American College of Emergency Physicians®
ADVANCING EMERGENCY CARE

Regulation Summary

No Surprises Act Interim Final Rule Part 1

On July 1, 2021, the Departments of Health and Human Services (HHS), Treasury, and Labor (the Departments) and the Office of Personnel Management (OPM) issued an interim final rule (IFR) implementing part of the *No Surprises Act*. The *No Surprises Act*, which was included in the Consolidated Appropriations Act, 2021, bans balance billing or out-of-network (OON) services starting in 2022 and establishes a back-stop independent dispute resolution (IDR) process to ensure that clinicians and facilities are paid appropriately for the OON services they deliver.

For the last two years, ACEP has advocated on behalf of you as emergency physicians and your patients to ensure that any legislation that would address surprise medical billing would truly keep patients out of the middle of billing disputes and include a fair payment mechanism that would hold health plans accountable and ensure adequate reimbursement for OON services. We believe that the *No Surprises Act* represents a mostly reasonable solution to this issue given how damaging initial Congressional proposals would have been for emergency physicians.

This first IFR implements specific sections of the law and includes the following major sections and topics:

Another IFR expected later this summer or early fall will focus on other parts of the law, mainly fleshing out the IDR process.

Comments on this first IFR are due 60 days after the rule is officially published in the Federal Register. At the time this summary was drafted, the IFR had not yet been posted in the Federal Register. Comments will likely be due in early September 2021.

Interim Final Rule vs. Proposed Rule

- Under traditional rulemaking, federal agencies release a proposed rule and then a final rule after a 30- or 60-day public comment period. However, this rule is an "interim final rule" with comment period. Although the Departments must eventually issue a final rule based on public comments, the policies included in this rule are considered final (and not just proposed) in the interim.

- As a rationale for why the Departments are issuing an interim final rule instead of a proposed rule, they explain how they wanted to allow enough time before January 1, 2022 for all stakeholders—health plans, patients, and providers— to understand and implement the requirements.

- The *No Surprises Act* requires the Departments to issue rulemaking on certain topics by July 1, 2021: the QPA methodology; information plans must share with providers regarding the plan's determination of the QPA; and a process to receive complaints related to the QPA. The Departments state that allowing time for a full rulemaking process (i.e., a proposed rule) prior to July 1, 2021 would not have provided enough time for the Departments to develop these requirements by the statutory deadline.

Background

- The IFR provides a summary of existing Section 2719A of the Public Health Service Act (PHS) related to OON emergency care, and an explanation of how balance billing was permitted in it. The IFR also provides "Greatest of Three" history.

- The IFR includes explanations of why the *No Surprises Act* and greater consumer protections are needed.
    - Balance billing scenarios are described, including Zack Cooper research citations and statistics.
    - The patchwork of state laws has grown over time but are limited in their ability to address issue since ERISA pre-empts them.
    - Surprise medical bill debt disproportionately impacts underserved communities.
        - Consistent with President Biden EO 13985, "On Advancing Racial Equity and Support for Underserved Communities Through the Federal Government," regulations must ensure all consumers, particularly those in minority and underserved communities understand and benefit from these consumer protections.
        - The Departments seek comment from those who are members of, advocate for, and work with underserved communities regarding impact of the IFR.
    - Description of *No Surprises Act* and other related provisions included in Consolidated Appropriations Act, 2021:
        - Regulations being issued in several phases this year:
            - Federal IDR process, patient transparency protections, and price comparison tools.
            - Form and manner for air ambulance services reporting.
            - Additional rulemaking for insurers of individual and short-term, limited duration plans to disclose and report on compensation to agents and brokers.
            - HHS enforcement of requirements on plans, providers, facilities, and air ambulance services.
        - Rulemaking for *No Surprises Act* provisions on transparency in insurance cards, continuity of care, accuracy of provider network directions, and prohibition on gag clauses may not occur until after Jan 1, 2022.
            - Will include prospective applicability date that provides reasonable amount to of time for entities to comply with new requirements.
            - Until this rulemaking occurs, plans are expected to implement them using a good faith, reasonable interpretation of the statute. The Departments intend to issue guidance on this in the "near future."

Overview of IFR and Various Definitions

- Definitions
    - Physician or health provider: one that is acting within the scope of practice of their license of certification under applicable state law.
        - Specifically excludes air ambulance services – if a provision also applies to air ambulance services, they will be explicitly referenced in the IFR.
    - The Departments seek comment on the terms defined in the IFR (appropriateness, usability, and whether additional term definitions needed).

- Scope of protections for emergency services
    - The terms "Emergency medical condition", "emergency services," and "to stabilize" generally have the meaning given to them by the Emergency Medical Treatment and Labor Act (EMTALA).
        - The IFR definition of emergency services includes pre-stabilization services provided after patient is moved out of the ED and admitted to the hospital.
        - Free Standing Emergency Departments (FSEDs): Expands definition to also include services provided at independent FSEDs (geographically separate and distinct from a hospital, and licensed by state to provide emergency services, even if not licensed under the term "independent FSED"
        - Urgent care centers: if under state licensure laws urgent care centers are permitted to provide emergency services, then those urgent care centers will now fall under independent FSED definition for purposes of the IFR. State regulation of urgent care centers vary significantly.
    - Post-stabilization services
        - Defined as any additional services covered under a plan and furnished by an OON provider or emergency facility, regardless of department of the hospital they are furnished in, after an emergency patient is stabilized and as part of outpatient observation or an inpatient or outpatient stay.

- Services are considered "emergency services" and subject to IFR's surprise billing protections unless all of the following conditions are met:
    - Emergency physician (EP) or treating provider must determine that the patient is able to travel using nonmedical transportation or nonemergency medical transportation to an available in-network provider or facility located within a reasonable travel distance, taking into consideration their medical condition. The patient should be involved in the decision-making process, if possible.
        - Transportation options may vary based on the patient's location, social risk, and other risk factors. Underserved individuals may face additional barriers to obtaining post-stabilization services without a disruption in care.
        - The Departments expect the EP or treating provider to consider such factors when assessing the patient's ability to travel.
        - The Departments seek comment on the definition of "reasonable travel distance."
    - The provider or facility furnishing post-stabilization services must satisfy the *No Surprises Act*'s notice and consent criteria.
    - The patient must be in a condition to receive the notice and information and provide consent, in accordance with applicable state law.
        - The attending physician will make this determination and should apply the same principles as they would when determining a patient is able to provide informed consent for treatment.
            - Consideration should be given to the patient's state of mind and emotional state at time of consent.
            - Consideration should also be given to cultural and contextual factors that may affect information decision-making and consent for members of underserved communities, including mistrust based on historical inequities, or language and literacy barriers to comprehension of the information.
            - Consent must be voluntary—if it is made through a threat of restraint or immediacy of the need for treatment, it is not voluntary.
            - Overall, post-stabilization notice and consent procedures should generally only be applied in limited circumstances, where the patient knowingly and purposefully seeks care from an OON provider or facility and should not be permitted to circumvent the consumer protections in the *No Surprises Act*.
    - The provider or facility must satisfy any additional requirements or prohibitions under state law. States may impose stricter standards by which post-stabilization services will be exempted from the IFR's protections, or states might not permit exceptions at all.
    - The Departments seek comment on these four conditions, as well as if any additional conditions should be added, such as relating to coordinating care transitions to in-network providers and facilities. They also

seek comment on what guidelines may be needed to determine if a patient is in a condition to receive notice and provide consent (i.e., severe pain, intoxication, dementia, etc).

- With respect to non-emergency services performed by OON providers at in-network facilities, surprise billing protections applies, unless notice and consent requirements of the IFR are met.

- Health care facilities
  - For non-emergency services, provides surprise billing protections to a facility that has a single case agreement with the insurer for a particular patient. The IFR rules apply the same protections in this circumstance as would apply at facilities that participate in-network with the insurer.
  - A health care facility is described for non-emergency services as a hospital, hospital outpatient department, critical access hospital, or ambulatory surgical center.
  - The Departments seek comment on other facilities that might be appropriate to so designate (for non-emergency services), including urgent care centers or retail clinics. They also seek comment on the degree to which people may be using urgent care centers in a similar way to how they use independent FSEDs, and data on how often surprise bills arise from urgent care centers. Further, they seek comment on if insurers generally contract separately with urgent care centers and the providers who work at the centers.

- Items and Services with the Scope of a Visit
  - Defines a "visit" to an in-network health care facility as including the furnishing of equipment and devices, telemedicine services, imaging services, laboratory, and pre- and post-op services, regardless of whether the provider furnishing them is at the facility itself.
  - For example, samples sent to an off-site lab, or a telemedicine consultation with a specialist, would all be considered as part of the patient's visit to an in-network facility.

- Air ambulance services
  - The *No Surprises Act* provisions on air ambulance bills apply to patients who receive services from an OON provider of air ambulance services, meaning medical transport by a rotary wing air ambulance, or fixed-wing air ambulance.
  - The IFR applies the *No Surprises Act*'s protections where an insurer generally has a network of providers or covers any benefits for air ambulance services, even if the plan or coverage does not have in it network any providers of air ambulance services.

Enforcement of the Prudent Layperson Standard

- The IFR includes strong language enforcing the PLP. It states that plans currently deny coverage of certain services provided in the emergency department (ED) by determining whether an episode of care involves an emergency medical condition based solely on final diagnosis codes. In addition, some plans 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.
  - The Departments state that these ***practices are inconsistent with the emergency services requirements of the No Surprises Act and the Affordable Care Act***. 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.**

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

- Reiterates that cost-sharing for care delivered by an OON provider for emergency services and certain non-emergency services must not be greater than cost-sharing would have been if care were delivered by in-network provider.
  - Cost-sharing payments must be counted toward any in-network deductible or out-of-pocket maximums applied under the plan or coverage.

- Cost Sharing Amount
  - The cost sharing amount is the "recognized amount."
  - The recognized amount is determined through the following process:
    - (1) an amount determined by an applicable All-Payer Model Agreement; (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 generally is the median of the contracted rates of the plan or issuer for the service in the geographic region.
      - The Departments refer to cases where the amount billed by the provider is less than the QPA. In those cases, the patient would pay the lesser amount.
  - The Recognized amount is not used for air ambulances. The IFR requires that plans base any coinsurance and deductible for air ambulance services provided by a nonparticipating (OON) provider on the lesser of the QPA or the billed amount. The Departments seek comment on this methodology.

- Out-of-network rate
  - The plan must make a total payment equal to one of the following amounts, less any cost sharing paid by the patient: (1) an amount determined by an All-Payer Model Agreement; (2) if there is no such All-Payer Model Agreement, an amount determined by a specified state law; (3) in the absence of an All-Payer Model Agreement or specified state law, if the plan or issuer and the provider or facility have agreed on a payment amount, the agreed on amount; or (4) if none of those three conditions apply, and the parties enter into the IDR process and do not agree on a payment amount before the date when the IDR entity makes a determination of the amount, the amount determined by the IDR entity.
  - These requirements may result in circumstances where a plan or issuer must make payment prior to an individual meeting their deductible (i.e., high deductible plans)
    - Example: recognized amount is $1,000, but patient is in high-deductible plan with $1,500 deductible. The out-of-network rate winds up being $1,500. The patient still only pays $1,000 and the plan must pay $500 (even though patient under current rules would have had to pay all $1,500).
    - High-deductible plans can still keep their status. On a related note, HHS interprets the *No Surprises Act* as permitting catastrophic plans to make payments without losing their status as catastrophic plans.

- Specified State Law
  - Defined as a state law that provides a method for determining the total amount payable under a health plan to the extent the state law applies.
  - **ERISA opt-in allowed**: The concept of "specified state law" still applies even to non-regulated state plans where the state allows plans (such as ERISA plans) to opt-in.
  - In order for a state law to determine the recognized amount or out-of-network rate, any such law must apply to: (1) the plan involved (allowing for plans to opt-in if they are not otherwise subject to the state law); (2) the nonparticipating provider or nonparticipating emergency facility involved; and (3) the service involved.
    - **In instances where a state law does not satisfy all of these criteria, the state law does not apply to determine the recognized amount or out-of-network rate.**
    - Example: If the recognized amount and out-of-network rate do not apply to nonparticipating neonatologists, the federal law would determine the recognized amount and out-of-network rate for neonatology services while the state law would apply with respect to other provider specialties covered under that state law.
    - The IFR also includes a few other examples of when/ when not a state law would apply. The Departments do not think there would be numerous instances when it would be unclear WHICH state law applied. However, in those rate cases, the Departments lay out a few possible options on which state law would apply and seek comment on which approach would work the best.
  - **The Departments seek comment on whether health insurance issuers, health care providers, or health care facilities who are not subject to state law can opt into a program established under state law, including on an episodic basis.**
    - The Departments are concerned that allowing providers and facilities to opt into 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 also seek comment from stakeholders in medically underserved, rural, and urban communities.

- State Law Interaction with ERISA
  - The IFR describes specific provisions of ERISA and states that ERISA plans can voluntarily opt-in to state laws. If an ERISA plan does choose to opt-in.
- **The Departments are BROADLY interpreting the following statutory definition of a specified state law: "a State law that provides for a method for determining the total amount payable under such a plan, coverage, or issuer, respectively."**
  - This definition not only means a mathematical formula for determining the out-of-network rate or a predetermined amount for an out-of-network service, but also a state law that requires or permits a plan and a provider or facility to negotiate, and then to engage in a state arbitration process to determine the out-of- network rate.
  - If the state law counts, the timeframes and processes under such a state law related to negotiations and arbitration would apply, as opposed to the timeframes and IDR process under the *No Surprises Act*.
- The IFR also says that the *No Surprises Act* does not pre-empt state law that address issues beyond how to calculate the cost-sharing amount and out-of-network rate. These state laws still apply.

- All-Payer Model Agreements
  - An All-Payer Model Agreement is an agreement between the Center for Medicare & Medicaid Innovation (CMMI) and a state to test and operate systems of all-payer payment reform for the medical care of residents of the state.
  - Certain all-payer models determine the total payment amount for specific services while excluding others. If the all-payer model does not have a way of determining the payment amount for a specific service, that service would be governed by the federal processes and timelines.
    - Example: under the All-Payer Model Agreement for the Maryland Total Cost of Care Model, all payers pay a specific amount for hospital services, but not for physician services. Thus, the federal law would be used to set cost-sharing and the OON rate for physician services.

The Calculation of the Qualifying Payment Amount (QPA)

- QPA is used for two purposes:
  - To determine cost-sharing requirements for patients in cases where an All-Payer Model or a specified state law does not apply.
  - A factor that IDR entities can consider when selecting between the offer submitted by a plan and the offer submitted by a facility or provider in order to determine the total payment for emergency services.

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

- Median Contracted Rate
  - Calculated by arranging in order from least to greatest the contracted rates of all and selecting the middle number.
    - For example, assume the contracted rates for all plans of a sponsor in the same insurance market for a particular service provided by a provider in the same or similar specialty in a specified geographic region are $475, $490, and $510. The median contracted rate for this service is $490. If there are an even number of contracted rates, the median contracted rate is the average of the middle two contracted rates.

- Contracted Rate
  - The total amount (including cost sharing) that a health plan has contractually agreed to pay a participating provider or facility.
  - **Each contracted rate is treated as a single data point when calculating a median contracted rate. The rate negotiated under a contract constitutes a single contracted rate regardless of the number of claims paid at that contracted rate.**

- Insurance Market
  - The term "insurance market" 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.
  - With respect to self-insured group health plans, the IFR defines the term "insurance market" to mean all self-insured group health plans of the plan sponsor, or at the option of the plan sponsor, all self-insured group health plans administered by the same entity. The Departments seek comment on the definition of insurance market.
  - Other more limited forms of coverage, such as excepted benefits, short-term, limited-duration insurance, and account-based plans, including health reimbursement arrangements, are NOT INCLUDED
  - **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," 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
  - 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 CPT, HCPCS, or DRG code. **It is unclear whether the health plan must base the QPA on the specific CPT code on the claim.**
  - Modifiers can be included, including codes indicating whether services or procedures were performed by certain types of non-physician practitioners. In addition, modifiers can be used to indicate that the work required to provide a service in a particular instance was significantly greater – or significantly less – than the service typically requires. Plans must calculate separate median contracted rates for CPT code modifiers that distinguish the professional services component ("26") from the technical component ("TC").

- Provider in the Same or Similar Specialty
  - **The IFR does not require plans to calculate the median contracting rate for each specialty that provides a service.** Instead, it provides plans the flexibility necessary to calculate the median contracted rate, relying on their contracting practices with participating providers.
  - The Departments considered requiring a plan to calculate separate median contracted rates for every provider specialty but concluded that this approach would put too much burden on health plans lead to more instances in which the plan would not have sufficient information to calculate the QPAs using its contracted rates.

- Facility of the Same or Similar Facility Type
  - Where a plan to have established contracts with both hospital EDs and independent FSEDs, and its contracts vary the payment rate based on the facility type, the median contracted rate is to be calculated separately for each facility type. The Departments seek comment on this approach.
  - The IFR does not allow plans to separately calculate a median contracted rate based on other characteristics of facilities, such as whether a hospital is an academic medical center or teaching hospital.

- Geographic Regions
  - The *No Surprises Act* directs the Departments, in consultation with the National Association of Insurance Commissioners (NAIC), to establish through rulemaking the geographic regions to be applied when determining the QPA, taking into account access to services in rural and underserved areas.

- NAIC recommended that geographic regions correspond to the applicable rating area used for purposes of the individual market and small group market rating rules, while allowing states the flexibility to establish alternative geographic regions.
- After consultation with the NAIC, the Departments are establishing geographic regions that reflect differences in health care costs based on whether care is provided in urban or rural areas. These geographic regions take into account access to services in rural and underserved areas, including health professional shortage areas.
- A geographic region is defined as one region for each metropolitan statistical area (MSA) in a state and one region consisting of all other portions of the state.
    - If a plan or issuer does not have sufficient information to calculate the median of contracted rates for a service provided in an MSA, the plan or issuer must consider all MSAs in the state to be a single region when calculating the median of contracted rates for the service provided in that MSA.

- Non-Fee-for-Service Contractual Arrangements
    - The *No Surprises Act* requires that the QPA to take into account payments that are made by a plan that are not on a fee-for-service basis. However, in the case of these alternative payment models, the IFR requires plans to calculate a median contracted rate for each service using the underlying fee schedule rates for the relevant services, if underlying fee schedule rates are available. If there is no underlying fee schedule rate for a service, the plan must calculate the median contracted rate using a derived amount.
    - The Departments believe that this approach minimizes the number of instances in which a would not have sufficient information to calculate a median contracted rate and ensures that arrangements that pay for value over service volume are reflected in the QPA. In addition, this approach will result in the calculation of a QPA that aligns with a service code.
    - **When calculating median contracted rates, the IFR requires plans to exclude risk sharing, bonus, or penalty, and other incentive-based and retrospective payments or payment adjustments.**

- Indexing
    - When the median contracted rate is determined as of January 31, 2019, the QPA for 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 QPA for 2022 is then adjusted annually for services furnished during 2023 or a subsequent year.
    - The increase for any year is the CPI-U for the year divided by the CPI-U for the prior year. 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.

- Special Rules
    - The Departments also have special rules for unit-based services (where payment is based on mileage or time), anesthesia services, and air ambulance services.

- Cases with Insufficient Information
    - The is 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 services in the first coverage year after 2019.
    - The Departments want to minimize the instances that an alternative methodology is used, and therefore sets a low bar for "sufficient information."
    - Definition of Sufficient Information
        - **A health plan is considered to have sufficient information to calculate the median of contracted rates if the plan or issuer has <u>at least three contracted rates</u> on January 31, 2019, to calculate the median of the contracted rates.**
        - If a plan initially does not have sufficient information and later gains sufficient information, the plan must calculate the QPA using the median contracted rate starting that year.
        - In cases in which contracted rates for a year AFTER 2019 must be used to calculate the median

contracted rate, a plan will be considered to have sufficient information to calculate the median contracted rate for a year if: (1) the plan or issuer has at least three contracted rates on January 31 of the year immediately preceding that year; and (2) the contracted rates account for at least 25 percent of the total number of claims paid for that service for that year with respect to all plans offered by the issuer in the same insurance market. **The 25 percent minimum claims volume requirement was required to account for the potential for plans to engage in selective contracting practices that artificially change the median contracted rate.**

- Eligible databases
  - If insufficient information exists, the *No Surprises Act* directs the plan to determine the QPA through use of any database that is determined to not have any conflicts of interest and to have sufficient information reflecting allowed amounts paid to a health care provider or facility.
  - State all payer claims databases are categorially included.
  - Other databases must:
    - Not 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.
    - Have sufficient information reflecting in-network amounts paid by health plans to providers.
    - database must have the ability to distinguish amounts paid to participating providers and facilities by commercial payers and public payors (like Medicare)
  - To calculate the QPA using an eligible database, the plan must:
    - Identify the rate in the database that is equal to the median of the in-network allowed amounts for the same or similar service in the geographic region in the year immediately preceding the year in which the service is furnished. The Departments' view that in-network allowed amounts for services are a reasonable proxy for contracted rates.
    - Once the median in-network allowed amount has been identified, that rate is then increased by the percentage increase in the CPI-U over the previous year.
  - Plans must use a consistent methodology—i.e., they must use the same database to determine the QPA for that service through the last day of the calendar year.

- New Plans and Coverage
  - Even if an insurer is offering a new plan in a geographic region, it still may have sufficient existing provider contracts under other current coverage in the geographic region where a service is furnished to calculate the QPA. In this case, the QPA is determined using the standard methodology for calculating median contracted rates.
  - In situations where the issuer did not offer any plan or coverage in 2019, the plan must determine the QPA in accordance with the rules applicable to plans with insufficient information, or for newly covered 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 by the percentage increase in the CPI-U.

- New Service Code
  - A "new service code" means a 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 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. The Departments seek comment on whether additional rules are needed regarding how plans should be required to identify a reasonably related service code.
  - **The Departments also believe that it is reasonable to use Medicare payment rates to approximate the relative cost of two different but reasonably related service codes.** If Medicare has not established a payment rate, the plan must calculate the QPA by first calculating the ratio of the rate that the plan or issuer reimburses for a service billed under the new service code compared to the rate that the plan reimburses for service under the related service code (the relativity ratio), and then multiplying the relativity ratio by the QPA for service billed under the related service code.

- Once the plan or an eligible database has sufficient information to calculate a QPA, the QPA for a new service code would be calculated using the median contracted rate of the plan, or the median of the in-network allowed amounts in the eligible database.

The Information on the QPA that the Health Plan Must Share with Health Care Providers

- The Departments seek to ensure transparent and meaningful disclosure about the calculation of the QPA while at the same time minimizing administrative burdens on plans.

- With each initial payment or notice of denial of payment, plans and issuers must provide:
  - The QPA for each service involved.
  - A statement certifying that: (1) the QPA applies for purposes of the recognized amount and (2) each QPA was calculated based on the methodology outlined in this IFR and that neither an All-Payer Model Agreement nor a specified state law applies.
  - A statement that a provider or facility can initiate a 30-day negotiation for purposes of determining the amount of total payment and that if the 30-day open negotiation period does not result in a determination the provider or facility may initiate the IDR process within 4 days after the end of the open negotiation period. The plan must also provide contact information for the appropriate office or person to initiate open negotiations.
  - Upon request of the provider or facility, information about whether the QPA includes contracted rates that were not set on a fee-for-service basis, and if so, how the QPA was calculated.
  - Upon request, a statement that the plan's contracted rates include incentive or other payments that were excluded for purposes of calculating the QPA.

- The Departments seek comment on these disclosure requirements.

Audits

- The process for determining the QPA must be audited by the HHS Secretary or state authority in order to make sure the plan is in compliance. HHS has enforcement authority over issuers in a state if the HHS Secretary makes a determination that the state is failing to enforce a provision.

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

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

- Plans are required 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. The Departments encourage providers and facilities to include information about whether the surprise billing protections apply to service on the claim form itself and to make it a **"clean claim."**
  - The Departments may specify additional standards if the Departments become aware of instances of abuse and gaming where plans 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.

- Denials: plans must provide written notice which explains the reason for denial.

- Initial Payment
  - **In the Departments' view, the statute's reference to an "initial" payment does not refer to a first installment—but should be the plans best effort to make a full payment.**
  - The IFR do not require plans to make any specific amount of minimum initial payment.

- **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 provide some clarifications on the type of disputes that can go through a plan's traditional appeals process, and which can go through the *No Surprises Act* negotiations and IDR process. Overall, when the patient's cost-sharing is involved, it can go through the plan's traditional appeals process. When the patient is not involved, and the dispute just involves the payment between the plan and the provider, it can go through the *No Surprises Act* negotiation and IDR processes. The Departments acknowledge that there may be instances where an enrollee appeals their cost-sharing amount 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

- The Departments establish a process for receiving complaints against health plans for any of the consumer protection and balance billing requirements that it violates. They are seeking comment on whether the complaints should be restricted to the QPA provisions. Further, HHS is establishing a process to receive consumer complaints regarding violations by health care providers and facilities.

- There is no time restriction for submitting complaints against health plans or providers. The Departments will respond to all complaints within 60 days. The Departments/ HHS may request additional information as necessary to review complaints.

- The Departments intend to provide the public with a seamless experience for filing complaints by creating one system to intake all complaints and will make the system easily accessible.

Applicability

- Included:
  - Plans in the individual and small group market. "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, and church plans. Individual health insurance coverage includes coverage offered in the individual market, through or outside of an Exchange, and includes student health insurance coverage.
  - FEHB carriers also must comply.
  - Grandfathered plans and indemnity plans also apply.

- No included:
  - The requirements in the IFR do not apply to health reimbursement arrangements, or other account-based plans, short-term limited duration plans, and retiree only plans.

Compliance and Enforcement

- HHS recognizes that compliance with these requirements may require nonparticipating providers and nonparticipating emergency facilities to not bill an individual directly, even in cases that are not subject to these requirements. 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 the IFR by billing individuals.

- Enforcement: In instances where a provider or facility does balance bill an enrollee for services in violation of the statute and the IFR, HHS may impose civil money penalties in states where HHS is directly enforcing the balance billing provisions. HHS must waive the penalties for a provider who does not knowingly violate the requirements. More details on the penalties and enforcement of the requirements will be included in future rulemaking.

Notice and Consent Exception to Prohibition on Balance Billing

- The protections that limit cost sharing and prohibit balance billing do not apply to certain non-emergency services or to certain post-stabilization services provided in the context of emergency care if the nonparticipating provider or nonparticipating emergency facility provides the enrollee with notice and the individual consents to waive the balance billing protections.

- The IFR details these new requirements—including:
  - Creating standards for notice.
  - Allowing for authorized representatives of patients to receive notice.
  - Specifying the timing of the notice (at least 72 hours before the date of the appointment in most cases and no earlier than 3 hours before a procedure if notice is provided on same day).
  - Having the notice include a good faith estimate of what the provider and facility will charge and include information as to whether prior authorization is necessary.
  - Creating standards for consent.
  - Including language requirements for notice and consent forms.

- **With respect to non-emergency services, the notice and consent exception does NOT apply to ancillary services, which include services related to emergency medicine, anesthesiology, pathology, radiology, and neonatology, whether provided by a physician or non-physician practitioner.**
  - The notice and consent exception also does not apply to services furnished as a result of unforeseen, urgent medical needs that arise at the time a service is furnished for which a nonparticipating provider satisfied the notice and consent criteria.

- Nonparticipating providers are required to retain written notice and consent documents for at least a 7-year period after the date on which the service in question was furnished.

- The provider or nonparticipating emergency facility must notify the plan in a timely manner as to whether balance billing and in-network cost sharing protections apply and provide to the plan a signed copy of any signed written notice and consent documents. HHS recognizes that it is critical that a group health plan or health insurance issuer have knowledge of whether the balance billing and in-network cost-sharing requirements apply. HHS seeks comment on whether additional rulemaking would be helpful regarding the process and timing for such notification.

Provider and Facility Disclosure Requirements Regarding Patient Protections against Balance Billing

- Providers and facilities must provide disclosures regarding patient protections against balance billing. Among other things, the statute requires health care providers and facilities to make publicly available, post on a public website of the provider or facility and provide to enrollees a one-page notice about the balance billing requirements.

- Plans and issuers must also provide information in plain language on the prohibition against balance billing and information on contacting appropriate state and federal agencies in the case that an individual believes that such a provider or facility has violated the prohibition against balance billing.

- To reduce burden and facilitate compliance with these disclosure requirements, the Departments are concurrently issuing a model disclosure notice that health plans, providers, and facilities can use. More guidance is forthcoming.

- The IFR outlines requirements regarding the content of the one-page disclosure, methods for disclosure, timing of disclosure to individuals, exceptions to the requirements, and a special rule to prevent unnecessary duplication with respect to providers.
  - To satisfy the required disclosure to the public, providers and facilities must display the required disclosure information on a sign posted prominently at the location of the health care provider or health care facility.
  - A health care provider or health care facility must provide the notice to enrollees no later than the date and time on which the provider or facility requests payment from the individual. In cases where the facility or

provider does not request payment from the individual, the notice must be provided no later than the date on which the provider or facility submits a claim to the plan.
    - Exceptions: First, health care providers are not required to make the disclosures if they do not furnish services at a health care facility. Second, health care providers are required to provide the required disclosure only to individuals to whom they furnish services, and then only if such services are furnished at a health care facility.

- If a provider delivers services in a facility, the facility can cover the notice requirement. The disclosure must include information about the balance billing requirements and prohibitions applicable to both the facility and the provider. HHS believes this will remove unnecessary burden and effort for the providers.

Impact of IFR

- The IFR describes the impact of the rule, including why it is needed. It discusses:
    - The prevalence of surprise billing, impact of surprise billing on patients, existing state laws on balance billing, and the expected benefits of the rule on patients.
    - Regulatory alternatives to different policies that were included in the IFR and why the alternatives were ultimately not selected.

- The IFR will result in costs to plans and to providers and facilities.
    - Total cost to all providers and facilities overall (estimated to be 16,992 facilities).
        - Notice and consent: The IFR estimates that the onetime cost to prepare the notice and consent documents will be approximately $22.6 million in 2021. The ongoing annual cost to provide the notice and obtain consent, retain records, and provide notice to plans and issuers is estimated to be approximately $117.2 million starting in 2022.
        - Publicly posting disclosure and one-page notice disclosure: The IFR estimates the one-time total cost, to be incurred in 2021, to be approximately $13.1 million and the ongoing annual cost, to begin in 2022, to be approximately $2.5 million.