



Requirements Related to Surprise Billing; Part II: Policy Update

Summary

On September 30, 2021, the US Office of Personnel Management and the US Departments of Health and Human Services (HHS), Treasury and Labor issued an Interim Final Rule with comment (IFR), entitled [Requirements Related to Surprise Billing: Part II](#), implementing additional portions of the No Surprises Act (NSA). Enacted in December 2020, the NSA regulates balance billing by out-of-network providers and requires payers to cover those bills at in-network rates effective January 1, 2022.

This is the third implementing regulation the agencies have released this year. This IFR focuses on the independent dispute resolution (IDR) process, good faith estimates for uninsured (or self-pay) individuals, the patient-provider dispute resolution process and expanded rights to external review. Of note, this IFR does not address the audit process for plans, which was supposed to be outlined through regulation by October 1, 2021, and therefore will need to be addressed in future guidance or rulemaking.

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

Key Takeaways

- The departments establish a process for initiating IDR, including the template forms, the criteria for becoming a certified IDR entity, and the mandatory ranges for IDR fees.
- The IDR entity must begin with the presumption that the Qualifying Payment Amount (QPA), based on the median contract prices in the area for the same medical service, is the appropriate out-of-network amount.
- The application process to become an IDR entity is now open and the departments will accept applications on a rolling basis. Organizations must submit the application and all documentation no later than November 1, 2021, to be certified by January 1, 2022.
- The departments establish a patient-provider select dispute resolution process for uninsured and self-pay individuals.

Key Resources

- [Interim Final Rule with Comment](#)
- [Fact Sheet One](#)
- [Fact Sheet Two](#)
- [Press Release](#)
- [Additional Resources, Templates and Materials](#)
- [CMS No Surprises Act Website](#)
- [Application Website to Become an IDR Entity](#)
- [McDermottPlus +Insight on Requirements Related to Surprise Billing: Part I](#)



Background on the No Surprises Act

On December 27, 2020, Congress enacted the [Consolidated Appropriations Act, 2021](#), which included the NSA, 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, 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 NSA, group health plans, insurers and providers (including hospitals, facilities, individual practitioners and air ambulance providers) are prohibited from collecting from 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. Under the law, a provider and plan have up to 30 days from when the provider receives an initial payment or notice of denial of payment from the plan to initiate open negotiation. The parties then have 30 days beginning on the date that negotiations started to reach an agreement on payment. If negotiations fail, the provider or plan has four days after the end of the 30-day period to initiate the IDR process. The IDR process requires each party to submit a final payment offer, and the arbiter must select one of these offers as the final payment amount (commonly referred to as "baseball style" arbitration). In selecting the final payment, the arbiter must weigh certain factors but is banned from considering the lower rates paid by federal government programs (e.g., Medicare and Medicaid).

The NSA is effective beginning January 1, 2022, although the departments responsible for implementing the law have announced that they will not enforce certain portions of the law until they have issued all of the necessary regulations, and in some instances, until they have given stakeholders more time to acclimate to the new law.

Congress tasked HHS and the US Departments of Treasury and Labor with developing several regulations to implement the provisions of the NSA. The US Office of Personnel Management has also participated in developing these regulations. The [first of these regulations](#) was published in the [Federal Register](#) on July 13, 2021, and focused on the methodology payers must use to determine patient 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. The second regulation, [Requirements Related to Air Ambulance Services, Agent and Broker Disclosures, and Provider Enforcement](#), was published as a proposed rule on September 16, 2021,



and primarily outlined issues related to air ambulance providers. The most recent regulation (and the subject of this +Insight) is the [Requirements Related to Surprise Billing; Part II](#), posted as an IFR on September 30, 2021, and expected to be published in the *Federal Register* on October 7, 2021.

The following summary highlights key provisions of the Requirements Related to Surprise Billing; Part II.

The law imposes specific obligations on providers, including physicians and other practitioners; healthcare facilities, including hospitals and other specified facilities; and payers, including group health plans and health insurance issuers offering group or individual health insurance coverage. The law also includes specific definitions of each of those terms. For ease of discussion, this +Insight refers to physicians, practitioners and facilities collectively as “providers,” and to group health plans and insurance issuers as “payers,” unless specific distinctions are relevant to the discussion.

Additionally, the NSA and accompanying regulations define several dozen terms, which are key to understanding the scope of the rules. Readers should carefully examine the regulations and the attendant definitions for a full understanding of the law.

INDEPENDENT DISPUTE RESOLUTION PROCESS

IDR Process/Timeline¹

Negotiation: The NSA seeks to minimize reliance on IDR by first requiring a period of negotiation. Under the law, a provider and payer have up to 30 days from when the provider receives an initial payment or notice of denial to initiate negotiations. This phase begins when the party that seeks to negotiate payment disagreements opens a negotiation notice, in writing (which may be in an electronic format). This notice includes, among other information, the items or services in dispute, the initial payment or notice of denial, and an offer for the out-of-network rate. Parties may reach an agreement before 30 business days, but they may not proceed to the next phase before the 30 business days have expired. The 30 business days begin the day the open negotiation notice is first sent by a party, assuming notice has been properly given. If these negotiations fail, the provider or payer have four days after the end of the 30-day period to initiate the IDR process.

Federal IDR Process: Parties that were unable to reach an agreement during the negotiation period can move on to the federal IDR process. A party initiates the federal IDR process by accessing the federal IDR online portal, which submits a notice to other parties and the

¹ The surprise billing statute generally provides timelines for phases of the process in days. Some components of the IDR process are measured in calendar days, while others are measured in business days. Taking into account stakeholder feedback, in order to maximize the time allowed at each phase of the process, the departments have decided to use “business days” unless otherwise indicated.



departments. The date of initiation is the date the departments receive the Notice of IDR Initiation, which is timestamped by the IDR portal. (For more information, see the [Notice of IDR Initiation Instructions](#).)

Parties must then select an IDR entity. The Notice of IDR Initiation includes the selection of a preferred IDR entity by the initiating party. The non-initiating party has three business days to object to the selection. If the non-initiating party fails to object, the IDR entity in the Notice of Initiation will be selected. If the non-initiating party objects, it must provide notification and explanation to the other party. Alternatively, the parties may agree upon an IDR entity within three business days of initiation. In either case, the initiating party must notify the departments no later than four business days after the date of initiation. From the date of initiation of the federal IDR process, the departments have six business days to select a certified IDR entity if the parties have not already mutually agreed on one. The certified IDR entity has three business days to attest that it has no conflicts of interest. If there is a conflict, the departments will notify the parties, and they will have three more business days to select another certified IDR entity, or else the departments will select one randomly for them. (For more information, see the [Notice of IDR Entity Selection](#).)

The certified IDR entity is also responsible for determining applicability of the federal IDR process, including interaction with state laws. If the federal process does not apply, the certified IDR entity must notify HHS within three business days of such a determination. Several states had already enacted comprehensive surprise billing laws prior to the NSA, and some of these states rely on different processes to address surprise bills. The federal law defers to existing state requirements with respect to state-established payment amounts, meaning that the NSA does not fully preempt or otherwise displace state payment standards. States can also continue to pass surprise billing laws and regulations in the future.

Within 10 days of the IDR entity selection, the parties each must submit a payment offer and other information requested by the IDR entity. The arbiter then has 30 days to choose one of the parties' offers as the payment determination. The IDR decision is final and binding, and is not subject to further judicial review, except in specific circumstances.

Administrative Fee for IDR and IDR Entity Fee

There are two fees associated with the IDR process: an administrative fee and the IDR entity fee. HHS published a separate notice, [Calendar Year \(CY\) 2022 Federal IDR Process Fee Guidance](#), which outlines these fees. Each party will be able to view the IDR entity fee and the administrative fee in the federal IDR portal.

At the time a certified IDR entity is selected, each party must pay a nonrefundable administrative fee, which the certified IDR entity in turn remits to the departments. For CY 2022, the administrative fee for each party is \$50. The administrative fee is non-refundable even in instances where the parties negotiate a settlement outside of the IDR process or the certified IDR entity determines that the case does not qualify for the federal IDR process.



The IDR entity fee varies and will be set by the IDR entity itself. However, the departments state that for CY 2022, certified IDR entities must charge a fixed certified IDR entity fee for single determinations within the range of \$200–\$500, and \$268–\$670 for batched determinations. The departments will publish annual guidance governing these fees. The IDR entity fee paid by the prevailing party whose offer is selected will be returned to that party within 30 days following the determination.

The party whose offer is not chosen must pay all fees charged by the IDR entity. If the parties reach a settlement independently before the IDR entity renders its final decision, the IDR fees will be split between the parties. Within 30 business days of making the determination, the certified IDR entity will issue a refund of the entity fee to the prevailing party.

Weight of the QPA and Other Factors in IDR Consideration

The NSA attempts to guide how the IDR entity should reconcile the two opposing payment offers. The NSA requires the arbitrator to “consider” the following factors when deciding on a payment amount: the QPA and, upon request by the IDR entity or either party, the provider’s training and experience; the complexity of the procedure or medical decision-making; the patient’s acuity; the market share of the insurer and provider; the facility’s teaching status; the scope of services; any demonstrations of good faith efforts to agree on a payment amount; and contracted rates from the prior year. In their initial comments to the agencies, providers and payers were divided over this issue. Payers generally commented that arbitrators should consider the QPA as the predominant factor, while providers sought a more balanced approach.

In the IFR, the departments primarily anchor arbitration outcomes to the QPA. The rule states that the “IDR entity must begin with the presumption that the QPA is the appropriate out-of-network rate for the qualified IDR item or service under consideration.” The rule acknowledges the other factors listed in the statute, but provides that they will only trump the QPA if there is a showing of credible information that clearly demonstrates that the QPA is materially different from the appropriate out-of-network rate (terms defined in the regulation). In a series of examples included in the IFR’s regulatory text, the departments outline how entities not only would need to submit additional evidence, but also would need to show that such evidence would further refute the basis of the QPA as the appropriate amount, creating what is likely a high bar for providers seeking to move the arbiter away from the QPA. The IDR entity may not consider certain factors in determining which offer is the out-of-network rate, including usual and customary charges, billed charges to the plan or issuer for the qualified IDR item or service, and payment or reimbursement by a public payer (including payment rates for demonstration projects under section 1115 waivers).

The IFR offers one other seemingly rare scenario when the QPA would not be determinative, and that is if the parties’ offers are equally distant from the QPA, but in opposing directions. In



such case, the certified IDR entity must select as the out-of-network rate the offer that the certified IDR entity determines best represents the value of the qualified IDR item or service, which could be either offer.

Once the certified IDR entity has made a determination, it must provide the underlying rationale for its determination in a written decision submitted to the parties and the Departments. If a certified IDR entity does not choose the offer closest to the QPA, the written decision's rationale must include a detailed explanation of the additional considerations relied upon, whether the information about those considerations submitted by the parties was credible, and the basis upon which the certified IDR entity determined that the credible information demonstrated that the QPA was materially different from the appropriate out-of-network rate.

This policy choice will likely draw significant feedback from providers as well as engagement from members of Congress who sought to direct the departments toward equal weighting of all factors. In the preamble to the IFR, the departments appear to justify their position by noting that the QPA was the sole factor identified in the NSA without qualification, and by highlighting the need to ensure predictive outcomes and efficiency, mitigate stakeholders' desire to seek out the IDR process, and avoid increasing market rates.

Batching

The NSA strives to provide efficiency by allowing parties to “batch” or combine multiple disputed claims into a single case before an IDR entity. The statute provides some parameters for when multiple disputed claims may be combined (*e.g.*, when the items or services are furnished by the same provider or facility, payment must be made by the same payer, the treatment relates to a similar condition, and the items and services were furnished during a 30-day period) but also leaves considerable discretion to the departments to define those terms and the corresponding requirements. Stakeholders focused intensely on these opportunities because the efficiency—or lack thereof—and cost of resolving disputes through the IDR process will influence decisions whether to pursue IDR as a resolution process. Many providers in particular pressed for a broad interpretation of batching to maximize efficiency and minimize the costs of appealing disputed claims to arbitration.

The departments' definition of batching in the IFR seems to be sufficiently broad to allow for considerable consolidation of claims for appeal. To combine claims into a single appeal, the following conditions must be met:

- The claims must be billed by the same provider, group of providers, facility or provider of air ambulance services. The departments will consider this condition to be met if the items or services are billed with the same National Provider Identifier or Taxpayer Identification Number.
- The payment for the items and services must be made by the same payer.



- The claims must be for items and services billed under the same CPT, HCPCS or DRG service code, or a comparable code under a different procedural code system.
- The items and services must be furnished within the same 30-business-day period, or within the 90-day “cooling off” period (described in more detail below) following an IDR determination, once the suspension period has ended.

The departments note that some claims may have different QPAs, such as when the provider and payer are the same, but the individuals to whom items or services were furnished have different plans offered by that payer. In these cases, the arbiter must consider each QPA for each item or service separately. Presumably, this could mean that different resolutions are made for different batched claims.

Cooling-Off Period

As outlined in the NSA and included in the IFR, once the IDR entity makes a determination, the party that requested arbitration may not submit a subsequent request involving the same opposing party for a claim for the same item or service for a 90-calendar-day period, referred to as a “cooling-off” period. The purpose of the cooling-off period is to avoid duplicate disputes for the same claims from the same parties, and to reduce disputes accessing the federal IDR process. After the end of the 90-day period, either party may initiate an IDR process. The IFR is unclear on how to define the same opposing party when it comes to payers, and on whether providers will be stalled in challenging health insurance companies broadly speaking, or whether they will be delayed in challenging individual plans issued by those companies.

IDR Entity Certification, Recertification and Petition for Decertification

The NSA requires that a sufficient number of IDR entities be certified to ensure timely and efficient determinations. The application process to become an IDR entity is [now open](#) and will remain open to accept applications on a rolling basis. Organizations must submit the application and all documentation no later than November 1, 2021, to be certified by January 1, 2022.

The departments will make a list of certified IDR entities available on the federal IDR portal. This list will include basic information about the entities, including contact information, websites and service areas. The departments seek comment on whether additional information about the certified IDR entities should be made public.

An IDR entity must meet certain standards and must be certified by the departments to guard against biases and other conflicts of interests. To become certified, an entity must submit a written application with supporting documentation to the departments demonstrating that the entity meets several requirements. Entities that meet the certification standards will be certified for a five-year period and will receive a certified IDR entity number. (For more information, see the [IDR Certification Application](#).)



Providers and plans can petition the departments to have an entity's certification denied or revoked for failure to meet the requirements. To facilitate the petition process, the departments will make a list of certified entities and a list of entities seeking certification publicly available. For now, petitioners seeking a certification denial will have five business days from the announcement that the entity is seeking certification to submit the petition. This five-business-day period applies until the departments issue additional guidance on the process.

If upon review the departments find that the petition demonstrates the entity's failure to comply with requirements, the departments will notify the entity by providing a de-identified copy of the petition. The entity will then have 10 business days to provide its response. The departments will review the response and determine whether a denial or revocation is warranted. The decision is subject to an appeals process. (For more information, see the [Petition for Certification Denial or Revocation](#).)

The departments can also deny or revoke certification outside of the petition process if the departments find that the entity is unable to comply with the certification requirements. If the departments deny or revoke an entity's certification, the entity can reapply for certification after coming into compliance. The entity must wait 180 calendar days after receiving the final notice of denial or revocation before it can reapply.

Reporting Information Relating to the Federal IDR Process

The NSA specifies that beginning in 2022, for each calendar quarter the departments shall make publicly available information regarding the federal IDR process, including for air ambulance services. Beginning January 1, 2022, each certified IDR entity must report on the federal portal certain data and information within 30 business days of the close of each month, and such reporting is a condition of ongoing certification.

Submitted data by the certified IDR entities is fully outlined in the IFR and includes:

- The number of IDR initiations submitted
- The size and type of the provider practice or facility
- The qualified number of final determinations
- A description of the items and services along with the relevant billing and service codes (such as CPT, HCPCS, DRG or National Drug Codes)
- Offers submitted by each party expressed as both a dollar amount and a percentage of the QPA, and whether the offer selected was submitted by the issuer or provider
- Rationale for selecting the offer.

Reporting requirements specific to air ambulance providers are outlined below. For more information, see the [Notice of Monthly IDR Entity Reporting Requirements](#).



The IFR provides clarity on the interaction of state and federal law in four key areas:

- **IDR Processes:** Many stakeholders hoped for clarity on when state (as opposed to federal) IDR processes would apply. The IFR notes that the federal IDR process may be used to determine rates where an all-payer model agreement or specified state law does not apply. In other words, where a state law exists, the state (not the federal) IDR process will apply. The departments anticipate that some states may want to change their existing IDR laws or adopt new IDR laws as a result of the IFR. Certified IDR entities are expected to review the information submitted in the Notice of IDR Initiation to determine whether the federal IDR process applies. If the federal IDR process does not apply, the certified IDR entity must notify HHS and the parties within three business days of making that determination. State IDR processes may also apply to insured ERISA plans. ERISA preemption contains a broad “savings” clause for insurance laws, saving such laws from ERISA preemption. Self-funded ERISA plans may use the federal IDR process.
- **Good Faith Estimates:** The IFR requires providers to provide good faith estimates of items and services to uninsured (or self-pay) individuals before services are rendered. HHS acknowledges that while some states have existing laws related to furnishing good faith estimates, uninsured individuals should still have the benefit of a good faith estimate that meets the minimum federal requirements established in the IFR. Therefore, providers and facilities that issue good faith estimates under state processes that do not meet the federal requirements will be deemed noncompliant.
- **Patient-Provider Dispute Resolution:** The IFR establishes a patient-provider dispute resolution process under which an uninsured (or self-pay) individual who received a good faith estimate of expected charges may seek a determination of the amount to be paid if the billed charges substantially exceed the expected charges. HHS notes that where a state law provides a similar process for resolving disputes between an uninsured individual and a provider or facility, the state process should continue to apply if it meets or exceeds the IFR’s consumer protections. HHS will establish a protocol for determining whether a state patient-provider dispute resolution process provides at least the same level of consumer protections as the federal process. If HHS determines that the state process provides such minimum protections, HHS will defer to the state process.
- **Enforcement:** The IFR briefly notes that states will play a large role in enforcing the new balance billing protections. HHS will only enforce in cases where the state notifies HHS that the state does not have authority to enforce or is otherwise not enforcing.

PROTECTIONS FOR UNINSURED AND SELF-PAY INDIVIDUALS

Good Faith Estimates

Section 112 of the NSA establishes requirements for providers, facilities and payers to make certain inquiries of and disclosures to patients, including about the anticipated cost of care, to



help patients make informed decisions regarding whether to seek care and from whom. The IFR implements aspects of this section that pertain to uninsured individuals, or to those who intend to self-pay for services. The IFR does not describe the requirements of providers, facilities and payers to provide information to insured individuals. The departments noted in an August 2021 [FAQ document](#) that those regulations would be coming later, and that the departments would exercise enforcement discretion in the meantime.

Under the new regulations, within a specified time period, all providers and facilities must (1) inquire about an individual's health coverage status, and (2) provide a notification that the individual may receive a good faith estimate of the expected charges for furnishing the item or service. The departments provided a slightly less strict interpretation of the NSA, requiring providers and facilities to merely inform patients of the "availability" of a good faith estimate, and to then provide that estimate upon request by the patient. While this interpretation may be less strict, in practical reality, the vast majority of patients likely will request the estimate when presented with the opportunity to receive it.

Good faith estimates must reflect the anticipated billed charges, including any discounts or other relevant adjustments that the provider or facility expects to apply.

The departments recognize that while patients often schedule a service with a single provider such as a hospital, other providers such as surgeons, radiologists, anesthesiologists or laboratories may also provide services in an episode of care. The departments therefore put the burden of informing the patient, providing the good faith estimate upon request, and gathering all of the components of that estimate, on the entity scheduling the service, known as the "convening entity." The departments also established regulations requiring the "co-providers" or "co-facilities" to cooperate with the convening entity. Convening providers and facilities will not be held responsible for the accuracy of expected charges for items or services for which the convening provider or facility does not bill. It may take time for convening providers and facilities to develop systems and processes for receiving and providing the required information from co-providers and co-facilities, and therefore the departments announced that they will exercise enforcement discretion in limited situations where a good faith estimate provided to an uninsured (or self-pay) individual does not include expected charges from co-providers or co-facilities during the period of January 1, 2022, through December 31, 2022.

Good faith estimates must be provided in writing and orally, and must be posted in specified locations. HHS anticipates providing a model notice for notifying uninsured (or self-pay) individuals of the availability of good faith estimates.

It is important to note that the departments are using a broader definition of "healthcare facility" in applying these rules. For purposes of these requirements, healthcare facility means a hospital, including its outpatient department, critical access hospital, ambulatory surgical center, rural health center, federally qualified health center, laboratory or imaging center.



Where a state provides similar requirements, entities must still comply with the federal requirements. Providers or facilities that issue good faith estimates under state processes that do not meet the minimum requirements under the federal regulations will be deemed noncompliant.

Patient-Provider Dispute Resolution Process

The NSA directs HHS to establish a patient-provider dispute resolution process for uninsured or self-pay individuals. This rule specifies that only instances where a patient is charged “substantially in excess” of the good faith estimate are eligible for the select dispute resolution (SDR) process. The departments define “substantially in excess” to mean that the amount billed to a patient for the service or item is at least \$400 more than the total amount of expected charges for the provider or facility listed on the good faith estimate.

An uninsured or self-pay individual may submit an initiation notice when the charge for an item or service is substantially in excess of the good faith estimate within 120 calendar days of receiving the bill. Once the initiation notice is submitted, the provider or facility cannot move to a collections process or threaten to do so, must pause any collections efforts and must stop the accrual of any late fees.

In determining payment, the SDR entity will review the copies of the bills, itemized good faith estimates and any additional documentation from the parties. The SDR entity may consider additional factors that support charges for medically necessary items or services that occurred because of unforeseen events.

When there is an unforeseen event or a new item or service that was not originally listed on the good faith estimate, and the SDR entity believes the provider or facility has provided credible information supporting those additional charges, the SDR entity must select as the amount to be paid by the uninsured (or self-pay) individual the lesser of (1) the billed charge or (2) the median payment amount for the same or similar service in the geographic area that is reflected in an independent database. For items or services not originally listed on the good faith estimate where the provider or facility did *not* provide credible information, the SDR entity will determine a payment amount equal to \$0.

After making the final determination, the SDR entity must add together the amounts to be paid for all items and services and subtract the administrative fee paid by the individual. This amount will be the final payment from the uninsured or self-pay individual. HHS will provide additional guidance regarding the administrative fee, but the IFR notes that the fee is expected to be about \$25.

While the SDR entity is reviewing the dispute, the parties can settle the dispute separately and notify the SDR entity to terminate the dispute process.



PROVISIONS RELATED TO AIR AMBULANCE PROVIDERS

The IFR's provisions, including the standards for IDR and the patient-provider dispute resolution process, generally apply consistently to providers of air ambulance services. However, the IFR includes two distinctions regarding the treatment of air ambulance services compared to other healthcare services, including (1) how certified IDR entities should select an offer and (2) the requirement to provide good faith estimates.

Selection of an IDR Offer: In determining which offer to select, the IDR entity must consider the QPA for the applicable year for air ambulance services, as with other healthcare services. The IDR entity may consider additional information to the extent that it determines that the information clearly demonstrates that the QPA is materially different from the appropriate out-of-network rate. To the extent that a party submits such credible information, the IDR entity must consider the following:

- Quality and outcomes measurements of the air ambulance provider
- Patient acuity
- Level of training, experience and quality of medical personnel
- Air ambulance vehicle type, to the extent that it is not already accounted for in the QPA
- Population density of the point of pick-up for the air ambulance
- Good faith efforts (or lack thereof) made by the provider and payers to enter network agreements, as well as contracted rates during the previous four years.

In establishing the criteria for certifying an IDR entity, the departments considered whether to require IDR entities to have personnel with air space law knowledge available for making determinations in air ambulance cases. The departments were concerned that such a requirement would limit the number of eligible IDR entities and increase the likelihood of conflicts of interest, however. Therefore, the departments do not currently require IDR entities to have familiarity with air space law, but solicit comments on whether this knowledge should be required in the future.

Good Faith Estimates: The IFR acknowledges that the term “provider” is not defined in the NSA and is used inconsistently when applied to providers of air ambulance services. In some instances, the NSA's provisions referring to a “provider” include air ambulance providers, whereas others do not. HHS clarifies in the IFR that for purposes of 45 CFR 149.610, including good faith estimates to uninsured individuals, it will interpret the term “provider” to include air ambulance providers to ensure that individuals can obtain good faith estimates for these services. HHS notes that, in practice, individuals will likely *not* obtain estimates for air ambulance services, since such services are generally used only in emergency situations that are not scheduled in advance. However, HHS will nevertheless apply the requirement to air ambulance providers so that individuals who *do* schedule care in advance may have access to the cost estimates.



EXTERNAL REVIEW

Under the NSA, non-grandfathered payers must comply with any applicable state external review process. If the state external review process does not meet certain standards, or if a payer is not subject to state insurance regulation, the payer must instead comply with the federal external review process for any adverse benefit determination by a plan that involves medical judgment and/or rescission of coverage. In the IFR, the departments interpret the NSA to extend these external review requirements to grandfathered plans for claims covered by the NSA's protections.

The departments state that many such claims subject to the NSA's surprise billing and cost-sharing protections would already be eligible for external review under regulations finalized in 2015. However, the IFR amends these regulations to make the application of external review more explicit. Accordingly, the IFR adds five new examples to demonstrate certain NSA-specific situations in which external review requirements would apply:

- The first new example illustrates that any determination of whether a claim is for emergency services or consideration of compliance with the cost-sharing and surprise billing protections is eligible for external review.
- The second new example clarifies that whether a claim for items and services furnished by a nonparticipating provider at an in-network facility is subject to NSA protections is eligible for external review.
- The third new example clarifies that whether an individual was in a condition to receive a notice about the availability of NSA protections and give informed consent to waive those protections is eligible for external review.
- The fourth new example illustrates that whether a claim for items and services is coded correctly, consistent with the treatment an individual actually received, is eligible for external review.
- The fifth new example illustrates that whether cost-sharing was appropriately calculated for claims for ancillary services provided by an out-of-network provider at an in-network facility is eligible for external review.

NEXT STEPS

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

Additional regulations are expected from the departments, including regulations covering payer auditing processes. Because this regulation, like the first one, is an IFR, and the second regulation is a proposed rule, all three must ultimately be published in final form. In the interim, the two IFRs are deemed to be effective and enforceable.