



Detailed Summary of the First Interim Final Rule on Requirements Related to Surprise Billing

On Thursday, July 1, 2021, the Office of Personnel Management; Internal Revenue Service, Department of the Treasury; Employee Benefits Security Administration, Department of Labor; and Centers for Medicare & Medicaid Services, Department of Health and Human Services released the first of what is expected to be a series of [interim final rules with comment \(IFC\)](#) to implement the No Surprises Act (NSA), which was enacted as part of the Consolidated Appropriations Act, 2021. The rules are designed to protect patients covered by individual and/or group health plans from “surprise” medical bills and are effective January 1, 2022.

There is a 60 day comment period for this IFC ending on September 7th.

What is “surprise” billing?

A surprise medical bill is an unexpected bill from a health care provider or facility that occurs when a covered person receives medical services from a provider or facility that, usually unknown to the participant, beneficiary, or enrollee, is a nonparticipating provider or facility with respect to the individual’s coverage. Surprise billing occurs both for emergency and non-emergency care. For example, a patient may choose to receive care at an in-network facility, but some physicians within the patient care team (e.g. anesthesiologist or radiologist) may be out of network, resulting in the patient being surprised by receiving a bill for out of network services. The rule notes that out-of-network cost sharing and payments for surprise bills usually do not count towards an individual’s deductible and maximum out-of-pocket expenditure limits. Therefore, individuals with surprise bills may have difficulty reaching those limits, even after a significant health care event.

The rule states that “evidence suggests that the ability to balance bill is used as leverage by some providers to obtain higher in-network payments, which results in higher premiums, higher cost sharing for individuals, and increased health care expenditures overall.”¹ The rule also cites a study using claims data from a large commercial issuer for the period 2010-2016 that shows the incidence of out of network bills from in network emergency visits increased from 32.3 percent in 2010 to 42.8 percent in 2016. The average potential amount of surprise medical bills also increased from \$220 in 2010 to \$628 in 2016.² The rule does not mention insurers narrowing physician networks as a potential cause for the increase in “surprise” billing.

To ensure all consumers, particularly those in minority and underserved communities, are able to understand and benefit from the NSA protections, deliberate attention must be paid to the unique

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

² Sun EC, Mello MM, Moshfegh J, Baker LC, Assessment of Out-of-Network Billing for Privately Insured Patients Receiving Care in In-Network Hospitals. *JAMA Intern Med.* 2019; 179(11):1543–1550 (2019). doi:10.1001/jamainternmed.2019.3451.

barriers and challenges underserved communities face in understanding and accessing health care. **The Departments seek comment on the impact of this IFC rules on underserved communities.**

Section 103 of the NSA established an independent dispute resolution (IDR) process that allows plans and issuers and nonparticipating providers and nonparticipating emergency facilities to resolve disputes over out of network rates. The Department will issue regulations regarding the federal IDR process, patient protections through transparency and the patient-provider dispute resolution process, and price comparison tools later this year.

With respect to emergency services, air ambulance services furnished by nonparticipating providers, and non-emergency services furnished by nonparticipating providers at participating facilities, this IFC limits cost sharing for out-of-network services to in-network levels, require such cost sharing to count toward any in-network deductibles and out-of-pocket maximums, and prohibit balance billing. The IFC specifies that cost-sharing amounts for such services furnished by nonparticipating emergency facilities and nonparticipating providers at participating facilities must be calculated based on one of the following amounts: (1) an amount determined by an applicable All-Payer Model Agreement under section 1115A of the Social Security Act; (2) if there is no such applicable All-Payer Model Agreement, an amount determined by a specified state law; or (3) if there is no such applicable All-Payer Model Agreement or specified state law, the lesser of the billed charge or the plan's or issuer's median contracted rate, referred to as the qualifying payment amount (QPA).

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

While the NSA includes an exception allowing providers to balance bill if appropriate "notice and consent" (discussed later in this summary) is obtained, it is important to note that the notice and consent exception does not apply to ancillary services, which includes radiology.

Applicability

This 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. Group health plans include private employment-based group health plans subject to ERISA, non-federal governmental plans (such as plans sponsored by states and local governments) subject to the PHS Act, and church plans subject to the Code. Individual health insurance coverage includes coverage offered in the individual market, through or outside of an Exchange, and includes student health insurance coverage.

Preventing Surprise Medical Bills

Scope of the New Surprise Billing Protections

Emergency Services

A plan or issuer providing coverage of emergency services must do so without the individual or the health care provider having to obtain prior authorization (including when the emergency services are provided out-of-network) and without regard to whether the health care provider furnishing the emergency services is a participating provider or a participating emergency facility with respect to the services. Emergency services include: (1) an appropriate medical screening examination that is within the capability of the emergency department of a hospital or of an independent freestanding emergency department, including ancillary services routinely available to the emergency department, to evaluate whether an emergency medical condition exists; and (2) such further medical examination and treatment as may be required to stabilize the individual (regardless of the department of the hospital in which the further medical examination and treatment is furnished) within the capabilities of the staff and facilities available at the hospital or the independent freestanding emergency department. The definition of emergency services in this IFC includes pre-stabilization services that are provided after the patient is moved out of the emergency department and admitted to a hospital, and these services will be subject to the protections of the NSA.

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

The Departments are aware that some plans and issuers currently deny coverage of certain services provided in the emergency department of a hospital by determining whether an episode of care involves an emergency medical condition based solely on final diagnosis codes, such as International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) codes. In addition, some plans and issuers might automatically deny coverage based on a list of final diagnosis codes initially, without regard to the individual’s presenting symptoms or any additional review. Following an initial denial, plans and issuers might then provide for complete consideration of the claim, and apply the prudent layperson standard, only as part of an appeals process if the participant, beneficiary, or enrollee appeals. These practices are inconsistent with the emergency services requirements of the NSA and the ACA. Instead, the determination of whether the prudent layperson standard is met must be made on a case-by-case basis before an initial denial of an emergency services claim.

Post-stabilization services

Emergency services include any additional items and services that are covered under a plan or coverage and furnished by a nonparticipating provider or nonparticipating emergency facility (regardless of the department of the hospital in which such items and services are furnished) after a participant, beneficiary, or enrollee is stabilized and as part of outpatient observation or an inpatient or outpatient stay with respect to the visit in which the other emergency services are furnished. Such additional items and services (referred to in the rule as post-stabilization services) are considered emergency services and are subject to surprise billing protections unless all of the following conditions are met.

1. The attending emergency physician or treating provider must determine that the participant, beneficiary, or enrollee is able to travel using nonmedical transportation or nonemergency medical transportation to an available participating provider or facility located within a reasonable travel distance, taking into consideration the individual's medical condition. **The Departments seek comment on the definition of "reasonable travel distance" and whether specific standards or examples should be provided regarding what constitutes an unreasonable travel burden. For example, should reasonable travel distance take into account only mileage, or also other factors, such as traffic or other route conditions that might make traveling difficult, time consuming, or hazardous?**
2. The provider or facility furnishing post-stabilization services must satisfy the notice and consent criteria.
3. The individual (or the individual's authorized representative) must be in a condition to receive the information in the notice and to provide informed consent in accordance with applicable state law. Whether an individual is in a condition to receive the information in the notice is determined by the attending physician or treating provider using appropriate medical judgment.
4. The provider or facility must satisfy any additional requirements or prohibitions as may be imposed under applicable state law. This IFC includes this criterion recognizing that some state laws do not permit exceptions to state balance billing protections, such as allowing individuals to consent to waive protections.

The Departments are of the view that the post-stabilization notice and consent procedures should generally be applied in limited circumstances, where the individual knowingly and purposefully seeks care from a nonparticipating provider or facility (such as deciding to go under the care of a specific provider or facility that the individual is familiar or comfortable with), and that the process should not be permitted to circumvent the consumer protections in the NSA.

The NSA authorizes the Departments to specify other conditions that must be satisfied for post-stabilization services to be excepted from the definition of emergency services for purposes of the protections provided by the NSA. **Therefore, the Departments seek comment on whether there are any additional conditions that would be appropriate to designate under the definition of emergency services, such as conditions relating to coordinating care transitions to participating providers and facilities. The Departments also solicit comments on what guidelines, beyond state laws regarding informed consent, may be needed to**

determine when an individual is in a condition to receive the written notice and provide consent.

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

The NSA applies surprise billing protections in the case of non-emergency services furnished by nonparticipating providers during a visit by a participant, beneficiary, or enrollee at a participating health care facility, unless the notice and consent requirements, as specified in this IFC, have been met.

The HHS Department notes that a nonparticipating provider may not have the information necessary to determine whether the services are a covered benefit under the plan or coverage. As a result, the nonparticipating provider may need to bill the plan or issuer directly for the services in order to determine whether the protections apply. Otherwise, the provider risks violating the statute and this IFC by billing individuals. HHS understands that nonparticipating providers and facilities frequently bill individuals directly for out-of-network services, leaving the individual to submit the bill to the plan or coverage. **HHS seeks comment on the impact this change will have on nonparticipating providers and facilities, and on plans and issuers receiving bills from nonparticipating providers and facilities.**

In instances where a provider or facility does balance bill a participant, beneficiary, or enrollee for services in violation of the statute and this IFC, the Secretary of HHS may impose civil money penalties in states where HHS is directly enforcing the balance billing provisions with respect to health care providers, facilities, and providers of air ambulance services. However, the statute provides that the Secretary shall waive the penalties with respect to a health care provider, facility, or provider of air ambulance services who does not knowingly violate, and should not have reasonably known it violated, the provisions, with respect to a participant, beneficiary, or enrollee, if such provider or facility, within 30 days of the violation, withdraws the bill that was in violation of such provision and reimburses the health plan or individual, as applicable, in an amount equal to the difference between the amount billed and the amount allowed to be billed under the provision, plus interest, at an interest rate determined by the Secretary. HHS intends to address enforcement of the requirements of the NSA applicable to health care providers, facilities, and providers of air ambulance services in future rulemaking.

Health Care Facilities

This IFC defines a participating health care facility, in the context of non-emergency services, as a health care facility that has a contractual relationship directly or indirectly with a group health plan or health insurance issuer offering group or individual health insurance coverage setting forth the terms and conditions on which a relevant item or service is provided to a participant, beneficiary, or enrollee under the plan or coverage, respectively. The IFC also specifies that a single case agreement between a health care facility and a plan or issuer, used to address unique situations in which a participant, beneficiary, or enrollee requires services that typically occur out-of-network constitutes a contractual relationship for purposes of this definition, and is limited to the parties to the agreement with respect to the particular individual involved.

Health care facility described in the statute is each of the following, in the context of non-emergency services: (1) a hospital; (2) a hospital outpatient department; (3) a critical access hospital; or (4) an ambulatory surgical center.

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

Given significant variation in state law definitions, urgent care centers are not included within the definition of health care facilities, in the context of non-emergency services. Thus, in cases where non-emergency services are furnished at participating urgent care centers by nonparticipating providers, those services would not receive the protections under this IFC. **The Departments seek data on how frequently surprise bills arise in the context of urgent care centers. The Departments also seek comment on whether plans and issuers generally contract separately with urgent care centers and the providers who work at the centers, and how frequently contracting practices result in nonparticipating providers furnishing services at participating urgent care centers.**

Items and Services within the Scope of a Visit

In addition to items and services furnished by a provider at the facility, a “visit” to a participating health care facility includes the furnishing of equipment and devices, telemedicine services, imaging services, laboratory services, and preoperative and postoperative services, regardless of whether the provider furnishing such items or services is at the facility. **The Departments solicit comments regarding other items and services that would be appropriate to include within the scope of a visit for purposes of this IFC.**

The NSA and this IFC provide for exceptions to the balance billing prohibitions and cost-sharing requirements if the participant, beneficiary, or enrollee is provided a compliant written notice and consents to receive such services from a nonparticipating provider at a participating health care facility. However, these exceptions do not apply with respect to certain ancillary services (in the context of non-emergency services).

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

Cost-sharing amount

For emergency services furnished by a nonparticipating emergency facility, and for non-emergency services furnished by nonparticipating providers in a participating health care facility, cost sharing is generally calculated as if the total amount that would have been charged for the services by a participating emergency facility or participating provider were equal to the recognized amount for such services, as defined by the statute and in this IFC. The “recognized

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

Under the statute and this IFC rules, the provider or facility and plan or issuer separately determine the total payment amount for the furnished items or services, but that amount generally does not affect the cost-sharing amount the individual must pay. In circumstances where a specified state law or All-Payer Model Agreement does not apply to determine the cost-sharing amount, cost sharing must be based on the lesser of the QPA or the amount billed by the provider for the item or service.

Out-of-Network Rate

In addition to establishing requirements related to cost sharing, the NSA and this IFC also establish requirements related to the total amount paid by a plan or issuer for items and services subject to these provisions, referred to as the out-of-network rate.

The plan or issuer must make a total payment equal to one of the following amounts, less any cost sharing from the participant, beneficiary, or enrollee: (1) an amount determined by an applicable All-Payer Model Agreement; (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.

Specified State Law

A specified state law is a state law that provides a method for determining the total amount payable under a group health plan or group or individual health insurance coverage to the extent the state law applies. In cases where a specified state law applies, the recognized amount (the amount upon which cost sharing is based) and out-of-network rate for emergency and nonemergency services subject to the surprise billing protections is calculated based on such specified state law. In instances where a state law does not satisfy all of these criteria, the state law does not apply to determine the recognized amount or out-of-network rate.

The Departments seek comment on whether health insurance issuers, health care providers, or health care facilities, in instances where they are not otherwise subject to a specified state law that provides for a method for determining the total amount payable under a group health plan or group or individual health insurance coverage, should have an opportunity, for purposes of this IFC, to opt in to a program established under state law, with respect to an item or service furnished by a nonparticipating provider or

nonparticipating emergency facility. The Departments seek comment on whether this approach would allow for more flexibility for state laws to apply when, for example, by their terms, they apply to the health insurance issuer and item and service in question, but not to the provider; whether an issuer, provider, or facility would still be subject to any specified state laws in their “home” state if they opt in to a program established under another state’s law; and whether an issuer, provider, or facility should be permitted to opt in on an episodic basis.

The Departments are concerned that allowing providers and facilities to opt in to a program established under state law could increase health care prices if providers and facilities selectively opt in to state programs that favor providers and facilities in the determination of the out-of-network rate.

The Departments are of the view that it would be uncommon for laws of more than one state to each apply to the same health insurance issuer, and to the same provider for a particular item or service. Therefore, the Departments do not foresee many instances where there might be a question as to which state’s law applies to determine the recognized amount or out-of-network rate. However, in such uncommon scenarios, one approach might be for the states involved to make that decision. Another approach might be that the law enacted by the state in which the service is provided would apply. Yet another approach would be for the QPA to apply to determine the recognized amount, and either a negotiated amount or an amount determined by an IDR entity to apply to determine the out-of-network rate. **The Departments seek comment on these and any other approaches for resolving this choice-of-law question. The Departments also seek comment on how states have handled such questions prior to the enactment of the NSA, should these types of conflicts exist.**

The Departments interpret the NSA to include state laws that require or permit a plan or issuer and a provider or facility to negotiate, and then to engage in a state arbitration process to determine the out-of-network rate. Such state laws provide a process for determining the total amount payable, and in such instances, the timeframes and processes under such a state law related to negotiations and arbitration would apply, as opposed to the timeframes and IDR process under the NSA.

In addition, the Departments are of the view that Congress did not intend for the NSA to preempt provisions in state balance billing laws that address issues beyond how to calculate the cost-sharing amount and out-of-network rate. To the extent state laws do not prevent the application of a federal requirement or prohibition on balance billing, the Departments are of the view that such state laws are consistent with the statutory framework of the No Surprises Act and would not be preempted. This view extends to any state law that provides balance billing protections beyond what this IFC provides. Congress specifically indicated that such state balance billing laws may continue in effect along with the balance billing protections set forth in the statute.

All-Payer Model Agreements

In instances where an All-Payer Model Agreement is applicable, the recognized amount (the amount upon which cost sharing is based with respect to items and services furnished by

nonparticipating emergency facilities, and nonparticipating providers of nonemergency items and services in participating facilities) and the out-of-network rate are determined using the amount that the state approves under the All-Payer Model Agreement for such items or services.

An All-Payer Model Agreement is an agreement between CMS and a state to test and operate systems of all-payer payment reform for the medical care of residents of the state. The Departments are of the view that it is important to maximally preserve states' abilities to test all-payer payment reform through these Agreements, including their abilities to do so using varied approaches to setting payment amounts. This IFC defers to the state to determine the circumstances under which, and how, it will approve an amount for an item or service under a payment system established by an All-Payer Model Agreement.

The Departments are proposing that in order for an All-Payer Model Agreement to determine the recognized amount or out-of-network rate, any such Agreement must apply to the coverage involved; to the nonparticipating provider or nonparticipating emergency facility involved (and in the case of the out-of-network rate, to the nonparticipating provider of air ambulance services involved); and to the item or service involved. In instances where an All-Payer Model Agreement does not satisfy all of these criteria, the Agreement does not apply to determine the recognized amount or out-of-network rate, and, unless a specified state law applies, the recognized amount would be determined by the QPA (or the billed charge if less than the QPA), and the out-of-network rate would be the amount determined through agreement between the provider or facility and plan or issuer or the IDR process.

Methodology for Calculating the Qualifying Payment Amount

The NSA directs the Departments to establish through rulemaking the methodology that a group health plan or health insurance issuer offering group or individual health insurance coverage must use to determine the qualifying payment amount (QPA). The NSA and this IFC require cost sharing requirements imposed by plans and issuers in connection with emergency services furnished by a nonparticipating emergency facility or nonparticipating provider, or in connection with non-emergency services performed by nonparticipating providers at certain participating facilities to be based on the lesser of the billed charge or the QPA where an All-Payer Model Agreement or a specified state law does not apply. In addition, IDR entities are directed by statute to consider the QPA when selecting between the offer submitted by a plan or issuer and the offer submitted by a facility or provider in order to determine the total payment for emergency services furnished by a nonparticipating emergency facility or nonparticipating provider, or non-emergency services performed by nonparticipating providers at certain participating facilities that are items and services subject to the IDR process.

The QPA is the median of the contracted rates recognized by the plan or issuer on January 31, 2019, for the same or similar item or service that is provided by a provider in the same or similar specialty and provided in a geographic region in which the item or service is furnished, increased for inflation. The median contracted rate is determined with respect to all group health plans of the plan sponsor or all group or individual health insurance coverage offered by the health insurance issuer that are offered in the same insurance market, consistent with the methodology established by the Departments.

The NSA specifies an alternative methodology for determining the QPA in cases where a plan or issuer has insufficient information to calculate a median contracted rate for an item or service. The statute, however, envisions that these alternative methodologies, such as use of a third-party database, will be used in only limited circumstances where the plan or issuer cannot rely on its contracted rates as a reflection of the market dynamics in a geographic region.

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

Median Contracted Rate

In general, the median contracted rate for an item or service is calculated by arranging in order from least to greatest the contracted rates of all plans of the plan sponsor (or of the administering entity, if applicable) or all coverage offered by the issuer in the same insurance market for the same or similar item or service that is provided by a provider in the same or similar specialty or facility of the same or similar facility type and provided in the geographic region in which the item or service is furnished, and selecting the middle number. In determining the median contracted rate, the amount negotiated under each contract is treated as a separate amount.

The IFC defines a “contracted rate” as the total amount (including cost sharing) that a group health plan or health insurance issuer has contractually agreed to pay a participating provider, facility, or provider of air ambulance services for covered items and services, whether directly or indirectly, including through a third-party administrator or pharmacy benefit manager.

The NSA envisions that each contracted rate for a given item or service be treated as a single data point when calculating a median contracted rate. Therefore, if a plan or issuer has a contract with a provider group or facility, the rate negotiated with that provider group or facility under the contract is treated as a single contracted rate, if the same rate applies to all providers of such provider group or facility under the single contract. Likewise, the rate negotiated under a contract constitutes a single contracted rate regardless of the number of claims paid at that contracted rate. However, if a plan or issuer has a contract with multiple providers, with separate negotiated rates with each particular provider for a given item or service, each unique contracted rate constitutes a single contracted rate for purposes of determining the median. Further, if a plan or issuer has separate contracts with individual providers, the contracted rate under each such contract constitutes a single contracted rate (even if the same amount is paid to other providers under separate contracts).

Insurance Market

The term “insurance market” for purposes of this IFC means one of the following: the individual market, small group market, or large group market. The relevant insurance market is determined irrespective of the state. For example, in calculating the QPA for an item or service furnished to an enrollee in individual health insurance coverage, an issuer must take into account the contracted rates with providers or facilities in the applicable geographic region across the issuer’s individual market offerings, inclusive of contracted rates for all individual health insurance coverage offered by the issuer in all states in which the issuer offers coverage in the individual market.

To reduce the burden imposed on sponsors of self-insured group health plans, this IFC permits sponsors of self-insured group health plans to allow their third-party administrators to determine the QPA for the sponsor by calculating the median contracted rate using the contracted rates recognized by all self-insured group health plans administered by the third-party administrator (not only those of the particular plan sponsor). Under this approach, the Departments anticipate there will be fewer instances where a self-insured group health plan sponsor will lack sufficient information to calculate a median contracted rate for an item or service. **The Departments seek comment on the definition of insurance market with respect to self-insured group health plans and whether any contractual or other issues may prevent an entity, such as a third-party administrator, from using contracted rates from the different self-insured plans it administers to calculate the QPA for a particular self-insured group health plan.**

The Departments have determined that including rates negotiated under other more limited forms of coverage, such as excepted benefits, short-term, limited-duration insurance, and account-based plans, including health reimbursement arrangements, could skew the calculation of the median contracted rate, and these forms of coverage should not be included in the definition of the applicable insurance market. The Departments also clarify that any plan or coverage that is not a “group health plan” or “group or individual health insurance coverage” offered by a “health insurance issuer,” as those terms are defined in the Code, ERISA, and the PHS Act, such as a Medicare Advantage or Medicaid managed care organization plan, must also not be included in any insurance market for purposes of determining the QPA.

Same or Similar Item or Service

A plan or issuer must calculate the median contracted rate for an item or service using contracted rates for the same or similar item or service. Under the IFC, the term “same or similar item or service” means a health care item or service billed under the same service code, or a comparable code under a different procedural code system. Service code means the code that describes an item or service, including a Current Procedural Terminology (CPT), Healthcare Common Procedure Coding System (HCPCS), or Diagnosis-Related Group (DRG) code.

This IFC includes specific requirements to account for modifiers (when applicable), which are codes applied to the service code that provide a more specific description of the furnished item or service and that may adjust the payment rate or affect the processing or payment of the code

billed. The Departments are of the view that it is important that the QPA methodology account for modifiers that affect payment rates under contracts with participating providers and facilities.

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

Provider in the Same or Similar Specialty

This IFC specifies that if a plan or issuer has contracted rates for a service code that vary based on provider specialty, the median contracted rate is calculated separately for each provider specialty, as applicable. This IFC defines “provider in the same or similar specialty” as the practice specialty of a provider, as identified by the plan or issuer consistent with the plan’s or issuer’s usual business practice. This definition is intended to provide plans or issuers with the flexibility necessary to calculate the median contracted rate, relying on their contracting practices with participating providers.

The Departments considered requiring a plan or issuer to calculate separate median contracted rates for every provider specialty, but concluded that this approach would lead to more instances in which the plan or issuer would not have sufficient information to calculate the QPAs using its contracted rates. In addition, the Departments understand that not all plans or issuers vary contracted rates by provider specialty, in which case requiring plans and issuers to calculate separate median contracted rates for each provider specialty would increase the burden associated with calculating the QPA without adding specificity to the QPA. Given that the NSA generally relies on using contracted rates to determine the QPA, the Departments conclude that plans and issuers should be required to calculate median contracted rates separately by provider specialty only where the plan or issuer otherwise varies its contracted rates based on provider specialty.

Facility of the Same or Similar Facility Type

If a plan or issuer has contracted rates for emergency services that vary based on the type of facility (that is, whether a facility is an emergency department of a hospital or an independent freestanding emergency department), the median contracted rate is calculated separately for each such facility type. Plans and issuers subject to the protections in the NSA are required to cover emergency services at both types of facilities.

This IFC does not allow plans or issuers to separately calculate a median contracted rate based on other characteristics of facilities that might cause contracted rates to vary, such as whether a

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

Geographic Regions

The NSA requires plans and issuers to calculate the median contracted rate for an item or service using contracted rates for the same or similar item or service provided in the geographic region in which the item or service is furnished.

The Departments are establishing geographic regions under this IFC that reflect differences in health care costs based on whether care is provided in urban or rural areas. The Departments are of the view that these geographic regions take into account access to items and services in rural and underserved areas, including health professional shortage areas, as defined at section 332 of the PHS Act. The Departments intend to monitor the effect of these geographic regions and periodically update such regions, as appropriate, taking into account the findings of the report submitted under section 109(a) of the NSA, which addresses, among other things, access to health care items and services in rural areas and health professional shortage areas.

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

Non-Fee-for-Service Contractual Arrangements

The NSA provides that rulemaking to establish the methodology used to determine the QPA must take into account payments that are made by a plan or issuer that are not on a fee-for-service basis. The Departments are aware that many types of alternative reimbursement models exist that are not standard fee-for-service arrangements.

In the case of these alternative payment models, such as bundled and fully or partially capitated arrangements, where payment made by a plan or issuer is not fully on a fee-for-service basis, this IFC provides that the plan or issuer must calculate a median contracted rate for each item or service using the underlying fee schedule rates for the relevant items and services, if underlying fee schedule rates are available. The term "underlying fee schedule rate" means the rate for a covered item or service from a particular participating provider, providers, or facility that a group health plan or health insurance issuer uses to determine a participant's, beneficiary's, or

enrollee's cost-sharing liability for the item or service, when that rate is different from the contracted rate.

This IFC specifies that when calculating median contracted rates, plans and issuers must exclude risk sharing, bonus, or penalty, and other incentive-based and retrospective payments or payment adjustments. The Departments are of the view that excluding these payments and payment adjustments from the median contracted rates used to determine cost sharing for items and services furnished by nonparticipating providers or facilities is consistent with how cost sharing is typically calculated for in-network items and services, where the cost-sharing amount is customarily determined at or near the time an item or service is furnished, and is not subject to adjustment based on changes in the amount ultimately paid to the provider or facility as a result of any incentives or reconciliation process.

Indexing

The NSA provides that, in instances when the median contracted rate is determined as of January 31, 2019, the QPA for items and services furnished during 2022 is calculated by increasing the median contracted rate by the percentage increase in the consumer price index for all urban consumers (U.S. city average) (CPI-U) over 2019, the percentage increase over 2020, and the percentage increase over 2021. The NSA further provides that the QPA for 2022 is then adjusted annually for items and services furnished during 2023 or a subsequent year. Therefore, the increase for any year is the CPI-U for the year, as so defined, divided by the CPI-U for the prior year. The combined percentage increase for 2019, 2020, and 2021 to determine the amount for 2022 is the product of the CPI-U increases for 2019, 2020, and 2021 multiplied together. For any year, the factor will be the quotient of CPI-U for the current year divided by the CPI-U for the prior year. For example, for an item or service provided in 2023, the 2023 QPA is the 2022 QPA multiplied by the $\frac{\text{CPI-U 2022}}{\text{CPI-U 2021}}$.

Cases with Insufficient Information

The NSA specifies an alternative process to determine the QPA in cases where a group health plan or health insurance issuer offering group or individual health insurance coverage lacks sufficient information to calculate the median of contracted rates in 2019, as well as for newly covered items or services in the first coverage year after 2019.

Under this IFC, a plan or issuer is considered to have sufficient information to calculate the median of contracted rates if the plan or issuer has at least three contracted rates on January 31, 2019, to calculate the median of the contracted rates in accordance with the methodology in this IFC.

Where a plan or issuer that initially does not have sufficient information to calculate the median contracted rate based on January 31, 2019 contracted rates (or for new plans and coverage or new service codes) later gains sufficient information, the plan or issuer must calculate the QPA using the median contracted rate for the first sufficient information year. The first sufficient information year is defined as: (1) in the case of an item or service for which a plan or issuer does not have sufficient information to calculate the median of contracted rates in 2019, the first

year after 2022 for which the plan or issuer has sufficient information to calculate the median of contracted rates in the year immediately preceding that first year after 2022; and (2) in the case of a newly covered item or service, the first year after the first coverage year for such item or service with respect to such plan or coverage for which the plan or issuer has sufficient information to calculate the median of the contracted rates in the year immediately preceding that first year.

Eligible Databases

In cases in which a plan or issuer does not have “sufficient information” to calculate a median contracted rate, the NSA directs the plan or issuer to determine the QPA through use of any database that is determined, in accordance with rulemaking issued by the Departments, to not have any conflicts of interest and to have sufficient information reflecting allowed amounts paid to a health care provider or facility for relevant services furnished in the applicable geographic region (such as a state all-payer claims database). This IFC establishes standards for databases, referred to as eligible databases, that may be used to determine the QPA. State all-payer claims databases are categorically eligible under this IFC because they are specifically identified as not having any conflicts of interest and as having sufficient information reflecting allowed amounts.

Other third-party databases may also be eligible, provided all of the following conditions are satisfied.

1. The database or the organization maintaining the database cannot be affiliated with, or owned or controlled by, any health insurance issuer, or a health care provider, facility, or provider of air ambulance services, or any member of the same controlled group as, or under common control with, any such entity.
2. The database must have sufficient information reflecting in-network amounts paid by group health plans or health insurance issuers offering group or individual health insurance coverage to providers, facilities, or providers of air ambulance services for relevant items and services furnished in the applicable geographic region. **The Departments seek comment on how to define when a database has sufficient information, including whether to establish specific criteria that a claims database would need to satisfy in order to demonstrate that it has sufficient information reflecting in-network payment amounts for providers or facilities in the applicable geographic region, such as a requirement that the database represents a specified minimum percentage of the claims volume for the region.**
3. The database must have the ability to distinguish amounts paid to participating providers and facilities by commercial payers, such as group health plans and health insurance issuers offering group or individual health insurance coverage, from all other claims data, such as amounts billed by nonparticipating providers or facilities and amounts paid by public payers, including the Medicare program, Medicaid program, and the Children’s Health Insurance Program.

New Plans and Coverage

The NSA directs the Departments to establish a methodology for the sponsor of a group health plan or a health insurance issuer that did not offer any plan or coverage in a geographic region in 2019 to determine QPAs for the first year in which the plan or coverage will be offered in the geographic region. For each subsequent year, that amount is increased by the percentage increase in the consumer price index for all urban consumers over the previous year.

The Departments recognize that while a sponsor or issuer may be newly offering coverage in a geographic region, the sponsor or issuer may have sufficient existing provider contracts under other current coverage in the geographic region where an item or service is furnished to calculate the QPA. The Departments clarify that it is not necessary to establish special procedures to calculate the QPA in these situations.

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

For each subsequent year the plan or coverage is offered in the geographic region, the plan or issuer must increase the QPA for items or services furnished in the immediately preceding year by the percentage increase in the CPI-U over the previous year to determine the QPA for items and services furnished in that year. **The Departments seek comment on whether the methodology should instead allow new plans and coverage to transition to calculating a QPA using median contracted rates in an applicable first sufficient information year.**

New Service Codes

When service codes are created, plans and issuers may be unable to calculate the QPA using the approaches discussed earlier, because neither the plan or issuer nor any eligible databases have sufficient information regarding the new service code. This situation may occur for new service codes when the service codes describe items or services that have not previously been widely furnished. This situation may also occur when service codes are substantially revised, resulting in new service codes or new descriptors for existing service codes that substantially alter the types of services that would be billed using the original service codes.

This IFC defines “new service code” to mean a service code that was created or substantially revised in a year after 2019. In situations in which a plan or issuer is billed for a covered item or service using a new service code, the plan or issuer must first identify a reasonably related service code that existed in the immediately preceding year. For example, a reasonably related service code might be another service code within the same family of codes, or might involve services that represent similar relative value units. This related service code will be used as a benchmark for determining the QPA for the new service code. **The Departments seek comment**

on whether additional rules are needed regarding how plans and issuers should be required to identify a reasonably related service code, and on whether the Departments should develop a crosswalk methodology to identify related service codes for each new service code.

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

For items and services billed using a new service code for which Medicare has not established a payment rate, the plan or issuer must calculate the QPA by first calculating the ratio of the rate that the plan or issuer reimburses for an item or service billed under the new service code compared to the rate that the plan or issuer reimburses for an item or service under the related service code (the relativity ratio), and then multiplying the relativity ratio by the QPA for the item or service billed under the related service code.

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

Information to be Shared about the QPA

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

The Departments expect that in most if not all cases where the QPA serves as the basis for determining the recognized amount, the federal IDR process will govern any dispute over payment instead of a specified state law or process. Therefore, this notice will also serve to direct providers or facilities to the federal IDR process if the parties cannot agree on an out-of-network rate.

A plan or issuer must provide a statement that if the provider or facility, as applicable, wishes to initiate a 30-day open negotiation period for purposes of determining the amount of total payment, the provider or facility may contact the appropriate person or office to initiate open negotiation, and that if the 30-day open negotiation period does not result in a determination,

generally, the provider or facility may initiate the IDR process within 4 days after the end of the open negotiation period. The plan or issuer must also provide contact information, including a telephone number and email address, for the appropriate office or person to initiate open negotiations for purposes of determining an amount of payment (including cost sharing) for such item or service.

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

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

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

Audits

The NSA requires rulemaking to establish a process under which group health plans and health insurance issuers offering group or individual health insurance coverage are audited by the applicable Secretary or applicable state authority to ensure that such plans and coverage are in compliance with the requirement of applying a QPA and that the QPA applied satisfies the definition under the NSA with respect to the year involved. The Departments will generally use existing processes to ensure compliance with Code, ERISA, and PHS Act requirements that apply to group health plans and health insurance issuers, including the provisions added by the NSA.

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

The NSA and this IFC establish several procedural requirements that apply to group health plans and health insurance issuers to ensure that billing disputes related to items and services subject to the balance billing protections in the NSA are resolved in a timely fashion. These include timeframes for: a plan or issuer to send a notice of denial of payment or make an initial payment;

the length of any open negotiation period regarding payment; and initiating the IDR process following an open negotiation period. Note that these requirements do not apply under certain circumstances with regard to post-stabilization services or to out-of-network non-emergency services (other than out-of-network air ambulance services) if the provider or facility provided notice to, and received consent from, the participant, beneficiary, or enrollee (or their authorized representative).

Providers and facilities are required to notify plans and issuers when the notice and consent criteria have been satisfied. Absent receiving this information, a plan or issuer must assume that the individual has not waived the protections provided in this IFC, and must therefore calculate cost sharing, apply cost sharing to deductibles and out-of-pocket limits, and make any payments to providers and facilities before an individual has satisfied the coverage deductible, accordingly. If a provider or facility indicates to a plan or issuer that the notice and consent described in this IFC was properly and timely given and received, the plan or issuer may rely on that information and apply out-of-network cost sharing for the applicable items and services.

The NSA requires plans and issuers to send “an initial payment or notice of denial of payment” not later than 30 calendar days after a nonparticipating provider or facility submits a bill related to the items and services that fall within the scope of the new surprise billing protections. The Departments specify in this IFC that the 30-calendar-day period generally begins on the date the plan or issuer receives the information necessary to decide a claim for payment for such services, commonly known as a “clean claim” under many existing state laws. To the extent feasible, the Departments encourage providers and facilities to include information about whether the surprise billing protections apply to an item or service on the claim form itself. With respect to non-emergency services, HHS requires nonparticipating providers (or the participating facility on behalf of the nonparticipating provider) to timely notify the plan or issuer that the item or service was furnished during a visit at a participating health care facility. In addition, in all cases, providers and facilities must notify the plan or issuer as to whether the requirements for notice and consent have been met when transmitting the bill, either on the bill or in a separate document. **The Departments seek comments with recommendations on how HIPAA standard transactions to submit claims could be modified to accommodate the submission of several types of information on the claim itself.**

The Departments may specify additional standards if the Departments become aware of instances of abuse and gaming where plans and issuers are unduly delaying making an initial payment or sending a notice of denial to providers on the basis that the provider has not submitted a clean claim. **The Departments solicit comment on whether any additional standards are necessary to prevent abusive claims payment practices.**

The IFC notes that in cases where the provider or facility is willing to accept the cost-sharing amount plus the initial payment (or the cost-sharing amount alone, in cases where a denial of payment is sent) as payment in full, this amount will be treated as the out-of-network rate. If plans and issuers make initial payments that providers and facilities are willing to accept (when combined with the cost-sharing amount) as payment in full, the administrative costs of determining the out-of-network amount will be significantly reduced through the avoidance of an open negotiation period and IDR process.

This IFC does not require plans and issuers to make any specific amount of minimum initial payment. However, several state balance billing laws set standards for minimum initial payment amounts. Requiring a minimum initial payment amount may help reduce the number of cases that go to arbitration in some states, and could help to reduce the number of cases that go to the federal IDR process established under the NSA. **The Departments seek comment on whether to set a minimum payment rate or methodology for a minimum initial payment in future rulemaking, and if so, what that rate or methodology should be. The Departments also seek comment on whether a minimum payment rate should be defined as a commercially reasonable rate based on payments for the same or similar services in a similar area, without requiring any specific methodology. In addition, the Departments seek comment regarding the impact of these provisions on underserved and rural communities, and other communities facing a shortage of providers.**

The Departments seek to minimize confusion about which types of disputes should be resolved through a plan or issuer's internal claims and appeals process instead of the IDR process established by the NSA. Consistent with the requirement that plans and issuers provide an initial payment or notice of denial of payment within 30 calendar days of a provider or facility submitting a clean claim, the Departments clarify that while the ERISA claims procedure regulation would require plans to make a benefit determination within 15 days of a claim being resubmitted with additional information, plans and issuers have 30 calendar days (which is an additional 15 days) to make an initial payment to a nonparticipating provider or facility, or send a separate notice of denial of payment. The Departments note that there is also a significant distinction between an adverse benefit determination (ABD), which may be disputed through a plan's or issuer's claims and appeals process, and a denial of payment or an initial payment that is less than the billed amount under this IFC, which may be disputed through the open negotiation process or through the IDR process.

In general, when adjudication of a claim results in a participant, beneficiary, or enrollee being personally liable for payment to a provider or facility, this determination may be an ABD that can be disputed through a plan's or issuer's claims and appeals process. Conversely, when: (1) the adjudication of a claim results in a decision that does not affect the amount the participant, beneficiary, or enrollee owes; (2) the dispute only involves payment amounts due from the plan to the provider; and (3) the provider has no recourse against the participant, beneficiary, or enrollee, the decision is not an ABD and the payment dispute may be resolved through the open negotiation or the IDR process. The Departments acknowledge that there may be instances where a participant, beneficiary, or enrollee appeals an ABD (such as, a determination of cost-sharing amounts) through the claims and appeals process concurrently with a provider's challenge to a payment amount through the IDR process.

Surprise Billing Complaints Regarding Group Health Plans and Health Insurance Issuers

This IFC establishes a process by which the Departments will receive complaints regarding violations by plans and issuers of the requirements under sections 9816 and 9817 of the Code, sections 716 and 717 of ERISA, and sections 2799A-1 and 2799A-2 of the PHS Act. **The**

Departments seek comment on whether the complaints process should be restricted to the QPA or extended as described in this IFC.

The NSA directs HHS to establish a process to receive consumer complaints regarding violations by health care providers, facilities, and providers of air ambulance services regarding balance billing requirements under sections 2799B-1, 2799B-2, 2799B-3, and 2799B-5 of the Public Health Service (PHS) Act and to respond to such complaints within 60 days. As such, HHS is issuing HHS-only IFCs to establish a process by which the Department will receive complaints regarding violations of these requirements by health care providers, facilities, and providers of air ambulance services.

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

This IFC does not include a time period upon which a complaint must be filed regarding an alleged violation of the requirements in this IFC by a plan, issuer, health care provider or provider of air ambulance services. **The Departments seek comment on whether a complainant should be required to file a complaint within a given time period and if so within what time period a complaint should be filed for the purpose of this section.**

Section 2799B-4 of the PHS Act directs HHS to respond to complaints regarding violations of balance billing protections by health care providers, facilities, and providers of air ambulance services within 60 days of receipt. The Departments are of the view that the timing for responding to complaints regarding plans and issuers should be the same as that for providers to ensure timely resolution. Therefore, upon receiving the information necessary to file a complaint regarding a plan or issuer, the Departments will respond to complainants no later than 60 business days after the complaint is received. The response will be by oral or written means, and will acknowledge receipt of the complaint, notify the complainant of their rights and obligations under the complaints process, and describe the next steps of the complaint resolution process. The Departments may also request any additional information needed to process the complaint.

The Departments understand that a complainant may not know which Department has enforcement jurisdiction; therefore, the Departments intend to provide one system that will direct complaints to the appropriate Department for processing, investigation, and enforcement action as necessary. The Departments will release guidance on where the public can file complaints and welcome comments on the operations, protections, user experience, or other facets of this complaint system. **The Departments also seek comment on ways to ensure consumers are aware and know how to use this system. The Departments specifically seek comment from individuals in underserved and rural communities, minority communities, and persons**

otherwise adversely affected by persistent poverty or inequality on specific barriers to the complaint process and solutions to address these barriers and ensure equitable access to all aspects of the complaint processes.

Provider and Facility Disclosure Requirements Regarding Patient Protections against Balance Billing

The NSA requires providers and facilities to provide disclosures regarding patient protections against balance billing for plan years beginning on or after January 1, 2022. To reduce burden and facilitate compliance with these disclosure requirements, the Departments are concurrently issuing a [model disclosure notice](#) that health care providers, facilities, group health plans, and health insurance issuers may, but are not required to, use to satisfy the disclosure requirements regarding the balance billing protections.

HHS encourages states to develop model language to assist health care providers and facilities in fulfilling the disclosure requirements related to applicable state law requirements and contact information.

Notice and Consent

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

The rule notes that the NSA does not universally protect individuals from every high or unexpected medical bill. For example, an individual may be enrolled in a group health plan or health insurance coverage that provides little or no coverage for their particular health care condition or the items and services necessary to treat that condition. In addition, balance billing continues to be permitted, unless prohibited by state law or contract, in circumstances where this IFC rule does not apply, such as for non-emergency items or services provided at facilities that are not included within the definition of health care facility in the IFC.

Non-emergency services furnished by a nonparticipating provider at a participating health care facility are exempt from cost sharing protections and balance billing protections when the notice and consent requirements are met. A nonparticipating provider or nonparticipating emergency facility may obtain notice and consent from the individual in order to balance bill for post-stabilization services only in the case where a participant, beneficiary, or enrollee has received emergency services and that individual's condition has stabilized.

If an individual receives a notice, but does not provide (or revokes) consent to waive their balance billing protections, those protections remain in place. A provider or facility may, subject to other state or federal laws, refuse to treat the individual if the individual does not consent.

In HHS's view, the option to consent to waive balance billing protections may be valuable to individuals in certain instances where they knowingly and purposefully seek care from a nonparticipating provider. **HHS seeks comment on striking the appropriate balance between allowing a specialist to refuse to treat an individual unless the specialist can balance bill the individual, while ensuring that the individual is not being pressured into waiving the balance billing protections.** In HHS's view, it is important that these consumer protections do not present a barrier to obtaining out-of-network care, when an individual knowingly seeks out such care. However, it is equally important that individuals are not unknowingly subject to balance billing.

Providers and facilities will be required to provide the notice using the standard notice document provided by HHS in guidance. The standard notice document will contain the elements required by the statute in a manner that is intended to be easy to read and comprehend. This IFC requires that the notice be provided with the consent document, and together these documents be given physically separate from, and not attached to or incorporated into any other documents.

Authorized Representatives

The notice may be provided to the individual's authorized representative instead of the individual, and consent may be provided by the authorized representative on behalf of the individual. An authorized representative is an individual authorized under state law to provide consent on behalf of the participant, beneficiary, or enrollee, provided that the individual is not a provider affiliated with the facility or an employee of the facility, unless such provider or employee is a family member of the participant, beneficiary, or enrollee. **HHS seeks comment on whether and how the term "family member" should be defined. HHS is sensitive to concerns that some individuals may not have a familial relation formally recognized under applicable state law, or other documented legal partnership with individuals whom they consider family. Therefore, when interpreting this requirement, HHS will construe the term "family member" broadly to include such individuals prior to the issuance of additional guidance.**

Timing of Notice

If an individual schedules an appointment for applicable items or services at least 72 hours before the date of the appointment, the provider or facility must provide the notice to the individual, or their authorized representative, no later than 72 hours before the date of the appointment; and if an individual schedules an appointment for such items or services within 72 hours of the date of the appointment, the provider or facility must provide the notice to the individual, or their authorized representative, on the day that the appointment is made. In 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.

HHS is of the view that the requirement that the notice be provided no later than 3 hours prior to furnishing items or services helps to ensure individuals can voluntarily provide informed consent, while not removing the informed consent option entirely in instances where the appointment is made the same day as the date the services are scheduled. **HHS seeks comment on whether such a time limit is a reasonable approach, as well as whether the 3 hours' time requirement should be shorter or longer, in order to best ensure that consent is freely given while also facilitating timely access to care.**

Content of Notice

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

HHS seeks comment regarding potential challenges nonparticipating emergency facilities may have in coordinating the development of a good faith estimate on behalf of both the facility and providers. HHS also seeks comment regarding the method by which this good faith estimated amount should be calculated, and anticipates addressing this requirement in future rulemaking. Finally, HHS seeks comment regarding whether the provider or the facility should be required to include information about what may be covered by the individual's plan or coverage and an estimate of the individual's out-of-pocket costs.

The notice must provide information about whether prior authorization or other care management limitations may be required in advance of receiving such items or services at the facility or from the provider. **HHS seeks comment on barriers or other burdens facing nonparticipating providers or facilities in obtaining this information from a plan or issuer.**

In cases where post-stabilization services are being furnished by a nonparticipating provider at a participating emergency facility, the notice must include a list of any participating providers at the participating emergency facility who are able to furnish the items or services involved.

Exceptions to the Availability of Notice and Consent

The notice and consent exception does not apply to ancillary services, which include items and services related to emergency medicine, anesthesiology, pathology, radiology, and neonatology, whether provided by a physician or non-physician practitioner; items and services provided by assistant surgeons, hospitalists, and intensivists; diagnostic services, including radiology and laboratory services; and items and services provided by a nonparticipating provider, only if there is no participating provider who can furnish such item or service at such facility. **HHS seeks comment on other ancillary services that should be considered to be made ineligible for the notice and consent exception. HHS seeks comment on what criteria HHS should consider in determining whether an advanced diagnostic laboratory test should be excepted from the definition of ancillary services, and on any specific advanced**

diagnostic laboratory tests that should be considered to be made eligible for the notice and consent exception.

Any notice provided and consent obtained with regard to the furnishing of certain items or services does not extend to additional items or services furnished in response to unforeseen, urgent medical needs either in the context of a nonparticipating provider in a participating facility, or of post-stabilization services.

Requirements to Notify the Plan or Issuer

For each item or service furnished by a nonparticipating provider or nonparticipating emergency facility, the provider (or participating facility on behalf of the nonparticipating provider) or nonparticipating emergency facility, as applicable, must timely notify the plan or issuer as to whether balance billing and in-network cost sharing protections apply to the item or service, and provide to the plan or issuer a signed copy of any signed written notice and consent documents. **HHS seeks comment on whether additional rulemaking would be helpful regarding the process and timing for such notification, including the definition of ‘timely,’ and what processes for conveying the notification would be most efficient.**

Choice of Health Care Professionals

The Departments note that, although the substantive requirements of these regulations have not changed, the NSA extends the applicability of the patient protections for choice of health care professionals to grandfathered health plans. The requirements regarding patient protections for choice of health care professional under this IFC will newly apply to grandfathered health plans for plan years beginning on or after January 1, 2022.

For questions about this summary, please contact Katie Keysor, Senior Director, Economic Policy at kkeysor@acr.org.