Requirements Related to Surprise Billing; Part II Interim Final Rules and Technical Guidance No. 2021 -01

Background

On December 27, 2020, the Consolidated Appropriations Act, 2021 (CAA), which includes the No Surprises Act ("NSA"), was enacted. The NSA established a Federal IDR process that allows plans and insurers, and nonparticipating providers and facilities to resolve disputes regarding out-of-network payments for emergency services furnished by nonparticipating providers/facilities/air ambulances, and for non-emergency services furnished by certain nonparticipating providers/facilities at participating health care facilities.

Interim Final Rules

On September 30, 2021, the federal Departments of the Treasury, Labor and Health and Human Services (the "Departments") issued interim final rules regarding the Federal independent dispute resolution (IDR) process that nonparticipating providers or facilities, nonparticipating providers of air ambulance services, and group health plans and health insurers in the group and individual market may use following the end of an unsuccessful open negotiation period to determine the out-of-network rate for certain services. More specifically, the Federal IDR provisions may be used to determine the out-of-network rate for certain emergency services, nonemergency items and services furnished by nonparticipating providers at participating health care facilities, and air ambulance services furnished by nonparticipating providers of air ambulance services where an All-Payer Model Agreement or specified state law does not apply.

Effective and Applicability Dates

These interim final rules are generally applicable for plan or policy years beginning on or after January 1, 2022, and apply to ERISA and Non-ERISA self-funded group health plans and fully insured group and individual insurers; grandfathered plans and the Federal Employees Health Benefits Program. These interim final rules do not apply to health reimbursement arrangements (HRAs), or other account-based group health plans, short-term, limited-duration insurance and retiree-only plans. These interim final rules apply to certified IDR entities, health care providers and facilities, and providers of air ambulance services beginning on January 1, 2022. The provisions related to the certification of IDR and SDR entities, apply beginning the date of publication in the Federal Register.

Thirty Business Day Open Negotiation Period and Notice

Upon receipt of an initial payment or notice of denial of payment from a plan/insurer for such items or services, such provider/facility/air ambulance provider (as applicable) or plan/insurer (as applicable) may initiate an open negotiation period within 30 business days beginning on the date the provider or facility receives the initial payment or notice of denial of payment. The party initiating the open negotiation must provide written notice ("Open Negotiation Notice") using the federally mandated form to the other party and identify the:

- item/service subject to negotiation
- date the item/service was furnished

- service code
- initial payment amount or notice of denial of payment, as applicable
- offer for the out-of-network rate (final payment amount)
- contact information of the party sending the open negotiation notice

The written open negotiation notice may be sent electronically (such as by email) if the following two conditions are met:

1) the party sending notice has a good faith belief that the electronic method is readily accessible to the other party; and
2) the notice is provided in paper form free of charge upon request

For example, if a provider sends an open negotiation notice to the email address identified by the group health plan in the notice of denial or initial payment, such electronic delivery would satisfy this requirement (as long as the provider also sends the notice in paper form free of charge upon request). Similarly, if a provider, facility, or provider of air ambulance services submits a claim electronically, this could provide the plan or insurer with a good faith belief that the electronic method is readily accessible to the other party.

The Departments caution that if the open negotiation notice is not properly provided to the other party (and no reasonable measures have been taken to ensure actual notice has been provided), the Departments may determine that the 30-business-day open negotiation period has not begun. In such case, any subsequent payment determination from a certified IDR entity may be unenforceable due to the failure of the party sending the open negotiation notice to meet the open negotiation requirement of the interim final rules. Therefore, the Departments encourage parties submitting open negotiation notices to take steps to confirm the other party's contact information and confirm receipt by the other party.

The open negotiation period may continue for up to 30 business days beginning on the date that either party first initiates the open negotiation period. The parties may discontinue the negotiation if they agree on an out-of-network rate before the last day of the 30-business-day open negotiation period. If the parties cannot agree on an out-of-network rate, they must exhaust the 30-business-day open negotiation period before initiating the Federal IDR process. A party may not initiate the Federal IDR process if, with respect to an item or service, the party knows or reasonably should have known that the provider/facility provided notice and obtained consent from a participant to waive surprise billing protections.

Four-Business-Day Period to Initiate Federal IDR Process Through Federal IDR Portal

Either party may initiate the Federal IDR process during the 4-business-day period beginning on the 31st business day after the start of the open negotiation period. To initiate the Federal IDR process, the initiating party must submit a certain notice to the other party as explained below and to the Departments (Notice of IDR Initiation) through the Federal IDR portal (explained further below).

The Notice of IDR Initiation must include:

1) Information sufficient to identify the qualified IDR items or services (and whether the qualified IDR items or services are designated as batched items and services), including the dates and

location of the items or services, the type of qualified IDR items or services (such as emergency services, post-stabilization services, professional services, hospital-based services), corresponding service and place-of-service codes, the amount of cost sharing allowed and the amount of the initial payment made by the plan or issuer for the qualified IDR items or services, if applicable;

2) The names and contact information of the parties involved, including email addresses, phone numbers, and mailing addresses;
3) The state where the qualified IDR items or services were furnished;
4) The commencement date of the open negotiation period;
5) The initiating party's preferred certified IDR entity;
6) An attestation that the items or services are qualified IDR items and services within the scope of the Federal IDR process;
7) The QPA;
8) Information about the QPA as required in the regulations; and
9) General information describing the Federal IDR process using the Federally mandated form content.

As with the open negotiation notice, the initiating party may provide the Notice of IDR Initiation to the opposing party electronically (such as by email) if the following two conditions are satisfied:

1) the initiating party has a good faith belief that the electronic method is readily accessible by the other party; and

2) the notice is provided in paper form free of charge upon request.

However, the initiating party must also furnish Notice of IDR Initiation to the Departments through the Federal IDR portal on the same day the notice is furnished to the non-initiating party, and such date is the initiation date of the Federal IDR process.

IDR Portal to Administer the Federal IDR Process

The Federal IDR portal will be available at https://www.nsa-idr.cms.gov and will be used throughout the Federal IDR process to satisfy various requirements, including provision of notices, Federal IDR initiation, submission of supporting documentation to certified IDR entities, submission of an application to be a certified IDR entity, as well as submission of certified IDR entity reporting metrics.

Selecting a Certified IDR Entity Within 3 Business Days of the IDR Initiation

The parties may select a certified IDR entity no later than 3 business days following the date of the IDR initiation. The Departments will make available on the Federal IDR portal a list of certified IDR entities which the parties may select.

If the parties agree on a certified IDR entity, the Notice of the Certified IDR Entity Selection must include the following information:

1) the name of the certified IDR entity;
2) the certified IDR entity number; and
3) an attestation by both parties (or by the initiating party if the other party has not responded) that the selected certified IDR entity does not have a conflict of interest. The

attestation must be submitted based on conducting a conflicts of interest check using information available (or accessible using reasonable means) to the parties (or the initiating party if the other party has not responded) at the time of the selection.

If the non-initiating party in receipt of the Notice of IDR Initiation fails to object within 3 business days of the date of initiation of the Federal IDR process, the preferred certified IDR entity identified in the Notice of IDR Initiation will be the selected certified IDR entity, provided that the certified IDR entity does not have a conflict of interest. If the party in receipt of the Notice of IDR Initiation timely objects, it must notify the initiating party, including an explanation of the reason for objecting, and propose an alternative certified IDR entity. The initiating party must then agree or object to the alternative certified IDR entity. In order to jointly select a certified IDR entity, the plan or insurer and the nonparticipating provider/facility/air ambulance services provider must agree on a certified IDR entity not later than 3 business days after the date of initiation of the Federal IDR process.

If both parties agree on and select a certified IDR entity, or fail to agree upon a certified IDR entity within the specified timeframe, the initiating party must notify the Departments by electronically submitting the notice of the certified IDR entity selection or failure to select (as applicable), no later than 1 business day after the end of the 3-business-day period (or in other words, 4 business days after the date of initiation of the Federal IDR process) through the Federal IDR portal.

In addition, in instances where the non-initiating party believes that the Federal IDR process is not applicable, the non-initiating party must notify the Departments through the Federal IDR portal within the same timeframe that the notice of selection (or failure to select) is required and provide information regarding the lack of applicability. Based upon this information and any additional information requested by the selected certified IDR entity, the selected certified IDR entity will determine whether the Federal IDR process is applicable. The Departments seek comment on this approach and whether any challenges exist in relying solely upon electronic notifications. If the parties do not select a certified IDR entity, the Departments will select one within 6 business days of the initiation of the IDR process.

The NSA and these Interim Final Rules specify that the certified IDR entity selected cannot be a party to the determination or an employee or agent of such a party, or have a material familial, financial, or professional relationship with such party. After selection by the parties (including when the initiating party selects a certified IDR entity and the other party does not object), or by the Departments, the certified IDR entity must also review its selection to ensure that it meets the requirements. If the selected certified IDR entity meets these requirements, the certified IDR entity must attest to meeting these requirements. If unable to attest, the certified IDR entity must notify the Departments through the Federal IDR portal within 3 business days, after which the Departments will notify the parties. Upon notification, the parties will have 3 business days to select another certified IDR entity. If the parties notify the Departments that they have not agreed on a certified IDR entity, the Departments may randomly select another certified IDR entity.

Agreement of the Parties after the Federal IDR Process is Initiated but before a Determination

When the parties agree on an amount for a qualified IDR item or service after the Federal IDR process is initiated but prior to a determination by a certified IDR entity, the agreed-upon amount will be treated as the out-of-network rate and will be treated as resolving the dispute. The initiating party must notify the Departments and the certified IDR entity (if selected) through the Federal IDR portal no later than 3

business days after the date of the agreement of the out-of-network rate (that is, the total payment amount, including both cost sharing and the total plan or coverage payment) and include signatures from an authorized signatory for each party.

The amount by which this agreed-upon out-of-network rate exceeds the cost-sharing amount for the qualified IDR item or service is the total plan or coverage payment. The plan or insurer must pay the balance of the total plan or coverage amount of the agreed-upon out-of-network rate (with any initial payment made counted towards the total plan or coverage payment) to the nonparticipating provider, nonparticipating emergency facility, or nonparticipating provider of air ambulance services not later than 30 business days after the agreement is reached. Each party must pay half of the certified IDR entity fee, unless the parties agree otherwise on a method for allocating the applicable fee. In no instance may either party seek additional payment from the participant.

Ten Business Days From Selection of IDR entity to Submit an Offer, Information and Fees

Offer and Information

Each party must submit via the Federal IDR portal to the certified IDR entity an offer for a payment amount as a dollar amount and as a percentage of the QPA for the qualified IDR item or service in dispute and other information related to the offer as requested by the certified IDR entity and may submit additional information for the certified IDR entity to consider within 10 business days of selection of the certified IDR entity. Where batched items and services have different QPAs, the parties should provide different QPAs and different offers.

Via the Federal IDR portal, the provider must submit information about its practice. Plans must provide:

1) the coverage area of the plan/insurer
2) relevant geographic region for purposes of the QPA,
3) for group health plans, whether they are fully-insured, or partially or fully self-insured.

The parties may submit any information relating to the offer, except not usual and customary charges, billed amounts and public payor rates or payment or reimbursement rates expressed as a proportion of rates payable by public payors.

Treatment of Batched items and Services

Multiple claims for qualified IDR items and services may be submitted and considered jointly as part of one payment determination by a certified IDR entity (batched items and services) only if:

1) The qualified IDR items and services are billed by the same provider or group of providers or facility or same provider of air ambulance services with the same National Provider Identifier (NPI) or TIN;
2) The payment for such items and services would be made by the same plan or insurer;
3) The qualified IDR items and services must be the same or similar i.e. billed under the same service code or a comparable code under CPT, HCPCS, or DRG codes;

4) All qualified IDR items and services must have been furnished within the same 30-business-day period or the 90-calendar-day suspension period described below.

Bundled services i.e. multiple services a person received during an episode of care may be submitted as part of one payment determination by a certified IDR entity.

IDR Entity must Presume QPA is Appropriate and Select Unless…

In making a determination, the certified 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 certified IDR entity must select the offer closest to the QPA unless the certified IDR entity determines that credible information submitted by either party rebuts the presumption and clearly demonstrates that the QPA is materially different from the appropriate out-of-network rate. In these cases or when the offers are equally distant from the QPA but in opposing directions, the certified IDR entity must select the offer that the certified IDR entity determines best represents the value of the items or services, which could be either party's offer.

Per the preamble to the Interim Final Rules, qualified IDR items or services should not necessitate an out-of-network rate higher than the offer closest to the QPA, simply based on the level of experience or training of a provider, as this would lead to an increase in prices without a valid reason and does not align with the goals of the NSA. For instance, the out-of-network payment amount for the simple repair of a superficial wound (CPT codes 12001-12007) in most cases would not necessitate a rate higher than the QPA just because a provider has 30 years of experience versus 10 years of experience. Alternatively, if the plan's or issuer's contracted rates included risk-sharing, bonus, penalty, or other incentive-based or retrospective payments that were excluded for purposes of calculating the QPA for the items and services as required by the July 2021 Interim Final Rules, a party may provide evidence as to why the provider's or facility's quality or outcome measures support an out-of-network rate that is different from the QPA and the certified IDR entity should consider whether this requires selecting an out-of-network rate that is higher (in the case of a bonus) or lower (in the case of a penalty) than the offer closest to the QPA.

Credible Information

To the extent credible information is submitted by a party, the certified IDR entity must consider whether the credible information about the *market share* held clearly demonstrates that the QPA is materially different from the appropriate out-of-network rate for the qualified IDR item or service.

For instance, a plan or insurer having the majority of the market share in a geographic region may signal a QPA that is unreasonably low, as plans and issuers with a large market share may drive down rates, in which case an out-of-network rate higher than the offer closest to the QPA may be appropriate. Alternatively, a provider having the majority of the market share in a geographic region may signal a QPA that is unreasonably high, as providers with a large market share may drive up rates, in which case an out-of-network rate lower than the offer closest to the QPA may be appropriate.

To the extent credible information is submitted by a party, the certified IDR entity must consider whether the credible information about *patient acuity or the complexity of furnishing* the item or service to the participant clearly demonstrates that the QPA is materially different from the appropriate out-of-

network rate. The Departments anticipate only rare instances in which the QPA would not adequately account for the acuity of the patient or complexity of the service.

The Departments believe the QPA, which is intended to reflect the market-driven rate, should be considered the prevailing rate unless a party provides credible information that the characteristic of the *teaching status, case mix, or scope of services* of the nonparticipating facility was in some way critical to the delivery of the qualified IDR item or service, and not adequately accounted for in the QPA, thereby rebutting the presumption that the QPA is the appropriate out-of-network rate

The certified IDR entity must also consider whether the credible information about any demonstrations of *good faith efforts (or lack thereof) made by the nonparticipating provider/facility/provider of air ambulance services or the plan or insurer, as applicable, to enter into network agreements and, if applicable, contracted rates* between the provider or facility and the plan or insurer, as applicable during the previous 4 plan years, clearly demonstrates that the QPA is materially different from the appropriate out-of-network rate for the qualified IDR item or service.

It is not the role of the certified IDR entity to determine whether the QPA has been calculated by the plan or issuer correctly, to make determinations of medical necessity, or review denials of coverage; however, if either the certified IDR entity or one of the parties believes the QPA has not been calculated in accordance with the regulations, the certified IDR entity or the provider or facility may notify the applicable state or federal authority, or submit a complaint against the plan or insurer.

For Air Ambulances

Additional information submitted by a party, provided the information is credible, relates to the circumstances i) through vi) below, with respect to a qualified IDR service of a nonparticipating provider of air ambulance services or group health plan that is the subject of a payment determination. This information must also clearly demonstrate that the QPA is materially different from the appropriate out-of-network rate.

i) The quality and outcomes measurements of the provider that furnished the services.
ii) The acuity of the condition of the participant or beneficiary receiving the service, or the complexity of furnishing the service to the participant or beneficiary.
iii) The training, experience, and quality of the medical personnel that furnished the air ambulance services.
iv) Ambulance vehicle type, including the clinical capability level of the vehicle.
v) Population density of the point of pick-up for the air ambulance (such as urban, suburban, rural, or frontier).
vi) Demonstrations of good faith efforts (or lack thereof) made by the nonparticipating provider of air ambulance services or the plan to enter into network agreements with each other and, if applicable, contracted rates between the provider of air ambulance services and the plan during the previous 4 plan years.

IDR Selects in Writing One of the Offers Within 30 Business Days

The certified IDR entity must submit the written decision and rationale through the Federal IDR portal within 30 business days after it is selected as the Certified IDR entity. If a certified IDR entity does not choose the offer closest to the QPA, the written decision must include a detailed explanation of the additional considerations relied upon, whether the information submitted by the parties was credible, and the basis upon which the certified IDR entity determined that the credible information demonstrated that the QPA is materially different from the appropriate out-of-network rate.

Effect of IDR Determination

A certified IDR entity determination is binding upon all parties involved, in the absence of fraud or evidence of intentional misrepresentation of material facts to the certified IDR entity by any party regarding the claim. A certified IDR entity's determination is not subject to judicial review, except where:

1) the award was procured by corruption or fraud;
2) there was evidence of partiality or corruption;
3) the certified IDR entity was guilty of misconduct; or
4) the certified IDR entity exceeded its powers.

After a determination, the party that submitted the initial Notice of IDR Initiation may not submit a subsequent Notice of IDR Initiation involving the same other party with respect to a claim that is the same as or similar to the item or service that was the subject of the initial determination during the 90-calendar-day period following the initial determination (90-calendar-day suspension period).

For claims for the same or similar item or service for which the end of the open negotiation period occurs during the 90-calendar-day suspension period, after the end of the 90-calendar-day suspension period, either party may initiate the Federal IDR process via a Notice of IDR Initiation within 30 business days following the end of the 90-calendar-day suspension period, as opposed to the standard 4-business-day period following the end of the open negotiation period.

Any Additional Payment Due 30 Calendar Days after the IDR Determination

The plan or insurer must make any additional payment, if applicable, of the amount of the offer selected by the certified IDR entity directly to the provider, facility, or provider of air ambulance services not later than 30 calendar days after the IDR determination. This amount will be the offer selected, reduced by the sum of any initial payment by the plan/insurer and any cost sharing paid or owed by the participant. If the offer selected by the certified IDR entity is less than the sum of the initial payment and any cost sharing paid by the participant, the provider/facility/air ambulance provider will be liable to the plan or insurer for the difference. This difference must be paid directly to the plan/insurer not later than 30 calendar days after the determination by the certified IDR entity.

Certified IDR Entity Fee and a Non-Refundable Administrative Fee

On September 30, 2021, CMS issued Technical Guidance No. 2021-01 which sets forth the administrative fee and the range of Certified IDR Entity fees for 2022.

IDR Entity Fee

Each party must pay the entire certified IDR entity fee at the time the parties submit their offer. For 2022, certified IDR entities must charge a fixed fee:

- for single determinations between $200 - $500, and
- for batched determinations between $268 - $670;

unless otherwise approved by the Departments.

Within 30 business days of making the determination, the certified IDR entity must refund the fee to the prevailing party. The certified IDR entity will retain the certified IDR entity fee submitted by the non-prevailing party. In the case of batched determinations, the certified IDR entity may make different payment determinations for each qualified IDR item or service under dispute. In these cases, the party with fewest determinations in its favor is considered the non-prevailing party and is responsible for paying the certified IDR entity fee. In the event that each party prevails in an equal number of determinations, the fee will be split evenly between the parties.

If the parties negotiate an out-of-network rate before the certified IDR entity makes a determination, the certified IDR entity is required to return half of each party's payment of the IDR entity fee, unless directed otherwise by both parties to distribute the total amount of that refund in different shares.

Non-Refundable Administrative Fee

Each party must also pay a non-refundable administrative fee **($50 in 2022)** at the time the certified IDR entity is selected for participating in the Federal IDR process to the certified IDR entity, which will remit the fee to the Departments.

Process for Certification of IDR Entities

To become certified for a 5-year period (subject to a petition and revocation process), IDR entities must provide written documentation demonstrating that they meet the eligibility criteria. These Interim Final Rules also establish a process whereby members of the public, providers, facilities, providers of air ambulance services, plans, or issuers may petition for the denial or revocation of certification of an IDR entity.

These Interim Final Rules set forth the confidentiality requirements applicable to certified IDR entities and include provisions regarding privacy, security, and breach notification. A certified IDR entity must provide notification no later than 60 calendar days after the discovery of a HIPAA breach.

ACA External Review Requirements Apply to Claims Subject to No Surprises Act Protections

These Interim Final Rules amend final external review regulations issued in 2015 to require grandfathered health plans/policies, which are generally exempt from requirements related to external review, to nevertheless provide for external review of adverse benefit determinations for claims subject to the cost-sharing and surprise billing protections in the NSA.

The following claims are eligible for external review:

1) Any determination of whether a claim is for treatment for emergency services that involves medical judgment or consideration of compliance with the cost-sharing and surprise billing protections;
2) Whether a claim for items and services furnished by a nonparticipating provider at an in-network facility is subject to the protections under the NSA;
3) Whether an individual was in a condition to receive a notice about the availability of the protections under the NSA and give informed consent to waive those protections;
4) Whether a claim for items and services is coded correctly, consistent with the treatment an individual actually received; and
5) Whether cost-sharing was appropriately calculated for claims for ancillary services provided by an out-of-network provider at an in-network facility.

See Exhibit A below for examples of adverse benefit determinations eligible for external review in light of these new Interim Final Rules.

Protections for the Uninsured

The NSA includes provisions that require providers and facilities to furnish good faith estimates to uninsured (or self-pay) individuals upon their request and at the time of scheduling the item or service. The definition of uninsured (or self-pay) individuals in the Interim Final Rules includes individuals enrolled in individual or group health insurance coverage offered by a health insurance issuer, or a health benefits plan from the Office of Personnel Management, but not seeking to have a claim for such item or service submitted to such plan or coverage. Thus, providers and facilities will be required to provide uninsureds a good faith estimate and such individuals will be able to avail themselves of the patient-provider dispute resolution process, where applicable. The requirements in the Interim Final Rules apply only to good faith estimate notifications for uninsured (or self-pay) individuals. HHS clarifies that while Selected Dispute Resolution (SDR) entities provide a similar function and must meet similar requirements as certified IDR entities, SDR entities are specific to the patient-provider dispute resolution process. Uninsured (or self-pay) individuals are eligible for the patient-provider dispute resolution process after being furnished an item or service for which they received a good faith estimate if the individual is billed, by the provider or facility, charges that are at least $400 more than the amount in the good faith estimate.

EXHIBIT A

Examples of Claims Eligible For External Review

Example 1 (i) Facts. A group health plan generally provides benefits for services in an emergency department of a hospital or independent freestanding emergency department.

Individual C receives pre-stabilization emergency treatment in an out-of-network emergency department of a hospital. The group health plan determines that protections for emergency services under regulations promulgated under NSA do not apply because the treatment did not involve "emergency services" within the meaning of the law. Individual C receives an adverse benefit determination and the plan imposes cost-sharing requirements that are greater than the requirements that would apply if the same services were provided in an in-network emergency department.

(ii) Conclusion. In this Example 1, the plan's determination that treatment received by C did not include emergency services involves medical judgment and consideration of whether the plan complied with the new regulations under the NSA. Accordingly, the claim is eligible for external review

Example 2. (i) Facts. A group health plan generally provides benefits for anesthesiology services. Individual D undergoes a surgery at an in-network health care facility and during the course of the surgery, receives anesthesiology services from an out-of-network provider. The plan decides the claim for these services without regard to the protections related to items and services furnished by out-of-network providers at in-network facilities under new regulations. As a result, D receives an adverse benefit determination for the services and is subject to cost-sharing liability that is greater than it would be if cost sharing had been calculated in a manner consistent with the federal regulations.

(ii) Conclusion. In this Example 2, whether the plan was required to decide the claim in a manner consistent with the new rules involves considering whether the plan complied, as well as medical judgment, because it requires consideration of the health care setting and level of care. Accordingly, the claim is eligible for external review.

Example 3. (i) Facts. A group health plan generally provides benefits for services in an emergency department of a hospital or independent freestanding emergency department.

Individual E receives emergency services in an out-of-network emergency department of a hospital, including certain post-stabilization services. The plan processes the claim for the post- stabilization services as not being for emergency services under the NSA regulations based on representations made by the treating provider that E was in a condition to receive notice from the provider about cost-sharing and surprise billing protections for these services and subsequently gave informed consent to waive those protections. E receives an adverse benefit determination and is subject to cost-sharing requirements that are greater than the cost-sharing requirements that would apply if the services were processed in a manner consistent with the regulations under NSA regulations.

(ii) Conclusion. In this Example 3, whether E was in a condition to receive notice about the availability of cost-sharing and surprise billing protections and give informed consent to waive those protections involves medical judgment and consideration of whether the plan complied with the federal NSA regulations. Accordingly, the claim is eligible for external review.

Example 4. (i) Facts. Individual F gives birth to a baby at an in-network hospital. The baby is born prematurely and receives certain neonatology services from a nonparticipating provider during the same visit as the birth. F was given notice about cost-sharing and surprise billing protections for these services, and subsequently gave informed consent to waive those protections. The claim for the neonatology services is coded as a claim for routine post-natal services and the plan decides the claim without regard to the requirements under the NSA regulations and the fact that those protections may not be waived for neonatology services[1] under the regulations.

(ii) Conclusion. In this Example 4, medical judgment is necessary to determine whether the correct code was used. Accordingly, the claim is eligible for external review. The Departments also note that, to the extent the nonparticipating provider balance bills Individual F for the outstanding amounts not paid by the plan for the neonatology services, such provider would be in violation of the NSA and its regulations.

Example 5. (i) Facts. A group health plan generally provides benefits to cover knee replacement surgery. Individual G receives a knee replacement surgery at an in-network facility and, after receiving proper notice about the availability of cost-sharing and surprise billing protections, provides informed consent to waive those protections. However, during the surgery, certain anesthesiology services are provided by an out-of-network nurse anesthetist. The claim for these anesthesiology services is decided by the plan without regard to the requirements under regulations under the Nor Surprises Act or to the fact that those protections may not be waived for ancillary services such as anesthesiology services provided by an out-of-network provider at an in-network facility . G receives an adverse benefit determination and is subject to cost- sharing requirements that are greater than the cost-sharing requirements that would apply if the services were provided in a manner consistent with the regulations.

(ii) Conclusion. The claim is eligible for external review.

[1] **Inapplicability of notice and consent exception to certain items and services**. The notice and consent criteria do not apply, and a nonparticipating provider will always be subject to the prohibitions of balance billing with respect to the following services:

(1) Ancillary services, meaning—

(i) Items and services related to emergency medicine, anesthesiology, pathology, radiology, and neonatology, whether provided by a physician or non-physician practitioner;

(ii) Items and services provided by assistant surgeons, hospitalists, and intensivists;

(iii) Diagnostic services, including radiology and laboratory services; and

(iv) Items and services provided by a nonparticipating provider if there is no participating provider who can furnish such item or service at such facility.

(2) Items or services furnished as a result of unforeseen, urgent medical needs that arise at the time an item or service is furnished, regardless of whether the nonparticipating provider satisfied the notice and consent criteria. 45 C.F.R. § 149.420