and translate those documents is estimated at roughly $22.6 million.

Starting in 2022, for all emergency and health care facilities, the total annual, ongoing burden related to the notice and consent, recordkeeping, and notification to plans will be 3,104,001 hours and the total cost, including printing and materials, will be approximately $117 million. For individuals receiving the notice, there is an estimated annual burden of approximately $99 million starting in 2022.

7. ICRs Regarding Provider Disclosure on Patient Protections Against Balance Billing (45 CFR 149.430)

Providers and facilities will incur costs for the public disclosure of patient protections against balance billing as well as providing individuals with that information in a one-page notice. HHS assumes that facilities will 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. Legal review of the language by both parties will result in aggregate estimated costs for the 17,647 facilities in 2021 of roughly $6.3 million. The costs for compliance with the requirement for the same number of facilities are estimated at roughly $6.7 million in 2021 and $2.5 million in 2022 and 2023 for a 3-year average of approximately $3.9 million. HHS notes that costs will vary among facilities due to the actual number of visits and the costs incurred in providing the disclosures.

For states that elect to develop language to assist providers and facilities in meeting this disclosure requirement, HHS estimates that each state will incur a one-time burden of 3 hours with an equivalent cost of approximately $325.

HHS seeks comment on the costs and burdens associated with posting the required information on a public website, on the number of facilities that will be affected by these requirements, and on the number of individuals that would be required to receive the required notice.

8. ICRs Regarding Plan and Issuer Disclosure on Patient Protections Against Balance Billing

Plans and issuers must make publicly available (and publicly post on their websites) as well as include in their explanation of benefits information on patient protections against balanced billing. The Departments assume that plans and issuers will used the HHS-developed model notice and that TPAs will develop the notice for self-insured plans. The total one-time burden estimate to review the notice, and modify it as needed, is $699,245 across 1,758 issuers and TPAs; HHS accounts for 50 percent of that burden. DOL and the Treasury Department will each account for 25 percent of the burden (approximately $349,622). The Departments assume that the disclosure will be included with the explanation of benefits at no additional cost.

The total annual cost to all issuers and TPAs for sending the notices is estimated to be approximately $23,390,445 starting in 2022; again, HHS accounts for 50 percent of that burden. HHS estimates that costs for compliance with the requirement for issuers and TPAs is $349,622 in 2021 and roughly $11.7 million in 2022 and 2023 for a 3-year average of approximately $7.9 million. DOL and the Treasury Department will each account for 25 percent of the burden.

E. Paperwork Reduction Act – Department of Labor and Department of the Treasury

1. ICRs Regarding Notice of Right to Designate a Primary Care Provider (26 CFR 54.9822-1T, 29 CFR 2590.722)

DOL estimates that there are 2.5 million ERISA-covered plans, that 16 percent of firms offering health benefits offer at least one grandfathered health plan, and that five percent of plans will relinquish grandfathered status in 2021. Thus, in 2022, 161,148 grandfathered plans will be subject to the notice requirement. Because DOL is unable to estimate the number of HMO and POS options that require the designation of a primary care physician or a prior authorization or referral before an OB/GYN visit, it believes its estimates of the number of affected entities is high.

The total burden for plans to individualize the model notice and add it to the plan documents in 2022 is 40,287 hours at a cost of $4,345,075. This burden is split evenly between DOL and Treasury. Printing and material costs for the disclosures for 730,346 notices is estimated at $18,259 in 2022.

2. ICRs Regarding Opt-In State Balance Bill Process (26 CFR 54.9816-3T, 29 CFR 2590.716-3)

Plans may opt in to state law that provides 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. DOL estimates that 617 self-insured plans will opt in (20, 231, 309, and 57 self-insured plans in Nevada, Virginia, Washington, and New Jersey, respectively) and thus will incur the one-time burden and cost to include the disclosure in their plan documents in 2022. DOL estimates a total burden of 926 hours at the 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. DOL

assumes that roughly one third of plan documents will be delivered electronically; thus in 2022, the cost to deliver 66 percent of the disclosures in print is estimated to be approximately $321. DOL estimates a 3-year average hour burden of 309 hours, with an equivalent cost of $25,143.

F. Regulatory Flexibility Act

The Regulatory Flexibility Act does not apply because the IFC was not preceded by a general notice of proposed rulemaking.

G. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act does not apply because the IFC was not preceded by a general notice of proposed rulemaking.

H. Federalism

The Departments believe that Congress did not intend for the No Surprises Act to supplant state law; rather, it was intended to supplement state law. They assert that the IFC is consistent with that policy by recognizing the traditional role of states as the primary regulators of health insurance issuers, providers and facilities. For example, states enforce the new requirements on health insurance coverage and HHS only enforces in those cases where states decline to act, believe they lack the authority to enforce, or where HHS determines a state has failed to substantially enforce the requirements. The Departments believe they have balanced states' interests in regulating issuers, providers and facilities with the need to ensure minimum federal consumer protections in every state. Further, OPM concluded that it would be inappropriate for FEHB plans to adopt varying state standards, and consistent with the FEHB Act, it would adopt state laws where appropriate pursuant to bilaterally negotiated FEHB contracts.

I. Congressional Review Act

The IFC is subject to the Congressional Review Act.