Requirements Related to Surprise Billing; Part I: Policy Update

Summary

On July 1, 2021, the US Departments of Health and Human Services (HHS), Treasury and Labor, and the Office of Personnel Management issued an Interim Final Rule with comment (IFR) implementing portions of the No Surprises Act, legislation enacted in December 2020 that bars surprise billing beginning January 1, 2022.

Under the law, payers and providers (including hospitals, facilities, individual practitioners and air ambulance providers) are prohibited from billing patients more than in-network cost-sharing amounts in certain circumstances. The prohibition applies to both emergency care and certain non-emergency situations where patients do not have the ability to choose an in-network provider.

The law establishes a pathway for resolving payer-provider payment disputes using negotiation and arbitration. If entities are unable to come to an agreement, the independent dispute resolution (IDR) process requires each party to submit a final payment offer, and the arbiter will select one of these offers as the final payment amount (commonly referred to as "baseball style" arbitration). In selecting the final payment, arbiters must weigh certain factors and are banned from considering the lower payment rates paid by federal government programs (*e.g.*, Medicare and Medicaid).

The No Surprises Act directs payers to determine the patient's cost-sharing amount based on all-payer models (if applicable), state law or a new term, the qualifying payment amount (QPA). The QPA is important as it also impacts the IDR process as one factor that the arbiter must consider when selecting between a payer and provider's offer for reimbursement.

This IFR establishes regulations defining the payment methodology. The regulation proposes the methodology payers must use to determine cost sharing and the QPA, information payers must share with out-of-network providers, the process for submitting and receiving consumer complaints, and the format and details of the notice and consent requirements.

Stakeholders will have 60 days to comment on the IFR once it is published in the *Federal Register*. The Departments will issue the No Surprises Act regulations in several phases. The second regulation should be published by October 1, 2021, and will establish a payer audit process. The third regulation should be published by December 27, 2021, and will detail the independent resolution dispute process and patient transparency provisions.

Key Takeaways

The IFR:

- Establishes the methodology for calculating the QPA, including further defining the similar items and services, providers and facilities, and geographic regions that will be used for calculating a median rate, and the methodology for arranging contracted rates to determine a median

amount. The IFR adds new methodologies for calculating the QPA for air ambulance and anesthesia services.

- Broadens the definitions of emergency services and emergency medical conditions and prevents payers from limiting coverage based on the final diagnosis code alone or general policy exclusions.

- Clarifies that consumers' cost sharing will be based on an all-payer model agreement amount. If this amount is not available, cost sharing will be determined by existing state law, then by the lessor of the billed charge or the QPA.

- Requires payers to disclose to nonparticipating providers the QPA for each item or service involved and, upon request, information regarding whether the QPA was based on an underlying fee schedule or derived amount, any alternative service codes or eligible databases, and whether any contracted rates were not set on a fee-for-service basis.

- Requires payers to act in a timely fashion in issuing an initial payment or notice of denial of payment. The initial payment must reflect what the payer considers to be payment in full. The notice of denial of payment does not include denials due to adverse benefit determinations.

- Begins to outline the consumer complaint processes for reporting payer and provider violations and notes that these processes may be expanded.

- Establishes the content, language and timing standards related to notice and consent forms and how these forms must be delivered. The Departments did not expand the exceptions to providing notice and consent.

- Gives states wide discretion in implementing All-Payer Claims Databases. These databases will be considered categorically eligible to serve as a resource for calculating the QPA.

- Clarifies that the No Surprises Act is not intended to displace states' balance billing laws and that the Departments are exploring options for providing more flexibility for state laws to apply.

Key Resources

- Interim Final Rule with Comment
- Fact Sheet One
- Fact Sheet Two
- Press Release
- Model Disclosure and Notice

Background

On December 27, 2020, former President Trump signed into the law the Consolidated Appropriations Act, 2021, which included the No Surprises Act, legislation that bars surprise billing in most healthcare settings and establishes new transparency requirements.

Surprise medical billing describes a situation when an insured patient unknowingly receives care from an out-of-network provider and then is presented with a bill for services and payment obligation beyond what the patient's insurer will cover. Surprise medical bills can arise in an emergency when the patient has no or limited ability to select the facility or provider rendering services. Surprise bills can also arise when a patient receives planned care, such as when a patient receives care at an in-network facility but later finds out that a provider who treated the patient is out-of-network.

Under the law, group health plans and insurers and providers (including hospitals, facilities, individual practitioners and air ambulance providers) are prohibited from billing patients more than in-network cost-sharing amounts in specified circumstances. The prohibition applies to both emergency care and certain non-emergency situations where patients do not have the ability to choose an in-network provider.

The law establishes a pathway for resolving payer-provider payment disputes using negotiation and arbitration. The IDR process requires each party to submit a final payment offer, and the arbiter will select one of these offers as the final payment amount (commonly referred to as "baseball style" arbitration). In selecting the final payment, arbiters must weigh certain factors, but are banned from considering the lower payment rates paid by federal government programs (*i.e.*, Medicare and Medicaid).

The No Surprises Act is effective beginning January 1, 2022. To implement the provisions of the law, Congress tasked HHS and the US Departments of Treasury and Labor with developing regulations by three milestones. The first of these regulations was published as an IFR on July 1, 2021, entitled Requirements Related to Surprise Billing; Part I.

This IFR establishes regulations defining the payment methodology. Specifically, the regulation establishes the methodology plans must use to determine cost-sharing and the QPA, information the plan must share with the out-of-network facility or provider, the process to receive complaints, and format and details of the notice and consent requirements.

Stakeholders will have 60 days to comment on the rule once it is published in the *Federal Register*.

The Departments will issue the No Surprises Act regulations in several phases. The second regulation should be published by October 1, 2021, and will establish a payer audit process. The third regulation should be published by December 27, 2021, and will detail the independent resolution dispute process and patient transparency provisions.

This summary highlights key provisions of the Requirements Related to Surprise Billing; Part I IFR.

QUALIFYING PAYMENT AMOUNT

Background

Under the law, when an insured patient receives emergency care and certain non-emergency services from an out-of-network provider, the patient's cost sharing obligation will be capped at amounts that would apply if the services had been furnished by a participating provider. The nonparticipating provider is prohibited from billing the patient or holding that patient responsible for costs beyond the in-network cost sharing. The statute provides that the patient's cost sharing liability will be: an amount determined by an applicable All-Payer Model Agreement; an amount defined under state law, where applicable; or the QPA, which generally is the median contracted rate recognized by the plan or issuer as provided in 2019 for the same or a similar item or service, by a similar provider in the same geographic region. This amount will be increased annually based on the Consumer Price Index for All Urban Consumers (CPI-U). Congress tasked the agencies with further defining and shaping the QPA through regulation.

How the QPA is defined and implemented is significant to plans and providers, and was one of the most anxiously awaited aspects of this rule, because it influences consumers' cost sharing, influences payments to providers, and will be considered by arbiters in determining payment during disputes. In pre-rulemaking comments, provider groups recommended that the QPA be based on actual amounts paid to providers and reflect amounts for comparable services only (*e.g.*, "like" facilities and geographies).

Regulation Provision

As outlined in the No Surprises Act, the QPA is generally defined as the median contracted rate in 2019 for the same or similar item or service, offered by a similar provider or facility type, in the same geographic region. Descriptions of these terms can be found in the "Definitions" section.

Calculating the Median Rate: Under the new regulations, to calculate the median rate, the same or similar contracted rates for all plans in the same insurance market will be arranged from least to greatest, with each contracted rate representing a single data point. Contracted rates through third parties are to be included. If payments are not made on a fee-for-service basis, the contracted rate for a particular item or service will be based on the underlying fee schedule or derived amount. The derived amount is the price the payer assigns to the item or service for purposes of internal accounting, reconciliation or data submission. The calculations will exclude any risk sharing, bonuses, penalties, or other incentive-based or retrospective payments.

Indexing: The median contracted rate will then be indexed to calculate the QPA. Beginning in 2022, the median rate will be based on the median contracted rate on January 31, 2019, increased by the percentage increase in CPI-U over 2019, 2020 and 2021. For 2023 and beyond, a payer must calculate the QPA by increasing the QPA for an item or service furnished in the immediately preceding year by the annual percentage increase published

by Treasury and the Internal Revenue Service. The IFR details how the percentage increase in CPI-U will be calculated to ensure that all payers adjust the percentage in a uniform manner.

Sufficient Information: For 2019, a payer is considered to have sufficient information if it had at least three contracted rates on January 31, 2019, to calculate the median rate according to the methodology described. The Departments believe that three contracts are the minimum necessary to reflect market negotiations. A payer that does not initially have sufficient information, but later gains sufficient information, must calculate the QPA using the first sufficient information year.

For 2022 and beyond, a payer will be considered to have sufficient information if (1) the payer has at least three contracted rates on January 31 of the immediately preceding year, and (2) the contracted rates account for at least 25% of the total number of claims paid for the specific item or service for that year with respect to all plans offered by the payer in the same insurance market. This 25% minimum claims volume requirement applies only where contracted rates for a year after 2019 are used to determine whether there is sufficient information to calculate a median in the first sufficient information year. The Departments included this volume requirement to ensure that contracted rates after 2019 represent a reasonable portion of payers' total claims. The Departments believe this will dissuade payers from engaging in selective contracting practices that might otherwise be used to "artificially change" the median rate used to determine the QPA.

New Plans: If a payer did not offer a plan in the geographic region in 2019 (*i.e.*, it is a "new plan") and it has insufficient information to calculate the median rate, a modified approach will be used. During 2022, new plans must identify the rate that is equal to the median of the in-network allowed amount for the same or similar item or service provided in the geographic region in the immediately preceding year, as determined by use of any eligible database. This amount must then be increased by the CPI-U percentage increase. Where an eligible database is used, the payer must use the same database for that item or service through the last day of the calendar year. For subsequent years (*i.e.*, before the first sufficient information year is established), the QPA will be calculated by increasing the QPA determined in the immediately preceding year by the CPI-U percentage increase. Payments for items and services rendered in and after the first sufficient information year will then be based on the standard methodology for calculating the QPA.

New Service Codes: If a payer does not have sufficient information to calculate the median rate because an item or service is billed under a new code, the payer must look to an established Medicare rate or related service code. For 2022 (or the first year of coverage for an item or service), the payer must identify a related service code that existed in the preceding year. If there is an established Medicare rate for the item or service under the new code, the payer must calculate the rate Medicare pays under the new code compared to what Medicare pays under the related code. The payer must then multiply this ratio by the QPA for the item or service under the related code. If there is not an established Medicare rate under the new code, the payer must calculate the ratio of what the payer reimburses for the item or service under the new code compared to what it reimburses under the related code, and multiply this

ratio by the billed amount under the related code. For subsequent years, the payer must calculate the QPA by increasing the QPA determined in the immediately preceding year by the CPI-U percentage increase, until the first sufficient information year is established.

The IFR also includes special methodologies for determining QPA for anesthesia and air ambulance services (as discussed below).

Implications

Many provider groups advocated that the QPA be based on actual paid claims amounts, since those amounts reflect what payers have historically been willing to offer, and providers have been willing to accept, for a given item or service. Providers further asserted that some providers accept certain contract rates for services they do not frequently or ever perform without negotiation. Providers worried that this methodology would negatively skew the QPA.

Instead, the QPA methodology will be based on contracted amounts and will not take into account amounts paid. Providers may feel that this approach does not adequately capture the true cost of care and may place too strong an emphasis on contracted rates that are agreed to based on a wide range of factors. Since the QPA influences cost sharing and ultimate payment, stakeholders will likely comment on these provisions. The Departments seek comment on all aspects of the methodology, including any factors that have not been accounted for; whether additional guidance is needed; and the impact of the methodology on cost sharing, payment amounts and provider network participation.

EMERGENCY SERVICES AND POST-STABILIZATION SERVICES

Background

The No Surprises Act prohibits providers and payers from balance billing patients for emergency services, regardless of the in-network or out-of-network status of the facility or treating provider. Emergency services can include items and services provided to patients after they are stabilized and as part of outpatient observation, or as part of an inpatient stay or outpatient visit that is connected to the original emergency visit, unless certain conditions are met. The patient is only responsible for the cost-sharing amount that would apply if the services had been provided at in-network facility and in-network provider.

Regulation Provision

The IFR adds clarity to the definition of emergency services. The IFR defines “emergency medical condition” to mean a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that a prudent layperson could reasonably expect the absence of immediate medical attention to result in (1) placing the health of the individual in serious jeopardy, (2) serious impairment to bodily functions, or (3) serious dysfunction of any bodily organ or part. This definition includes mental health conditions and substance use disorders.

The IFR specifies that payers must cover emergency services without limiting what constitutes an emergency medical condition solely on the basis of diagnosis codes. When a payer denies coverage of an emergency service, the determination of whether the prudent layperson standard has been met must be based on all pertinent documentation and be focused on the presenting symptoms.

The IFR identifies that post-stabilization services also are emergency services, unless all of the following conditions are met:

- The treating provider must determine that the patient is able to travel using nonmedical transportation to an available participating provider located within a reasonable travel distance.
- The provider furnishing post-stabilization services must satisfy the notice and consent criteria.
- The individual (or authorizing representative) must be in a condition to receive the information in the notice.
- The provider must satisfy any additional requirements or prohibitions as may be imposed under applicable state law.

Implications

The use of the prudent layperson definition in determining whether a service is an emergency service reflects an expansive view to protect patients against surprise billing. The Departments note that they are aware of instances in which payers currently deny coverage of services provided in an emergency department based solely on the final diagnosis code, sometimes without consideration of an individual's presenting symptoms. The Departments explain that this approach, as well as denial of emergency services based on general plan exclusions, is "inconsistent" with the requirements of the Affordable Care Act and the No Surprises Act. By expanding the definition of emergency services, the Administration seeks to prevent activities that may circumvent coverage in emergency situations. It is not clear whether the scope of the prudent layperson standard applies to air ambulance providers, since the Departments did not explicitly make reference to these providers when defining emergency services.

METHODOLOGY FOR DETERMINING COST SHARING

Background

Under the No Surprises Act, cost sharing for emergency services provided at an out-of-network emergency facility and for non-emergency services provided by out-of-network providers in an in-network facility must be calculated as if the services were provided by in-network facilities and providers. Patient cost sharing cannot be greater than the recognized amount and will count toward any in-network deductible or out-of-pocket maximums. The recognized amount may be determined by either (1) an All-Payer Model Agreement or (2) existing state law or regulation, or if no All-Payer Model Agreement or state law is in place, (3) the lesser of the billed amount or the QPA.

Regulation Provision

The IFR largely adopts the statutory language with few additions. The regulation clarifies that cost sharing will be equal to the recognized amount for such services based on the All-Payer amount, existing state law, or the lesser of the billed amount or QPA. Where a payer does not have an established cost-sharing requirement that applies to participating providers, the payer must calculate the cost-sharing amount using the generally applicable cost-sharing requirement under the plan or coverage.

For air ambulance services, the recognized amount will not be used to determine cost sharing. Instead, cost sharing will be the same as if the services had been provided by a participating provider. Payers must base consumers' coinsurance and deductibles for air ambulance services provided by nonparticipating providers on the lesser of the QPA or billed amount.

Implications

By tying cost sharing to the recognized amount instead of the amount that payers reimburse nonparticipating providers and facilities, the Departments seek to limit the financial burden of payer-provider disputes on consumers' cost sharing. This structure allows payers and providers to determine the final payment amount separately without involving or affecting the amount that consumers must pay out of pocket. The Departments seek comment on alternate approaches for calculating the cost-sharing amount for air ambulance services provided by out-of-network providers.

PAYER DISCLOSURES: SURPRISE BILLING REQUIREMENTS AND QUALIFYING PAYMENT AMOUNT

Background

The No Surprises Act requires that payers make publicly available, post on their public website and include in their explanation of benefits a description of the prohibitions related to surprise billing and the circumstances in which they apply. These disclosures must include any additional state-based requirements regarding the amounts that providers may charge consumers. Payers must also provide information on how consumers may contact state and federal agencies if they believe that a provider has violated any of the surprise billing requirements. Additionally, the law directs the Departments to specify the information that payers must share with nonparticipating providers when making a determination of the QPA.

Regulation Provisions

The IFR incorporates the law's language on payer disclosures of the surprise billing requirements, and the Departments note that HHS will develop a model notice to satisfy this requirement.

The IFR outlines the information that payers must disclose to nonparticipating providers regarding the QPA, which includes (1) the QPA for each item or service involved, and (2) a statement that the QPA applies for purposes of the recognized amount

and that each QPA shared was determined in compliance with the IFR's methodology. Payers must include in the disclosure a statement that if the provider wishes to initiate the negotiation period for the payment amount, it may contact the payer to do so. The disclosure must explain that if negotiation fails, the provider may initiate IDR. Payers must include appropriate contact information in the disclosure.

Upon request by the provider, a payer must provide information about whether the QPA includes contracted rates that were not set on a fee-for-service basis and whether the QPA was determined using underlying fee schedule rates or a derived amount. If the payer used a related service code or an alternative eligible database in its QPA calculations, it must identify the code or database used. Finally, the payer, upon request, must provide a statement that the payer'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.

Implications

Information contained in the payer disclosures will give providers greater clarity on how the payment amount was reached and whether they should pursue IDR. For example, by requiring payers to disclose the QPA, providers will know that neither the All-Payer nor state law amount applies for calculating a consumer's cost sharing. The Departments expect that when the QPA serves as the basis for the recognized amount, the federal IDR process will likely govern. Therefore, the disclosure serves as early notice that providers are likely to enter the federal IDR process if a payment amount cannot be reached. In negotiations or IDR, payers and providers will share a greater balance of information, which may help to expedite a resolution.

INITIAL PAYMENT AND NOTICE OF DENIAL OF PAYMENT

Background

The No Surprises Act requires payers to send an initial payment or notice of denial of payment not later than 30 days after a provider submits a claim that falls within the scope of the law. Following this 30-day period, either party may initiate the negotiation phase and later reach IDR.

This requirement sparked many comments from stakeholders. Some providers expressed concern that payers may not take definitive action within the 30-day period, thereby delaying the negotiation and IDR stages. Some stakeholders asked whether an initial payment must be a certain minimum amount. Others questioned whether an adverse benefit determination or a zero dollar payment constitutes a notice of denial of payment.

Regulation Provisions

The IFR reiterates that payers must send either an initial payment or notice of denial of payment not later than 30 days after the bill for service is transmitted. The regulation does not add to this requirement, but the Departments clarify their expectations related to each point stakeholders raised.

First, the Departments note that the requirement for payers to act within 30 days is one of the procedural requirements in the Act that must be resolved "in a timely fashion." Since payers cannot make a determination until they have a clean claim and information on whether the provider gave and obtained proper notice and consent, where applicable, the Departments encourage providers to include in their claim forms information on whether the surprise billing protections apply. The Departments expect payers to act in good faith when requesting additional information necessary for a claim determination. If the Departments become aware of payers abusing or gaming this process in order to delay payments or notifications, the Departments may impose additional standards.

Second, the Departments do not establish a minimum initial payment amount, but explain that this amount should represent what the payer reasonably believes to be payment in full, and that this amount should not be considered a first installment.

Third, the Departments clarify that a notice of denial of payment means a written notice from the payer to provider that payment will not be made, with an explanation of the reason for denial. "Notice of denial of payment" does not include a notice of benefit denial due to an adverse benefit determination (i.e., a denial of coverage in whole or in part). The Departments note that there is a "significant distinction" between an adverse benefit determination, which may be disputed through a payer's internal appeals process, and a denial of payment or initial payment that is for less than the billed amount, which may be disputed through negotiation or IDR. The Departments distinguish these pathways as follows:

- If adjudication of a claim leaves a consumer personally liable to the provider, this may be an adverse benefit determination that can be resolved through the payer's appeals process.
- If adjudication of a claim does not affect the amount the consumer owes, the dispute involves only the payment amount due from the plan to the provider, and the provider has no recourse against the consumer, then the decision is not an adverse benefit decision. This decision may be disputed through negotiation and IDR.

The Departments acknowledge that this approach creates the possibility that a consumer may appeal an adverse benefit determination through a payer's internal processes at the same time a provider challenges the payment amount through IDR.

Implications

The requirement that payers take action within 30 days helps to ensure that payment disputes will be resolved in a timely manner, consistent with congressional intent. By not imposing an enforcement mechanism for this requirement, however, the Departments seem to acknowledge some flexibility in the process. They note that payers cannot comply with the requirement unless providers submit complete information and, therefore, hold payers to a good faith standard in requesting additional information to perfect a claim. This approach gives payers time to make their determination but may prolong the period before negotiation may be initiated. The Departments seek comment on whether additional standards are necessary to prevent abusive claims payment practices.

Although the Departments did not establish a minimum initial payment amount, they requested comment on whether a minimum rate or methodology should be established in future rulemaking. The clarification that the initial amount reflects what payers consider to be payment in full may allow parties to start negotiations with less disagreement, closing the gap between the amounts offered and saving time in resolving disputes.

The Departments' approach to what constitutes a notice of denial of payment is likely to spark comment from providers. Because adverse benefit determinations are excluded from the definition of notice of denial, some providers that render services only to have those claims later denied as non-emergent or non-necessary may have few avenues for obtaining reimbursement. Consumers may continue to receive surprise medical bills in these situations.

PROCESSES FOR RECEIVING CONSUMER COMPLAINTS

Background

To inform patients and consumers about the new law, the No Surprises Act requires plans, healthcare providers and facilities to make and post notices about the new requirements related to surprise billing. The Act also requires the Departments to establish a process to receive consumer complaints regarding violations of payers' application of the QPA, and directs HHS to establish a parallel complaints process for consumer complaints related to providers' violations of the balance billing requirements. The Act requires HHS to respond to consumers' provider-related complaints within 60 days of receipt.

Regulation Provisions

To reduce burden and facilitate compliance with the disclosure requirements, the Departments are concurrently issuing a model disclosure notice that healthcare providers, facilities, group health plans and health insurance issuers may (but are not required to) use to satisfy the disclosure requirements regarding the balance billing protections. The IFR outlines the requirements and procedures related to the consumer complaint processes. Under the IFR, a complaint can be a written or oral communication that indicates that there has been a potential violation by a payer or provider. The complaint will be considered to be filed on the date on which the Departments receive enough information to identify the parties involved and the subject of the complaint. This information may include the timing of the alleged violation and the state where the alleged violation occurred. The IFR does not establish a time period within which a complaint must be filed, and the Departments seek comment on an appropriate timeframe for submitting a complaint.

Rather than establish separate complaint systems, the IFR intends to provide one system that will direct complaints to the appropriate Department for consideration and enforcement action if necessary. The IFR imposes the same 60-day period for the Departments to respond to potential payer violations and grants the Departments the ability to request additional information necessary to process a complaint. The IFR states that the Departments will make reasonable efforts to notify the complainant of the outcome of any investigation or

enforcement action, but it does not require notification to be given. The Departments seek comment on whether complainants should receive notification of the final outcome of the complaint.

The Departments also expressed a desire to extend the payer complaints process to all consumer protection and balance billing requirements, rather than restricting the process to QPA application alone. The Departments requested comment on whether to expand this process.

Implications

While the IFR begins to establish the guardrails for the complaints processes, many details have not been finalized. The Departments intend to issue guidance on how to file a complaint, and HHS expects to shoulder most of the administrative burden for managing the process. At this time, it is unclear how many consumers may go through the process of filing a complaint, whether consumers will be notified of the investigation results, how long it will take the Departments to conduct and conclude an investigation, and what consequences may arise if a payer or provider is found to have violated the Act.

Although these processes are intended to provide consumers an avenue for submitting complaints, it is not clear whether payers or providers may also take advantage of the complaint system to advance complaints against one another. The IFR notes that payers may submit complaints against providers, but it does not address whether providers may use the system to submit complaints against payers. The Departments seem to express an interest in providing one system for all complaints, but additional guidance may be needed to clarify which parties have access to the process. At a minimum, the Departments' annual audits will take into account any complaints received, including those from payers and providers.

PROVIDER NOTICE AND CONSENT

Background

The No Surprises Act provides exceptions to the balance billing protections for non-emergency services if the patient is given notice and consents to be financially liable for out-of-network financial obligations. This exception does not apply to certain ancillary services.

Providers that are eligible to request a consent waiver must include a written notice to the patient not later than 72 hours before the date on which the items or services are provided. This notice must include the following information:

- Notification that the provider or facility is out-of-network
- Clear statement that consent is optional and the patient can seek care from an in-network provider
- Good faith estimate of the amount the patient may be charged
- If the service is to be furnished by an out-of-network provider in an in-network facility, a list of in-network providers that are able to provide the service
- Information on whether prior authorization is needed.

Once the patient receives the notice, she has the option to consent. The notice must be signed by the patient where the patient acknowledges that he was provided with written notice and informed about the payment and how it may affect cost-sharing. The consent must include the date on which the patient received the notice and the date on which the patient signed the consent. The provider must retain the consent for seven years and must timely notify the payer as to whether balance billing and in-network cost sharing protections apply to the item or service.

The Departments were tasked with issuing guidance on the format and details of the notice and consent requirements, and with defining which services are subject to these balance billing exceptions. Stakeholders raised several technical and practical questions regarding the notice and consent requirement, including which entity is responsible for engaging consumers in coverage and cost discussions, how the federal notice will interact with state-based notice and consent requirements, and whether the forms must follow a prescribed format. Stakeholders offered suggestions on what type of information should be included in the notice and how the notice and consent process should be managed for out-of-network providers.

Regulation Provisions

The IFR outlines the requirements related to the content, method and timing of the notice and consent communications; requirements related to language access; exceptions to the applicability of the notice and consent process; requirements for the retention of notice and consent documents; and requirements to notify the payer regarding consent provided by the patient. The IFR provides substantial detail on each of these components. For example, in addition to the requirement that a patient receive notice not later than 72 hours before the date on which the items or services are provided, it provides that if an individual schedules an appointment and is provided notice on the same day of the appointment, this notice must be given at least three hours prior to furnishing services.

Similar to ancillary services, which may not use the notice and consent exception, the exception is not available for 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 otherwise satisfied the notice and consent criteria.

The Departments seeks comment on other ancillary services that should be considered to be made ineligible for the notice and consent exception and what criteria should be considered in determining whether an advanced diagnostic laboratory test should be excepted from the definition.

Implications

The Departments' goal in implementing the notice and consent provisions is to ensure that individuals are able to maintain provider choice and that they are not pressured into waiving the balance billing protections and then unwittingly receive a balance bill. The IFR establishes many of the standards for implementing the notice and consent requirement and suggests that more guidance is to come, including a standard template notice from HHS that

will contain all of the necessary elements for satisfying notice. At a minimum, the regulation will require providers to develop a system for coordinating outreach to patients, organizing and retaining the notices, and notifying payers of whether balance billing and in-network cost sharing protections apply. Payers must then use this information to assign cost sharing and adjudicate the claim in compliance with the law. Implementing this aspect of the law will require increased collaboration between payers and providers.

AIR AMBULANCE SERVICES

Background

The No Surprises Act applies the same consumer protections to services rendered by nonparticipating air ambulance providers, including that patient cost sharing for such services must be the same as if the services had been furnished by a participating air ambulance provider, that cost-sharing amounts must count towards in-network deductibles and out-of-pocket maximums, and that parties may ultimately resolve payment disputes in IDR. The Act distinguishes air ambulance providers from all other healthcare providers, but applies a similar methodology for calculating the QPA, conducting IDR and disclosing balance billing protections to consumers.

Regulation Provisions

The IFR uses a different methodology for calculating the QPA for air ambulance services and treats air ambulance services differently in defining geographic regions. Typically, payers reimburse air ambulance providers, at least in part, using air mileage service codes and taking into account the number of miles that an individual is transported (referred to as “loaded miles”). The final payment amount is calculated by multiplying the negotiated rate for these service codes (known as the “air mileage rates”) by the number of loaded miles. Recognizing that this is the standard method of reimbursement in the air ambulance industry, the Departments include in the IFR a unique methodology for calculating the QPA for these service codes. For 2022, the QPA for these codes will be determined by increasing the median contracted rate by the CPI-U, then multiplying this indexed median air ambulance rate by the number of loaded miles. For 2023 and beyond, payers must increase the median air ambulance mileage rate determined by services furnished in the immediately preceding year, and then multiply this amount by the number of loaded miles.

The geographic region used to calculate the QPA also is defined differently for air ambulance providers, since these services often involve rendering care across state lines. Geographic region means one region consisting of all metropolitan statistical areas in the state and one region consisting of all other portions of the state, determined based on the point of patient pick-up. If a payer does not have sufficient information to calculate the median based on this definition, geographic region will instead mean one region consisting of all metropolitan statistical areas in each Census division and one region consisting of all other portions of the Census division, determined based on the point of pick-up.

The IFR also requires payers to base any coinsurance and deductible amounts for air ambulance services provided by nonparticipating providers of the lesser of the QPA or the billed amount. The Departments believe this is consistent with the Act's intent to protect consumers from excessive bills and to remove patients from payer-provider disputes. However, they seek comment on alternative approaches for calculating cost sharing for air ambulance services provided by nonparticipating providers.

Implications

The modified methodology for calculating the QPA and defining geographic region better account for the nature of air ambulance services, by taking into account miles traveled and the broader region in which services are provided. However, providers of air ambulance services may feel that these distinctions do not go far enough. For example, the Departments acknowledged that hospital-based and non-hospital-based air ambulance providers often have different contracted rates, yet the Departments declined to offer an avenue for these median rates to be calculated separately. Instead, the Departments consider all air ambulance providers to be of the same specialty and type for purposes of the QPA. This approach may tie some air ambulance providers to a median contracted rate that is not reflective of their true costs.

ANESTHESIA SERVICES

Background

The No Surprises Act includes anesthesiology services in the definition of ancillary services and clarifies that anesthesiology services are not eligible for the notice and consent exception (*i.e.*, they may not balance bill, even with the patient's consent). The anesthesia community sought to allow anesthesiologists who furnish pain management services to use the notice and consent exception, noting that there are circumstances in which patients knowingly seek out-of-network care on a non-emergent basis. In these situations, anesthesiologists believe it would be fair to balance bill. Anesthesiologists also noted that their existing reimbursement structure for anesthesia services does not align well with the QPA methodology described under the law.

Regulation Provisions

The IFR reaffirms that anesthesiology services are included in the definition of ancillary services, and does not explicitly establish an exception for pain management services, but the absence of that clarification does not necessarily signal a deliberated decision on this issue.

The IFR adds a unique methodology for calculating the QPA for anesthesia services. Payers typically reimburse for anesthesia services by multiplying the anesthesia conversion factor (*i.e.*, the negotiated rate to which the payer and anesthesiologist agree) by the base unit for the particular anesthesia code, the time unit measured in 15-minute increments, and a physical status modifier, which accounts for the status of the patient and the service complexity. The IFR refines the QPA methodology with respect to

anesthesia services to account for this structure. For 2022, payers must calculate the QPA for anesthesia services by increasing the median contracted anesthesia conversion factor to account for changes in the CPI-U, then multiplying this rate by the sum of the base, time and physical status modifier units. For 2023 and beyond, payers must increase the indexed median rate for the anesthesia conversion factor determined in the immediately preceding year to account for the percentage increase in the CPI-U.

Implications

The modified QPA methodology for anesthesia services will alleviate some of the administrative burden on anesthesiology groups in implementing the law. This approach aligns with the reimbursement scheme that payers and anesthesiologists use today, and makes it easier for parties to identify the median and resolve payment disputes using the same terminology in IDR.

ALL-PAYER CLAIMS DATABASES & DEFAULT DATABASES

Background

The No Surprises Act directs the Secretary to make one-time grants available to states for the purposes of establishing or improving an existing All-Payer Claims Database (APCD). The Act defines the grant periods and amounts, describes the requirements for applying for funding and establishes standards for data reporting. APCDs play a meaningful role in the No Surprises Act because they are one measure by which the recognized amount and out-of-network rates are calculated and, when there is insufficient information to calculate a median contracted rate, APCDs may be used as a default database for calculating this amount.

Given the emphasis placed on APCDs, stakeholders commented that parties should have greater access to APCD data; states should work to improve the quality of the data contained in APCDs; and, if APCDs are used as a default for calculating the QPA, only commercial claims should be used in the calculations (*i.e.*, public payer amounts should be excluded). Stakeholders requested clarification on when a default database may be used and what constitutes "insufficient information" for calculating the QPA.

Regulation Provisions

The Departments express that it is important to "maximally preserve" states' abilities to test all-payer payment reforms and, therefore, will grant states flexibility to determine:

- The circumstances under which, and how, they approve an amount for an item or service
- Whether participation is voluntary or mandatory for a given payer
- Whether the reforms apply statewide or only in certain regions
- Whether payments under the reform apply only to certain providers or facilities and certain items or services.

The IFR clarifies that for an APCD to be used in determining the recognized amount or out-of-network rate, the APCD Agreement must apply to (1) the payer and coverage involved, (2) the

nonparticipating provider or facility involved, and (3) the item or service involved.

The IFR also establishes the standards by which default or "eligible" databases may be used in calculating the QPA. The Departments note that APCDs are "categorically eligible" to serve as these databases because they have no conflicts of interest and have sufficient information. Other third-party databases may be eligible if they satisfy the following conditions:

- The database or organization maintaining the database cannot be affiliated with, or owned or controlled by, any payer or provider, or any member of the same controlled group as, or under common control with, any such entity.
- The database must have sufficient information reflecting in-network amounts paid.
- The database must have the ability to distinguish amounts paid to participating providers by commercial payers from all other claims data (*i.e.*, public payers).

The Departments did not establish a specific definition for when a database is considered to have sufficient information. The Departments seek comment on how to define this threshold. They also seek comment on ways to ensure that payers are charged only reasonable costs for accessing the databases.

Implications

The Departments grant states broad discretion in designing APCDs, which may spark concern from some stakeholders. Some stakeholders believe that data in some existing APCDs is not reflective of market realities and may be both under- and over-inclusive regarding the types of payment arrangements included. Since APCDs are considered "categorically eligible" to serve as a backstop for QPA calculations, stakeholders will want to ensure that APCD data is comprehensive, accurate and accessible. Stakeholders have some opportunity to shape what third-party databases may be considered eligible by offering comments on how the sufficient information threshold may be defined.

INTERACTION OF FEDERAL AND STATE LAWS

Background

Prior to the No Surprises Act, several states had enacted comprehensive surprise billing laws. The federal law defers to existing state requirements with respect to state-established payment amounts, meaning that the No Surprises Act does not fully preempt or otherwise displace state payment standards. States can also continue to pass surprise billing laws and regulations in the future.

The interaction of state and federal balance billing laws has raised many questions. For example, a specified state law may be used to determine consumers' cost sharing and out-of-network rates if an APCD is not applicable. Stakeholders have asked when a law qualifies as a "specified state law" and whether there is a minimum standard for defaulting to a state's balance billing structure. Some stakeholders have advocated that when a state's balance billing law is limited, for instance, it creates only a voluntary IDR process, that parties should have access to through the federal IDR process. Other stakeholders requested guidance on how

patients, payers and providers should navigate the different federal and state regulatory schemes.

Regulation Provisions

The Departments clarify in the IFR that the No Surprises Act "supplement[s], rather than supplant[s]" state balance billing laws. The Departments interpret the federal law as creating a floor for consumer protections, and they will defer to states where a higher standard is imposed. The Departments explained that they believe Congress did not intend for the No Surprises Act to preempt states' balance billing laws that address issues beyond how to calculate cost sharing and out-of-network rates. To the extent that state laws do not prevent application of the federal law, state laws will be considered consistent with the No Surprises Act and not preempted.

The IFR defines "specified state law" to mean a state law that provides for a method for determining the total amount payable under a group health plan to the extent such state law applies for an item or service furnished by a nonparticipating provider or nonparticipating emergency facility. For a state law to be used in determining the recognized amount or out-of-network rate, the law must apply to (1) the payer and coverage involved, (2) the nonparticipating provider or facility involved, and (3) the item or service involved. Where a state law does not satisfy these criteria, the state law will not apply to determine the recognized amount or out-of-network rate. A group health plan that opts in to the specified state law must do so for all the items and services to which the law applies and must prominently display in its plan materials that it has opted into the state law.

The IFR also allows self-insured plans to voluntarily opt in to a state law that provides a method for determining cost sharing and payment. Plans that opt in to the state law will satisfy their obligations under the Act. Currently, only four states allow self-insured plans to opt in: Nevada, New Jersey, Virginia and Washington.

Implications

While the IFR provides some guidance on what constitutes a specified state law, it remains unclear how the federal and state balance billing laws will interact and how patients, payers and providers will navigate the complex schemes. For organizations that provide services across multiple states, this approach is likely to create a patchwork of varying laws that may be difficult to track and with which to ensure compliance. The Departments have requested comment on whether payers, such as ERISA-governed self-funded group plans, and providers should have the ability to opt in to state laws even in instances where they are not otherwise subject to the specified state laws. Although the Departments expressed interest in providing more flexibility for state laws to apply, they also raised concern that providers may selectively opt in to state law programs that have more favorable out-of-network rates. Additional analysis is needed to determine what state laws will qualify under the Departments' threshold, and the Departments are likely to issue further guidance on the interaction of federal and state laws.

With regard to payers and the implication of state laws, states generally cannot regulate self-funded group health plans or require these plans to comply with state

surprise medical bill protections because of ERISA preemption. Because state surprise billing protections likely result in cost savings to employers that sponsor ERISA plans, some states have avoided ERISA preemption challenges by making such state laws optional for self-funded plans. Not surprisingly, many employers sponsoring self-funded ERISA plans have opted into these state laws in an effort to curtail costs and avoid surprise billing for their employees.

The No Surprises Act does not disturb the long-standing preemption of state laws as they apply to group health plans under ERISA, nor does it appear to disrupt states' ability to offer self-funded plans the ability to opt in to such state laws. Therefore, self-funded group health plans will be subject to the No Surprises Act but not state surprise medical bill laws, unless the employer has opted in.

The No Surprises Act adopts the long-standing preemption framework that was first adopted under the Health Insurance Portability and Accountability Act and continued under the Affordable Care Act. This framework, in Section 2724 of the Public Health Service Act, addresses the potential preemption of state laws that regulate insurers that offer fully insured individual and group plans. State laws are preempted only when those laws impose a requirement that "prevents the application" of the No Surprises Act. As a result, state laws can generally exceed standards in the No Surprises Act by adopting heightened standards that are more protective of consumers. But state laws cannot impose requirements that undermine or prevent the operation of the No Surprises Act. According to the IFR, the Departments view the current surprise medical billing laws established by states as consistent with the statutory framework of the No Surprises Act, and therefore these laws would not be preempted.

Given this framework, state laws that differ from the No Surprises Act are not necessarily preempted by the new law and could continue to apply. Some states, for instance, do not allow patients to consent to waiving surprise medical bill protections; others include a broader scope of providers in state law compared to the No Surprises Act. These could be examples of state laws deemed more protective than the No Surprises Act and thus not preempted.

DEFINITIONS

The IFR adds to many of the law's defined terms relevant to implementation and compliance. The following are general definitions of key terms in the law. Please refer to the law itself for a specific understanding of defined terms. The Departments seek comment on the terms as defined, including the appropriateness and usability of the definitions, and whether additional terms should be defined in future rulemaking.

Air ambulance service: Medical transport by a rotary wing air ambulance or fixed wing air ambulance for patient.

Ancillary services: Items and services provided at an in-network facility that are related to emergency medicine, anesthesiology, pathology, radiology and neonatology, whether or not provided by a physician or non-physician practitioner, and items and services provided by assistant surgeons, hospitalists and intensivists; diagnostic services

(including radiology and laboratory services); items and services provided by a nonparticipating provider if there is no participating provider who can furnish such item or service at such facility; and other items and services provided by such other specialty practitioners, as HHS specifies through rulemaking.

***Contracted rate**:* The total amount (including cost sharing) that a group health plan has contractually agreed to pay a participating provider, facility or provider of air ambulance services for covered items and services, whether directly or indirectly, including through a third-party administrator or pharmacy benefit manager. A single case agreement, letter of agreement or other similar arrangement between a provider, facility or air ambulance provider and a plan, used to supplement the network of the plan for a specific participant or beneficiary in unique circumstances, does not constitute a contract.

Cost sharing: Generally includes copayments, coinsurance and amounts paid towards deductibles, but does not include amounts paid towards premiums, balance billing by out-of-network providers, or the costs of items/services that are not covered by a payer.

Emergency department of a hospital: Hospital outpatient department that provides emergency services.

Emergency medical condition: A medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that a prudent layperson, who possesses an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in: 1) placing the health of the individual in serious jeopardy, 2) serious impairment to bodily functions, or 3) serious dysfunction of any bodily organ or part. This definition includes mental health conditions and substance use disorders.

Emergency services: An appropriate medical screening examination that is within the capability of a hospital's emergency department or of an independent freestanding emergency department, including ancillary services routinely available to the emergency department to evaluate such conditions. Emergency services can also include items and services provided to patients after they are stabilized and as part of outpatient observation or an inpatient or outpatient stay that is connected to the original emergency visit, unless certain conditions are met. These conditions include the patient's ability to travel using non-medical transportation, and whether the provider gives notice and the patient is in a condition to provide consent.

First Sufficient Information Year: Where the payer does not have sufficient information to calculate the median rate in 2019, this will be the first year after 2022 for which the payer has sufficient information to calculate the median rates. In the case of a newly covered item or service, this will be the first year after the first coverage year for which the payer has sufficient information to calculate the median rates.

Geographic region: For items and services other than air ambulance services, this means (1) one region for each metropolitan statistical area in a state and one region consisting of all other portions of the State; (2) if there is not sufficient information to calculate rates based on the definition in (1), then geographic region means one region consisting of all

metropolitan statistical areas in the state and one region consisting of all other portions of the state; (3) if there is still not sufficient information, then geographic regions means one region consisting of all metropolitan statistical areas in each Census division and one region consisting of all other portions of the Census division.

For air ambulance services, geographic region means one region consisting of all metropolitan statistical areas in the State and one region consisting of all other portions of the State, determined based on the point of pick-up. If there is not sufficient information to calculate rates based on this definition, then geographic region means one region consisting of all metropolitan statistical areas in each Census division and one region consisting of all other portions of the Census division, based on the point of pick-up.

Healthcare facility: In the context of non-emergency services, this includes a hospital, hospital outpatient department, critical access hospital, ambulatory surgical center and any other facility specified by HHS. HHS decided not to expand the definition in this IFR, but may expand the definition in future rulemaking.

Notably, a participating healthcare facility is one that has a contractual relationship directly or indirectly with a group health plan or health insurance issuer offering group or individual health insurance coverage setting forth the terms and conditions on which a relevant item or service is provided to a participant, beneficiary or enrollee under the plan or coverage, respectively.

Independent freestanding emergency department: A healthcare facility that is geographically separate and licensed separately from a hospital and provides emergency services.

Nonparticipating emergency facility: An emergency department of a hospital or an independent freestanding emergency department that does not have a contractual relationship directly or indirectly with a group health plan.

Nonparticipating provider: A physician or other healthcare provider, acting within the licensed scope of practice, who does not have a contractual relationship with a health plan.

Notice of denial of payment: Written notice from the plan to the provider, facility or provider of air ambulance services that payment for an item or service will not be made and which explains the reason for denial. The term does not include a notice of benefit denial due to an adverse benefit determination.

Out-of-network rate: An item or service furnished to patients by a nonparticipating provider or nonparticipating emergency facility. The amount is either specified through state law or an All-Payer Model or, if not specific by the state, the amount of agreed upon through open negotiation as described above or the amount determined by the IDR.

Participating emergency facility: An emergency department of a hospital or an independent freestanding emergency department of a hospital that has a direct or indirect contractual relationship with a health plan.

***Participating provider**:* A physician or other healthcare provider, acting within the licensed scope of practice, who has a contractual relationship with a health plan.

Physician or healthcare provider: A physician or other healthcare provider who is acting within the scope of practice of that provider's license or certification under applicable state law, but the definition specifically excludes providers of air ambulance services.

***Provider in the same or similar specialty**:* The practice specialty of a provider, as identified by the plan consistent with the plan's usual business practice. All providers of air ambulance services are considered to be a single provider specialty.

Provider of air ambulance services: An entity that is licensed under applicable state and federal law to provide air ambulance services.

Qualifying payment amount: For items and services furnished in 2022, the median contracted rates recognized by the plan on January 31, 2019, for the same or similar item or service, by a provider in the same or similar specialty or facility of the same or similar facility type, in the same geographic region. This amount is increased by the consumer price index annually.

Recognized amount: Is based on 1) an amount determined by an applicable All-Payer Model Agreement under section 1115A of the Social Security Act (*e.g.*, Maryland's All-Payer Model); 2) if there is no such applicable All-Payer Model Agreement, an amount determined under a specified state law; or 3) if neither of the above apply, the lesser amount of either the billed charge or the QPA, which is generally the payer's median contracted rate.

Same or similar item or service: A healthcare item or service billed under the same service code, or a comparable code under a different procedural code system.

Specified state law: A state law that provides for a method for determining the total amount payable under a group health plan to the extent such state law applies for an item or service furnished by a nonparticipating provider or nonparticipating emergency facility.

Sufficient information: For purposes of determining the median contracted rate and geographic regions, this means (2) the plan has at least three contracted rates on January 31, 2019; or (2) after 2022, the plan has at least three contracted rates on January 31 of the year immediately preceding that year and the contracted rates account for at least 25% of the total number of claims paid for that item or service for that year with respect to all plans of the sponsor that are offered in the same insurance market.

Visit: Includes equipment and devices, telemedicine services, imaging services, laboratory services, preoperative and postoperative services, and other items and services as HHS may specify, regardless of whether the provider furnishing such items or services is at the facility.

NEXT STEPS

Stakeholders will have 60 days to comment on the rule once published in the *Federal Register*.

The Departments will issue the No Surprises Act regulations in several phases. The second regulation should be published by October 1, 2021, and will establish a payer audit process. The third regulation should be published by December 27, 2021, and will detail the independent resolution dispute process and patient transparency provisions.

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