



## **Initial AMA Summary of Interim Final Rule (Part 1) Implementing Certain Provisions of the No Surprises Act**

On July 1, 2021, the Departments of Health and Human Services (HHS), Labor, and Treasury (the Departments) and the Office of Personnel Management (OPM) issued an [interim final rule](#) (IFR) implementing several provisions of the No Surprises Act (NSA), enacted as part of the Consolidated Appropriations Act, 2021 (CAA).

Given statutory timeframes required under the NSA and the pending implementation of most provisions by January 1, 2022, the Departments made the decision to issue an IFR. As a result, the requirements outlined in the IFR are final and will become effective on September 13, 2021. However, the Departments request comments on several aspects of the rule. The AMA will be responding by the September 7, 2021, comment period deadline.

The IFR states that this is the first of several regulations that the Departments will be issuing to implement the NSA. Regulations on the Independent Dispute Resolution process, price comparison tools, and certain transparency requirements are expected later this year. Rules on other NSA provisions, including insurance card requirements, continuity of care, provider network directions, and prohibition on gag clauses, may not be published until next year. (Guidance on using a good faith interpretation of the statute in the interim will be issued soon.)

Below is a detailed summary of the IFR. In general, the IFR provides the following:

- In determining how the qualifying payment amount (QPA) is calculated, the IFR reduces the likelihood that plans will need to use data from outside, independent databases. This is done through broad definitions of “markets” and “geographic regions,” allowing reliance on small data sets, benchmarking for “new service codes,” etc.
- Reduces the role of bonuses, risk sharing, penalties, and other incentive-based and retrospective payments or payment adjustments in the calculation of the QPA.
- Establishes a structure for the interaction of state and federal surprise billing requirements, where state law preempts federal law when either a set payment amount or dispute resolution process is in place for state-regulated plans and, when applicable, self-funded ERISA plans that opt-in to the state law.
- Outlines a process by which a patient receives notice and potentially provides consent to receive out-of-network care and forgo the financial protections of the NSA.
- Establishes criteria for facilities and physicians/providers to provide required disclosure to patients about balance billing protections—both state and federal.
- Broadens complaint processes for patients, physicians, and plans.
- Reaffirms several patient protections for emergency medical care, including the prudent layperson standard.

The AMA has several initial concerns about the way the QPA (median contracted rate) will be determined. Additionally, while the Departments attempt to consolidate and standardize some administrative requirements on physicians, in other areas they expand them in ways that may not benefit patients but result in burdens on physicians. The AMA will provide detailed comments to the Departments upon a full analysis of the IFR.

## **I. Background and Definitions**

### **Emergency services and post-stabilization**

The IFR includes several patient protections in reaction to recent insurer attempts to limit coverage for emergency services.

- Enforcing the prudent layperson standard, the IRF states that if a plan provides any benefits with respect to services in an emergency department of a hospital or with respect to emergency services in an independent freestanding emergency department, the plan or issuer must cover emergency services without limiting what constitutes an emergency medical condition solely on the basis of diagnosis codes. The IFR states that 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 and these practices are inconsistent with the No Surprises Act and the Affordable Care Act.
- The IRF also states that emergency services must be provided "without regard to any other term or condition of the plan or coverage (other than the exclusion or coordination of benefits)." This prohibits plans from excluding benefits that would otherwise constitute benefits for an emergency medical condition.
- Additionally, the IFR states that a plan may not impose any administrative requirement or limitation on coverage for emergency services received from nonparticipating providers or nonparticipating emergency facilities that is more restrictive than the requirements or limitations that apply to emergency services received from participating providers or participating emergency facilities.

### **Scope of emergency services under the NSA**

- The IFR clarifies that the NSA amended section 2719A of the Public Health Services Act ("greater of three rule") to include a sunset provision effective for plan years beginning on or after January 1, 2022, when the new surprise medical billing protections under the No Surprises Act take effect.
- Emergency services, for purposes of protections under the NSA, include pre-stabilization services that are provided after the patient is moved out of the emergency department and admitted to a hospital.
- Expands the protections to include emergency services provided at an Independent Freestanding Emergency Department licensed by state to provide emergency services.
- Includes emergency services provided at urgent care centers if they are permitted/licensed by the state to provide emergency services.

Post-stabilization services are considered emergency services under the NSA unless the following are met:

1. The attending emergency physician or treating provider determines that the patient can 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. This determination is binding on the facility. Unreasonable travel burden includes barriers such as the ability to pay for a taxi, access to a car, safely taking public transit, or the availability of public transit options.
2. The provider and facility satisfy notice and consent criteria. The patient must be in condition to receive notice and provide consent as determined by the attending physician or treating provider using appropriate medical judgment. Factors to be considered include:
  - The patient's state of mind and emotional state at time of consent.

- The 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 is provided voluntarily.
  - Generally, this should only be applied in limited circumstances, where the patient knowingly and purposefully seeks care from an out-of-network provider or facility.
3. The provider and facility meet state law requirements. States may impose stricter standards by which post-stabilization services will be exempted from the surprise billing protections under federal law or states might not permit exceptions at all.

### **Facilities**

The IFR clarifies that when non-emergency services are furnished by a nonparticipating provider at a health care facility that has a single case agreement in place with respect to the individual being treated, as opposed to an agreement or contract that would apply to all the plan's enrollees, those non-emergency services would be subject to the NSA protections.

As states above, emergency services provided at urgent care centers that are licensed in a way that brings them within the definition of independent free standing emergency departments would be subject to balance billing protections and cost-sharing requirements.

### **Visits**

The IFR states that out-of-network services such as telemedicine and radiology that are performed while a patient is at a participating hospital, but possibly performed outside of the facility, fall under the NSA's protections.

## **II. Determination of the Cost-Sharing Amount and Payment Amount to Providers and Facilities**

### **Cost sharing**

Under the NSA, for out-of-network emergency services or out-of-network nonemergency services provided at participating facility where notice and consent requirements were not met or not applicable, the plan cannot impose cost-sharing requirements that are greater than the cost-sharing requirements if the services had been provided in-network. Additionally, the cost-sharing must be counted toward the patient's in-network deductible and in-network out-of-pocket maximum.

The amount used to determine cost sharing is generally the **recognized amount**.

- The recognized amount is: (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 qualifying payment amount (QPA), which is generally defined as the median of the contracted rates of the plan for the service in the geographic region.
- In circumstances where a specified state law or All-Payer Model Agreement does not apply to determine the cost-sharing amount, cost sharing is based on lesser of the QPA or the amount billed by the provider.

The **out-of-network rate** is the total payment made to the provider or facility and must be equal to 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;
3. in the absence of an applicable All-Payer Model Agreement or specified state law, if the plan or issuer and the provider or facility have agreed on a payment amount, the agreed on amount; or
4. if none of those three conditions apply, and the parties enter into the IDR process and do not agree on a payment amount before the date when the IDR entity makes a determination of the amount, the amount determined by the IDR entity.

**The Departments interpret the cost-sharing requirements to apply even when a patient has not satisfied their deductible**, i.e., the patient’s out-of-pocket costs are limited to the amount of cost-sharing originally calculated using the recognized amount. The IFR states that although such a payment would normally cause a high deductible health plan (or other catastrophic plan) to lose its status, the NSA prevents this.

### **Specified state law**

A specified state law is a state law that provides a method for determining the total amount payable (for a surprise medical bill) to a provider or facility under a plan to the extent the state law applies. The IFR states that specified state laws that allow self-funded ERISA plans to “opt-in” will continue to apply.

When the specified state law applies, the patient’s cost sharing and the out-of-network rate for services subject to the surprise billing protections is calculated based on state law.

In order for a state law to determine the recognized amount or out-of-network rate, any such law must apply to: (1) the plan, issuer, or coverage involved; (2) the nonparticipating provider or nonparticipating emergency facility involved; and (3) the item or service involved.

The IFR clarifies that the NSA will fill in the gaps of state laws in terms of determining recognized amount and out-of-network rate. For example, if a state law does not apply to certain specialties, only applies to HMOs, etc., the federal law will then determine the recognized amount and out-of-network rates.

The IFR poses several questions for comment including:

1. Whether plans, in instances where they are not otherwise subject to a specified state law that provides for a method for determining the total amount payable, should have an opportunity to opt-in to a program established under state law, with respect to an item or service furnished by a nonparticipating provider or emergency facility.
2. Whether this approach would allow for more flexibility for state laws to apply when, for example, by their terms, they apply to the health plans 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.
3. The potential impact of expanding the ability to opt into a state program to providers and facilities. The Departments specifically seek comment from issuers, providers, or facilities located within or serving underserved and rural communities, and other communities facing a shortage of providers on the impact of these provisions on services, coverage, and payment for and within medically underserved, rural, and urban communities.

### **State law interaction with ERISA**

As stated above, the IFR allows self-insured ERISA plans (including non-federal governmental plans) to voluntarily opt-in to state laws that provides for a method for determining the cost-sharing amount or total amount payable under such a plan, where a state has chosen to expand access to such plans. The IFR

requires that a group health plan that opts into such a state law must do so for all items and services to which the state law applies.

Additionally, a plan that has chosen to opt into a state law must prominently display in its plan materials a statement that the plan has opted into a specified state law, identify the relevant state (or states), and include a general description of the items and services provided by nonparticipating facilities and providers that are covered by the specified state law.

In terms of preemption issues, the IFR holds that state laws that impose comparable or additional requirements on plans generally constitute a “specified state law” notwithstanding section 514 of ERISA and would continue to apply.

Examples where the state law would not apply include:

- If provider and facility licensed in separate state than insurer and specified state law, state law does not apply
- If the definition of emergency services in state law does not include post-stabilization, then emergency services fall under state and post-stabilization fall under federal.

**The IFR interprets a specified state law to be both a state law that sets a predetermined amount, as well as law that requires or permits a plan and a provider/facility to negotiate and then to engage in a state arbitration process to determine the out-of-network rate.** The timeframes and processes under a state law related to negotiations and arbitration would apply.

Additionally, the Departments conclude 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.

### **All payer model Agreements**

The Departments are interested in maximally preserving states’ abilities to test all-payer payment reform through All Payer Model Agreements, including their abilities to do so using varied approaches to setting payment amounts. The IFR 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. 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 to the item or service involved.

### **III. Calculating the QPA**

The Qualifying Payment Amount (QPA) is used to determine patient cost-sharing (the recognized amount) when the federal law applies, as well as a factor for consideration by the Independent Dispute Resolution (IDR) entity when determining the out-of-network rate.

The QPA is defined as 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 issuer that are offered in the same insurance market, consistent with the methodology established by the Departments.

The Departments state their interest in ensuring that health plans can meet the sufficient information standards and that QPAs can be largely calculated on median contracted rates, rather than calculated using alternative methods included in the NSA.

### **Median contracted rate**

The IFR states that the median contracted rate 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 service is furnished, and selecting the middle number.

In determining the median, the amount negotiated under each contract is treated as a separate amount and each contracted rate for a given item or service should be treated as a single data point when calculating a median contracted rate.

The IFR defines a contracted rate as the total amount, including cost sharing, that plan has contractually agreed to pay a provider or facility for covered services, whether directly or indirectly, including through a third-party administrator or pharmacy benefit manager.

The IFR states that each *unique* contracted rate constitutes a single contracted rate:

- If the plan has a contract with a group or facility, the rate negotiated with group or facility is treated as a single contracted rate *if the same rate applies to all providers under the contract*.
- A rate negotiated under a contract constitutes a single contracted rate regardless of the number of claims paid at the contracted rate.
- If a plan has a contract with multiple providers with separate negotiated rates for each provider for an item or service, each rate is a single contracted rate when determining the median contracted rate.

For rented networks, the contracted rate between providers and the entity responsible for managing the network for the plan would be the contracted rate, and ad hoc arrangements outside of the network do not count as a contracted rate.

### **Market**

Under the IFR:

- The term “insurance market” means the individual market, small group market, or large group market. The IFR states that the relevant insurance market is determined irrespective of the state.
- For self-insured group health plans, the term “insurance market” means 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. Sponsors of self-insured group health plans may 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.
- The individual market excludes short-term, limited-duration insurance and account-based plans.
- 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, is not to be included in any insurance market for purposes of determining the QPA.

### **Same or Similar Item or Service**

The Departments define “same or similar item or service” to mean a health care item or service billed under the same service code, or a comparable code under a different procedural code system. Service code means the code that describes an item or service, including a Current Procedural Terminology (CPT), Healthcare Common Procedure Coding System (HCPCS), or Diagnosis-Related Group (DRG) code. A service code is a unique identifier, typically consisting of a string of numeric digits or alphanumeric characters, that corresponds to a standardized description, which is used to identify with specificity the item or service that was furnished to a patient.

Regarding modifiers, the IFR requires that:

- Plans must calculate separate median contracted rates for CPT code modifiers that distinguish the professional services component from the technical component.
- Where a plan’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 considered when calculating the median contracted rate.

### **Provider in the Same or Similar Specialty**

The Departments considered, but decided against, requiring plans to calculate a separate QPA for each specialty providing a service in order to provide plans with greater flexibility. Therefore, the IFR 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 usual business practice.

Plans are required to calculate median contracted rates separately by provider specialty only where the plan otherwise varies its contracted rates based on provider specialty. If a plan’s usual business practice for identifying a provider’s practice specialty differs for contracting purposes and other business needs, they should use the method of identifying the practice specialty that it uses for contracting purposes.

### **Geographic regions**

After consulting with the National Association of Insurance Commissioners (NAIC), as directed by the statute, the IFR establishes geographic regions that reflect differences in health care costs based on whether care is provided in urban or rural areas. As such, a geographic region is generally defined as one region for each metropolitan statistical area (MSA) in a state and one region consisting of all other portions of the state.

The Departments believe that these geographic regions take into account access to items and services in rural and underserved areas, including health professional shortage areas. The Departments state that they intend to monitor the effect of these geographic regions and periodically update such regions, as appropriate, and consider 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.

### **Alternative payment models:**

Despite the NSA requirement that alternative payment arrangements be considered when calculating the QPA, the Departments require:

- That in the case of alternative payment models where payment made by a plan or issuer is not fully on a fee-for-service basis, the plan must calculate a median contracted rate for each item or service using the underlying fee schedule rates, if available.

- If there is no underlying fee schedule rate, the plan or issuer must calculate the median contracted rate using a derived amount.
- 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.

### **Special Rules for Unit-Based Services (Anesthesia)**

To calculate the QPA for anesthesia services furnished during 2022 the plan must:

- First take the median contracted rate for the anesthesia conversion factor for the same or similar item or service as of January 31, 2019, and increase that amount to account for changes in the CPI-U. This amount is referred to as the indexed median contract rate; and
- Then multiply this indexed median contracted rate for the anesthesia conversion factor by the sum of the base unit, time unit, and physical status modifier units of the patient to whom anesthesia services are furnished.

To calculate the QPA for anesthesia services after 2022, the plans must:

- Use the indexed median contracted rate for the anesthesia conversion factor and adjust that amount by the percentage increase in the CPI-U over the previous year using the methodology described earlier; and
- Then multiply that amount by the sum of the base unit, time unit, and physical status modifier units for the participant, beneficiary, or enrollee to whom anesthesia services are furnished.

### **Sufficient information to calculate the median contracted rates**

The NSA requires a plan to use a specified alternative method for determining a QPA when it lacks sufficient data to calculate the median contracted rate in 2019. The Departments seemingly make every effort to prevent the use of such an alternative method.

A plan 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. When a plan that initially does not have sufficient information but later gains sufficient information, the plan must calculate the QPA using the median contracted rate for the first year after 2022 for which the plan has sufficient information to calculate the median of contracted rates in the year immediately preceding that first year.

When contracted rates for a year after 2019 must be used to calculate the median contracted rates, the plan will be considered to have sufficient information to calculate the median contracted rate for a year if:

- The plan or issuer has at least three contracted rates on January 31 of the year immediately preceding that year to calculate the median of the contracted rates; and
- The contracted rates account (or are reasonably expected to account) for at least 25% of the total number of claims paid for that service for that year with respect to all plans or all coverage offered by the issuer in the same insurance market.

The “25% requirement” is meant to help ensure that when contracted rates for years after 2019 are used to calculate a median contracted rate, those network contracts represent a reasonable proportion of a plan’s claims and are not designed to manipulate the QPA.

### **Eligible Databases (for when insufficient data exists to calculate median rate)**

When a plan does not have “sufficient information” to calculate a median contracted rate, the plan must determine the QPA through use of any database. State APCDs are categorically eligible. The criteria for other databases include:

- 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.



- 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.
- Must have the ability to distinguish amounts paid to participating providers and facilities by commercial payers from all other claims data, such as amounts billed by nonparticipating providers or facilities and amounts paid by public payers.

The IFR states that in-network allowed amounts are a reasonable proxy for contracted rates and that using the median of in-network allowed amounts for all private payers in an eligible database is a reasonable method for approximating the median contracted rate for items and services in a geographic region.

The IFR requires that plans must continue to use this methodology until the first sufficient information year and for any item or service, a plan using a database must use the same database to determine the QPA through the last day of the calendar year. (If a different database is selected for some items or services, the basis for that selection must be one or more factors not directly related to the rate of those items or services (such as sufficiency of data for those items or services)).

### **New Plans and Coverage**

According to the IFR:

- If the new plan/coverage for a year after 2019 has sufficient information to calculate a 2019 median contracted rate, the QPA should be determined using the standard methodology for calculating median contracted rates.
- If there is insufficient information, the plan must determine the QPA in accordance with the rules related to insufficient information, or for newly covered items and services, including the use of an eligible database.
- Under this approach, new plans and coverage that initially do not have sufficient information to calculate a median contracted rate must use a QPA based on information for the first year of coverage from an eligible database indefinitely, updated only by the inflation adjustment. (The Departments ask for comment on whether they should be able to transition to calculating QPA using median contracted rates at any point.)

### **New service code**

A new services code is a service code that was created or substantially revised in a year after 2019. Plans may be unable to calculate the QPA using the approaches above because the neither the plan nor any databases have sufficient information.

Therefore, the IFR suggests the plan must identify a reasonably related service code that existed in the immediately preceding year to be used as a benchmark:

- The Departments suggest it is reasonable to use Medicare rates to approximate the relative cost of two different but reasonably related service codes. If CMS has established a payment rate under Medicare for the new service code, the plan must calculate the ratio of the rate that Medicare pays compared to the rate that Medicare pays under the related service code and multiply that ratio by the QPA for the related service code.
- If Medicare does not establish a payment rate under a new service code, a plan can calculate the QPA by first calculating the ratio of the rate that the plan pays for a service billed under the new service code compared to the rate that the plan pays for a service under the related service code (the relativity ratio), and then multiplying the relativity ratio by the QPA for the service billed under the related service code.

The IFR states that using rates from two different contracts would *not* be a reasonable method for calculating the relativity ratio, as this approach could introduce into the relativity ratio, variation from factors that are unrelated to the relative cost of furnishing the item or service, such as the negotiating power of the parties to the contract.

#### **Information to be shared about QPA with providers**

The IFR highlights the importance of transparency and disclosing how a QPA is calculated to health care providers. According to the IFR, a plan must disclose:

- The QPA for each item or service involved.
- A statement certifying that (1) the QPA applies for purposes of the recognized amount and (2) each QPA shared w/ the provider or facility was determined in compliance with methodology in IFR.
- A statement that the provider or facility may initiate a 30-day open negotiation to determine the payment and that if the 30-day period does not result in a determination, the provider or facility may initiate the IDR process within 4 days.
- 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, in a timely manner, information about whether the QPA includes contracted rates that were not set on a fee-for-service basis and whether the QPA for 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.
- Upon request, if applicable, a statement that the plan's contracted rates include risk-sharing, bonus, penalty, or other incentive-based or retrospective payments or payment adjustments for the items and services involved that were excluded for purposes of calculating the QPA

#### **IV. QPA Audits**

HHS has enforcement authority over issuers in a state if the HHS Secretary determines a state is failing to substantially enforce a provision (or provisions) of Part A or D of title XXVII of the PHS Act. HHS also has primary enforcement authority over non-federal governmental plans, such as those sponsored by state and local government employers. 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. OPM has jurisdiction over FEHB plans.

The IFR includes an audit provision establishing HHS's existing enforcement procedures will apply with respect to ensuring that a plan or coverage is in compliance with the requirement of determining and applying a QPA. HHS intends to amend its enforcement regulations through future notice and comment rulemaking to reflect the amendments made to the PHS Act by the NSA.

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

##### **Initial payments**

There are several procedural requirements for plans that include timeframes for:

- a plan or issuer to send a notice of denial of payment or make an initial payment;
- the length of any open negotiation period regarding payment; and
- initiating the IDR process following an open negotiation period.

However, these requirements do not apply under certain circumstances if the provider or facility provided notice to, and received consent from, the patient.

Therefore, the IRF states that it is important for plans to have information regarding notice and consent in order to meet deadlines and determine initial payments. Under the IFR:

- Absent receiving information from the provider, the plan can assume patient has not waived protections
- If the plan receives info from provider, it may rely on the provider's or facility's representation as being true and accurate.
- If a plan believes that notice was not properly and timely given and received, notwithstanding a provider's or facility's assertion to the contrary, the plan or issuer should apply the cost-sharing and requirements by, among other actions, reprocessing any claims.
- The plan or issuer may also submit a complaint against the provider or facility.

Under the NSA, plans must 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 that falls under the NSA protections. The IFR requires that, generally, the 30-day clock starts on the date the plan receives the info necessary to decide claim for payment – i.e., receives a clean claim.

The Departments *encourage* providers and facilities to include information about whether the surprise billing protections apply on the claim form itself.

HHS *requires* that nonparticipating providers provide timely notification to the plan that the service was furnished during a visit at a participating facility and notify the plan 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 recommendations on how HIPAA standard transactions to submit claims could be modified to accommodate the submission of several types of information on the claim.

Additionally, the Departments may specify further standards if they 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 asked for comment on whether any additional standards are necessary to prevent abusive claims payment practices.

### **Amount of initial payment**

While there is no requirement under the NSA on the amount of the initial payment, the Departments suggest that the initial payment should reflect the amount that the plan reasonably intends to be payment in full prior to the beginning of any open negotiations or initiation of the IDR process. The Departments are asking for comment on whether there should be a minimum initial payment and if so, what methodology should be used.

### **Notice of Denial**

A notice of denial means a written notice from the plan to the provider that payment will not be made by the plan with an explanation of the reason for denial. (Could include, e.g., when an item or service is covered but is subject to a deductible greater than the recognized amount.) The term “notice of denial of payment” does not include a notice of benefit denial due to an adverse benefit determination (ABD) (i.e., a denial of coverage in whole or in part), as defined in 29 CFR 2560.503-1.

The IFR suggests that the difference between a notice of denial under the NSA that can be taken to IDR and an ABD is:

- When adjudication of the claim essentially leaves the patient liable to the provider, this is likely an adverse benefit determination that can be resolved through the payer’s appeals process.
- When adjudication of the claim (1) does not affect patient’s financial liability (cost-sharing amount), (2) the dispute only relates to the payment amount to the provider from the plan, and (3) the physician has no recourse against the patient, then the denial is not an ABD and can, eventually go to IDR.

The Departments acknowledge that under this distinction, there is the possibility that a patient may appeal an ABD through a payer’s internal processes at the same time a provider challenges the payment amount through IDR.

## **VI. Surprise billing complaints regarding plans**

While the NSA only requires a complaint process regarding the application of the QPA requirements by group health plans and health insurance issuers, the IFR establishes a broader process by which the Departments will receive complaints regarding violations by plans of all the consumer protections and balance billing requirements under the IFR.

HHS also establishes a process by which HHS will receive complaints regarding violations of requirements by health care providers, facilities, and providers of air ambulance services.

For purposes of the complaint processes for plans and issuers, providers, facilities, and providers of air ambulance services, a complaint is defined as a written or oral communication that indicates there has been a potential violation by a plan or issuer. Additionally, the IFR specifies 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 that is 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 IFR does not include a time period for filing a complaint, but the Departments will respond to complaints within 60 days for them being received. The Departments will release guidance on where the public can file complaints.

## **VII. Choice of Provider changes**

The IFR adds a sunset clause to the current patient protection provisions codified in the Patient Protections Final Rule and recodifies the Affordable Care Act’s choice of health care professional requirement with no substantial changes to apply to all group health plans and group and individual health insurance programs, including grandfathered plans beginning in 2022.

## **VIII. Applicability**

The IFR generally applies to:

- Group health plans including 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.

- Individual health insurance coverage including coverage offered in the individual market, through or outside of an Exchange, and student health insurance.
- Grandfathered and grandmothered plans.
- Indemnity plans
- FEHB carriers subject to OPM regulation and contract provisions.

The IFR does not apply to short-term limited duration plans, account-based plans and retiree-only plans.

## **IX. Enforcement/Compliance**

Given that the statute and IFR authorize HHS to impose civil money penalties on facilities and providers that violate these requirements, nonparticipating providers should take steps necessary to ensure compliance by, among other actions, determining whether a given item or service is being furnished under circumstances that would trigger the surprise billing protections.

In the IFR, HHS recognizes that compliance with these requirements may require nonparticipating providers and emergency facilities to not directly bill a patient, even in cases that are not subject to these requirements, when a provider may not have the information necessary to determine whether the services are a covered benefit. As a result, the nonparticipating provider may need to bill the plan or issuer directly for the services to determine whether the protections apply. HHS requests comments on the impact of these changes.

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.

## **X. Notice and Consent Requirements**

The NSA surprise billing protections 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 emergency facility provides the patient with notice, and the patient consents to waive the balance billing protections.

If a patient receives a notice but does not provide (or revokes) consent, 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. However, the cost-sharing and balance billing protections applicable to plans, issuers, providers, and facilities would apply subsequent to the provision of the notice, and absent consent. (HHS is of the view that an individual cannot provide consent freely if a provider or facility will require the individual to pay a fee if the appointment is cancelled because the individual refuses or revokes consent.) HHS created a [standard notice and consent documents](#) for comment.

### **Standards for Notice**

The IFR allows a patient to waive balance billing protections in limited circumstances only, and only if the nonparticipating providers or emergency facility have provided the patient with appropriate notice explaining the applicable protections and the implications of providing consent.

The IRF also requires:

- Providers and facilities to provide notice using the standard notice document provided by HHS in guidance, which HHS states will contain the elements required by the statute in a manner that is intended to be easy to read and comprehend.

- The notice be provided with the consent document, and together be given physically separate from, and not attached to or incorporated into any other documents.
- The notice be written and provided on paper, or, as practicable, electronically, as selected by the patient.

The notice may be provided to the patient's authorized representative instead of the patient, and consent may be provided by the authorized representative. However, the authorized individual should generally not be the provider.

### **Timing of Notice**

If a patient schedules an appointment at least 72 hours before the date of the appointment, the provider or facility must provide notice no later than 72 hours before the date of the appointment.

If a patient schedules an appointment within 72 hours of the date of the appointment, the provider or facility must provide the notice on the day that the appointment is made.

In the situation where a patient is provided the notice on the same day care is provided, providers and facilities are required to provide the notice no later than 3 hours prior. HHS seeks comment on whether this timeframe is appropriate.

### **Content of Notice**

The IRF requires that the notice must include the good faith estimated amount that the nonparticipating provider or emergency facility may charge the patient, including any item or service that the nonparticipating provider reasonably expects to provide in conjunction with such care.

- The estimate must only include services that the provider will provide.
  - However, if a nonparticipating provider has not satisfied the notice and consent criteria, balance billing and cost-sharing protections will apply to the patient with respect to items and services furnished by that nonparticipating provider, even if a different nonparticipating provider has satisfied the notice and consent criteria with respect to the same visit.
  - Multiple nonparticipating providers may provide a single notice to the patient that includes:
    - each provider's name listed on the notice document;
    - notice and a good faith estimate for each service that each provider is furnishing;
    - information on which services are being furnished by which providers; and
    - a statement that the patient has the option to consent to waive protections with respect to each provider separately.
- The good faith estimate should reflect the amount the provider or facility expects to charge for furnishing such items or services, even if the provider or facility intends to bill the plan or coverage directly.

The notice must also provide information about whether prior authorization or other care management limitations may be required in advance of receiving such items or services; however,

- HHS recognizes that there may be challenges to identifying what care management limitations may apply and allows providers and facilities to provide general information to satisfy this requirement.
- To the extent possible, HHS encourages providers and facilities to contact plan about any such limitations so that they can include specific information in the notice.

The notice must also provide information on participating providers at participating emergency facilities who can provide the care.

### **Standards for Consent**

Patients must acknowledge that they consent to be treated and balance billed by the nonparticipating emergency facility or nonparticipating provider, and the consent must be provided voluntarily, meaning that the patient has consented freely, without undue influence, fraud, or distress. An incomplete form will not be considered consent.

The notice and consent documents must:

- Meet language access requirements.
- Acknowledge that the patient has been provided with the written notice in the form selected by the patient.
- Acknowledge that the individual has been informed that their payment might not count toward meeting any limitation on cost-sharing.
- Only apply to the services furnished by the provider or providers specifically named in the notice.
- Include the date on which the patient received the notice.
- The date and time that the patient signed such consent to be furnished the items or services covered in the notice.

The patient may revoke consent by notifying the provider or facility in writing prior to care. If a patient revokes consent, the balance billing protections apply to applicable items or services provided after the revocation as if consent was never provided.

### **Languages**

The IFR requires that the notice and consent documents be made available in any of the 15 most common languages in the geographic region in which the applicable facility is located. Providers and facilities will need to translate the standard notice and consent documents specified by HHS in guidance into the applicable 15 languages.

Notice and consent are not met if the patient cannot understand the documents due to language barriers, regardless of the 15 most common language requirements, as well due to other barriers.

### **Exceptions to the Availability of Notice and Consent**

The notice and consent exception is not applicable with respect to some non-emergency items or services:

- 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.
- Items or 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.
- 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.

### **Retention of documents**

If a nonparticipating provider obtains signed consent from a patient where the facility does not otherwise obtain the consent on behalf of the provider, the provider may either coordinate with the facility so that

the facility retains the written notice and consent for a 7-year period, or the provider must retain the written notice and consent for a 7-year period.

### **Requirements to Notify Plans**

The provider (or participating facility on behalf of the nonparticipating provider) or emergency facility must timely notify the plan as to whether balance billing and in-network cost sharing protections apply to the item or service and provide a signed copy of any notice and consent documents so that the plan is aware when the balance billing and in-network cost sharing protections apply and can process the claim appropriately.

- For non-emergency services, the provider must notify the plan that the service was provided during a visit at a participating facility.
- For post-stabilization services, the provider or facility must notify the plan as to whether all the conditions are met with respect to each service for which a bill is submitted.
- For non-emergency services only, when the provider bills (and is permitted to bill) the patient, the provider may satisfy the requirement to timely notify the plan by including the notification with the bill to the patient.

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

The NSA requires health care providers and facilities to make publicly available, post on a public website of the provider or facility (if applicable) and provide to patients a one-page notice about the balance billing requirements and prohibitions that apply to the provider or facility, including the state requirements and how to contact appropriate regulators if the patient believes there is a violation of requirements. The Departments are issuing a [model disclosure notice](#) that providers, facilities, group health plans, and health insurance issuers may, but are not required to, use to satisfy the disclosure requirements.

### **Content of Disclosure**

The disclosure must comply with all applicable civil rights laws, including those meant to provide access for individuals with limited English proficiency and with disabilities, and must include:

- Clear and understandable statements that explains the federal requirements and prohibitions related to balance billing,
- Clear and understandable explanations of state requirements regarding the amounts a provider or facility may charge a patient after receiving payment from the plan and any patient cost-sharing.
- Contact information for the appropriate state and federal agencies that a patient may contact if they believe the provider or facility has violated a requirement.

If state laws are more protective for patients, the inapplicable federal law need not be disclosed.

HHS has developed a model notice and encourages states to do the same to comply with state laws.

### **Methods of Disclosure**

In terms of making the disclosure publicly available:

- The disclosure or a link to the disclosure must be searchable on the provider's or facility's public website. HHS is of the view that the required disclosure information would not be publicly available unless displayed in a manner that is easily accessible, without barriers, and that ensures that the information is accessible to the general public, including findable through public search engines.



- Providers and facilities must also display the required disclosure information on a sign posted prominently at the location of the health care provider or health care facility. HHS considers a sign to be posted prominently, if the sign is posted in a central location, such as where individuals schedule care, check-in for appointments, or pay bills.

To satisfy the requirement to provide patients with the disclosure, the disclosure notice that must be provided to patients may be one double-sided page and may not include print smaller than 12-point font.

### **Timing of Disclosure**

The IFR generally requires a provider or facility to provide the notice to a patient no later than the date and time on which the provider or facility requests payment from the patient (including requests for copayment made at the time of a visit to the provider or facility). In cases where the facility or provider is not requesting payment from the patient, the notice should be provided no later than the date on which the provider or facility submits a claim for payment to the plan. Disclosure may be provided earlier (e.g., when a patient schedules an appointment).

### **Exceptions to Disclosure Requirements**

The following are exceptions to the disclosure requirements:

- Providers are not required to make the disclosures if they do not furnish items or services at a health care facility, or in connection with visits at health care facilities.
- Providers are required to provide the required disclosure only to patients to whom they furnish items or services, and then only if such items or services are furnished at a health care facility, or in connection with a visit at a facility.
- Disclosure is required only to patients of a group health plan or group or individual health insurance coverage offered by a health insurance issuer (the requirements do apply to providers/facilities with respect to patients in a FEHB plan).

### **Preventing Unnecessary Duplication with Respect to Providers**

Because there may be instances where a patient could receive disclosure notices from both the facility and provider, the IFR clarifies that the provider satisfies the disclosure requirements if the facility agrees to provide the information, in the required form and manner, pursuant to a written agreement. In such instance, the disclosure must include information about the balance billing requirements and prohibitions applicable to both the facility and the provider. (This does not apply with respect to the requirement that each health care provider and facility post the required disclosure on a public website.)

If there is a written agreement in place between the facility and the provider to provide such disclosure and the facility fails to do so, then the facility, but not the provider, would violate the provider disclosure requirements.