No Surprises Act Guidance – Part 2

The Departments of the Treasury, Labor, and Health and Human Services (the Departments) issued the second set of regulations (the Part 2 regulations) implementing the surprise medical billing provisions of the Consolidated Appropriations Act, 2021 (CAA). This portion of the CAA which, is also referred to as the "No Surprises Act" or NSA, and is intended to protect individuals, group health plans, and group and individual health insurance from "surprise" balance billing for care provided by out-of-network providers in specific situations. In general, those situations include emergency medical treatment by an out-of-network provider, care provided by an out-of-network provider while the patient is in an in-network facility, and air ambulance services from an out-of-network provider. Balance billing is the practice of billing a patient for the difference between (1) an out-of-network provider's billed charges and (2) the amount paid by the plan or insurer plus the individual's cost-sharing obligation (e.g., deductible, copayment, or coinsurance).

In July 2021, the Departments issued the first set of regulations implementing the NSA. That guidance describes the methods that must be used to determine the participant's cost-sharing and the initial payment that must be made by the plan or insurer. It also includes guidance on notice requirements, such as notices from plan to participant, provider to patient, provider to plan, and plan to provider. More detailed information about the July 2021 guidance can be found in Gallagher's Technical Bulletin – *No Surprises Act Guidance – Part 1.* This Technical Bulletin provides an overview of the new Independent Dispute Resolution (IDR) process as governed by the Part 2 regulations. Note that an Appendix to this Technical Bulletin contains definitions of key terms.

Independent Dispute Resolution

Under the Part 2 regulations, IDR will apply when negotiations between individuals, plans, or health insurers and out-of-network providers (including facilities and air ambulance providers) do not result in an agreement on payment for specific items and services provided to a patient under circumstances where NSA protections apply. The IDR process does not apply to situations where a State All-Payer Model Agreement or Specified State Law applies. The IDR process does not apply to self-pay situations. Self-pay occurs when either an individual does not have benefits coverage or insurance for an item or service, or when an individual who has benefits for an item or service does not seek to have a claim for such item or service submitted to the plan or insurer. The Part 2 regulations provide detailed requirements applicable to self-pay situations and include a similar (Selected Dispute Resolution or SDR process) that is binding on individuals and healthcare providers. A discussion of the self-pay and SDR requirements is outside the scope of this Technical Bulletin.

IDR PROCESS

The Part 2 regulations provide guidance on how the new IDR process applies to nonparticipating healthcare providers or facilities, nonparticipating providers of air ambulance services, group health plans, and health insurers. This new IDR process will be used to determine the out-of-network rate for specified emergency services, nonemergency items and services provided by out-of-network providers at in-network facilities, and out-of-network air ambulance providers when the rate cannot be determined by reference to a

State All-Payer Model Agreement or a Specified State Law. The new process starts with an open negotiation period of 30 business days, which begins on the date the nonparticipating provider, facility, or nonparticipating air ambulance provider receives either an initial payment or a notice of denial of payment. Negotiation may be initiated by either the plan/insurer or the provider/facility. If the parties cannot agree on the out-of-network rate, then the parties may initiate a review using a federally Certified Independent Dispute Resolution entity. The Departments are establishing a web portal to administer the federal IDR process (https://www.nsa-idr.cms/gov). A summary of the steps in the process follows.

IDR Process Initiation

First, the provider or facility must receive the initial Qualifying Payment Amount (QPA) payment or notice of the denial of payment. Then, either the provider/facility or the plan/insurer may initiate the process. The party initiating the open negotiation process must provide written notice of its intent to negotiate to the other party within 30 business days of the date on which the QPA payment was made (or the denial was issued). The Departments assume that the notices will be sent and received on the same day because they assume that most notices will be sent electronically. The open negotiation notice must include specific information about the services, such as service codes, date services were furnished, the initial payment amount (or notice of denial), the offer for the out-of-network rate, and contact information. The regulations include a notice with instructions that must be used. The notice may be provided electronically as long as certain requirements are satisfied. More specifically, the party sending the open negotiation notice may provide the notice electronically (such as by email) if the following two conditions are satisfied: (1) the party sending the open negotiation 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.

Multiple items and services may be considered jointly as part of one payment determination (called batching) as long as four conditions are satisfied. The four conditions are: (1) the qualified IDR items and services must be billed by the same facility, provider group of providers, or provider of air ambulance services using the same National Provider Identifier or Taxpayer Identification Number; (2) payment for the items and services would be made by the same group health plan or health insurer; (3) the qualified items and services must be the same or similar (defined using service codes such as those established under Current Procedural Terminology (CPT) codes, Diagnosis Related Group (DRG) codes, or Healthcare Common Procedure Coding System (HCPCS)) codes; (4) all of the qualified IDR items and services must have been furnished within the same 30-business-day period.

If the parties cannot agree during the 30-business-day open negotiation period on an out-of-network rate, either party may begin the IDR process. In order to initiate the process, one party must provide written notice to the other party and must notify the Departments using a new Federal IDR portal. Note that the parties cannot initiate the IDR process until the 30-business-day open negotiation period ends. The parties have four business days beginning on the 31st day after the start of the open negotiation period to begin the IDR process. The Part 2 guidance includes a notice with instructions that parties must use to initiate the IDR process. The required notice captures information such as: who is initiating the process (e.g., provider, group health plan); a description of the service or services including date(s), place(s), and code(s); contact information for the provider) and plan or insurer; cost-sharing allowed; and initial payment amount(s).

The party initiating the IDR process will indicate a preferred certified IDR entity when completing the IDR initiation notice by selecting from a list of certified federal IDR entities available on the federal IDR portal. The other party has three business days following the date of the IDR initiation to object to the certified IDR entity selected by the initiating party. If the non-initiating party objects, the two parties may agree upon another certified IDR entity. In all cases, the initiating party must notify the Departments by electronically submitting the notice of IDR selection (or failure to agree) no later than one business day after the three-business day IDR initiation period ends. If the parties do not agree upon an IDR entity within the allotted timeframe, or if the selected IDR entity has a conflict of interest, the Departments will randomly select a certified IDR entity and notify both parties of the selection within six days after initiation of the process.

Once the IDR entity has been selected, both parties have 10 business days to submit specific information including an offer for a payment amount for each qualified IDR item or service. The amount must be expressed as both a dollar amount and as a percentage of the QPA. Data elements that must be included in the offer, along with guidance on additional optional information that may be provided, are listed in Appendix 3 of the guidance.

Selection of an Offer

The IDR entity will review the information submitted and select one of the two offers not later than 30 business days after the selection of the IDR entity. The regulations state that when selecting an offer, the IDR entity must look first to the QPA amount. In general, the IDR entity is expected to select the offer that is closest to the QPA. However, in some cases the IDR may consider other factors. Other factors that the IDR entity may consider include information about:

- The level of training, experience, and quality and outcome measurements of the provider or facility that were necessary for providing the service or impact the care provided that the QPA fails to take into account.
- Information about the market share held by the nonparticipating provider, group health plan (including the market share of the plan's Third Party Administrator (TPA)), or health insurer in the geographic region in which the service was provided.
- Information about patient acuity or the complexity of furnishing the qualified IDR service that is not adequately accounted for in the QPA.
- Information about the teaching status, case mix, and scope of services of the nonparticipating facility that is in some way critical to the delivery of the qualified IDR service that is not adequately accounted for in the QPA.
- Demonstration of good faith (or lack thereof) by either party.

In the case of air ambulance services, similar information (along with information about the population density of the point of pick-up) may be taken into consideration. For example, the IDR entity may consider information about the ambulance vehicle type, including the clinical capability level of the vehicle, if the air ambulance service provider demonstrates that the QPA is materially different from the appropriate out-of-

network rate for air ambulance services. The IDR entity may not consider whether the air ambulance is fixed wing or rotary wing because the QPA will reflect that difference.

Parties should not submit and IDR entities are not permitted to consider: (1) usual and customary charges; (2) billed amounts (amounts that would be charged if the service was not subject to IDR); or (3) reimbursement rates paid by public programs such as Medicare and Medicaid.

The regulations include four examples illustrating when an IDR entity may (or may not) consider other factors when making its determination:

1. A nonparticipating provider submits written information asserting that the provider has made good faith efforts to enter into network agreements with the insurer, but fails to provide documentation such as correspondence or records of conversations. The IDR may not consider the provider's assertion of good faith efforts because the provider has not provided documentation.

2. A nonparticipating provider submits information demonstrating the provider's level of training and expertise and demonstrates that the level was necessary for providing the service at issue. The provider also provides information demonstrating that the QPA generally presumes that the service would be delivered by a provider with a lower level of training and experience and quality and outcome measurements. The information taken together shows that the QPA is not an appropriate payment amount. The provider's offer is higher than the QPA. The insurer submits the QPA as its offer with no additional information. In this case, the IDR entity must select the provider's offer.

3. A nonparticipating provider submits an offer higher than the QPA along with information relating to the acuity of the patient and the complexity of furnishing the service to the patient by providing details of the service at issue and the training required to furnish the complex service. However, the evidence submitted by the provider does not clearly demonstrate that the QPA amount fails to encompass the acuity and complexity of the service. The insurer submits the QPA as its offer along with information that demonstrates how the QPA was calculated for this particular service taking into account the acuity of the patient and the complexity of the service. In this case, the IDR entity must select the insurer's offer.

4. An insurer submits evidence demonstrating that the patent for an item that is the subject of the payment determination has expired, including documentation that demonstrates how much the cost of the item was at the time the provider rendered the service and how the QPA amount exceeds that cost. The insurer submits an offer that is lower than the QPA and commensurate with the cost of the item at the time services were rendered. The provider submits the QPA as its offer and submit evidence of the provider's level of training, experience, and quality and outcomes measurements, but does not explain how this additional information is relevant to the cost of the service. The IDR must select the insurer's offer.

In the preamble to the Part 2 regulations, the Departments state that an IDR entity must consider additional information submitted where the information clearly demonstrates that the QPA fails to take into account that the experience or level of training of a provider was necessary for providing the item or service to the patient or that the experience or training made an impact on the care that was provided. The Departments

do not believe that IDR items or services should necessitate out-of-network rates higher than the offer closest to the QPA simply based on the level of experience or training of a provider. The Departments also expressed concern about the potential for plans or insurers to alter service codes or modifiers submitted by the provider to lower levels that a plan or insurer deems more appropriate. In this case, both parties could submit evidence demonstrating that the QPA is materially different from the appropriate out-of-network rate. When that occurs, the IDR entity must select the offer that it determines best represents the value of the qualified IDR item or service.

IDR Entity Decision

Following review of the information submitted by both parties, the IDR entity will provide written notice of its decision to both parties and to the Departments using the Federal IDR portal. If the IDR entity does not choose the offer closest to the QPA, the IDR entity must provide its underlying rationale which must include a detailed explanation of the other factors considered as part of the written decision. Once the IDR entity has issued its written decision, payment must be made within 30 business days. If the amount selected by the IDR entity is greater than the QPA paid by the plan or insurer, the plan or insurer must pay the additional amount to the healthcare provider. If the amount approved by the IDR entity is less than the QPA already paid to the healthcare provider, the healthcare provider must return the difference to the group health plan or insurer.

The decision of the IDR entity is binding on the parties (absent fraud or misrepresentation of material facts) and in most cases is generally not subject to judicial review. Judicial review may be available in limited circumstances such as those involving fraud or misconduct.

IDR Timeline

The guidance specifies the following steps and time frames for the process:

IDR Step	Timeline
Initiate open negotiation period	30 business days, starting on the day of initial payment (or denial)
Initiate IDR process when open negotiation fails	4 business days, starting on the business day after the open negotiation period ends
Mutual agreement on selection of certified IDR entity	3 business days after the IDR process initiated
Departments select IDR entity (required only if the parties to not agree on an IDR entity)	6 business days after the IDR process initiated
Parties submit payment offers and any additional information	10 business days after the date of IDR entity selection
Payment determination made	30 business days after IDR entity selected
Payment submitted to applicably party	30 business days after payment determination made

An appendix in the interim final regulations also includes a form with instructions to be used to request an extension of time due to extenuating circumstances. Extenuating circumstances are limited to situations that are beyond the control of the party requesting the extension. A chart illustrating the process is contained in the Appendix.

Process Cost

Two specific fees will be charged to use the NSA's IDR process. First, there is an administrative fee that the parties pay to the IDR entity which the IDR entity will remit to the Departments. The amount will be established annually in guidance issued by the Departments and has been set at $50 for 2022. The $50 administrative fee is nonrefundable.

The second fee is the IDR entity's fee for its review and decision. The fee will vary by IDR, but must be within a range specified by the Departments unless the Departments have given the IDR entity written authorization to charge a fee outside the range. The IDR fee range for 2022 will be $200-$500 for single determinations. For batched determinations in 2022, the IDR fee range will be $268 to $670. Both parties to the IDR process must pay this fee to the IDR entity when the party submits its payment amount offer. The IDR entity service fee will be refunded to the party whose offer is accepted at the conclusion of the IDR process. If the parties reach a settlement after the payment offers are made, but before the IDR entity renders a decision, the IDR entity fee will be split between the two parties. In such cases, each party will pay half of the fee unless the parties have agreed to a different allocation.

CERTIFIED IDR ENTITIES

The NSA external review process relies on open negotiation between plans or insurers and healthcare providers with an IDR process applicable if open negotiation between the parties fails. The NSA requires these disputes to be settled by a certified IDR entity. An IDR entity must be certified by the Departments and must satisfy specific criteria in order to qualify for certification including:

- Possessing sufficient arbitration, and claims administration, and legal expertise to make payment determinations;
- Employing a sufficient number of personnel to make determinations on a timely basis;
- Maintaining current accreditation from a nationally recognized and relevant accrediting organization, such as URAC;
- Having a process to ensure that no conflict of interest exists between the parties and the personnel assigned to a payment determination;
- Having a process to maintain the confidentiality of individually identifiable health information obtained when making determinations – including requirements for handling and notification in the event of a breach;
- Meeting appropriate indicators of fiscal integrity and stability;

- Providing a fixed fee for single determinations and a separate fee for batched determinations with the upper and lower limits set by the Departments;
- Having a procedure in place to retain IDR entity fees in a trust or escrow account and to return fees to prevailing parties;
- Having a procedure in place to retain the administrative fees and remit those fees to the Departments; and
- Meeting obligations to collect and report required information to the Departments.

IDR entities will generally be certified for a period of five years. The appendices in the Part 2 regulations include information on the certification process for an IDR entity, data elements for reporting, and a sample petition that may be filed to request that a certification be denied or revoked.

External Review

The regulations also address two changes to the external review process that apply to group medical plans under the Patient Protection and Affordable Care Act (ACA). First, the scope of adverse benefit determinations that are subject to review (e.g., decisions that involve medical judgement) is expanded to include issues related to compliance with the NSA. Second, the ACA external review process must be provided for claims that are subject to the NSA under grandfathered medical plans even though for other types of adverse benefit determinations grandfathered plans may not be required to provide external review. The Departments believe that many of the claims relating to services subject to the NSA rules will be eligible for external review. The Part 2 regulations include five examples of situations that are eligible for external review under the NSA:

1. Any claim for treatment of emergency services because it will involve medical judgment.
2. A claim furnished by a nonparticipating provider at an in-network facility because adjudication of the claim requires consideration of the health care setting.
3. Any claim that involves a question about whether an individual was in a condition to receive a notice about the availability of the NSA protections and able to give informed consent to waive those protections because it will involve medical judgment.
4. A claim where there is a question about whether the items and services are coded correctly consistent with the treatment actually received because adjudication of the claim will involve medical judgment.
5. Any claim that involves consideration of whether cost-sharing was appropriately calculated for claims for ancillary services provided by an out-of-network provider at an in-network facility because it involves consideration of compliance with cost-sharing and NSA protections.

The change in scope will have a greater impact on grandfathered plans than on non-grandfathered plans. Grandfathered plans that do not currently have an ACA-compliant external review process will need to implement a process for claims eligible for NSA protection. Under insured plans, the health insurer should

handle the external review process. Employers with self-insured grandfathered plans will need to provide the ACA external review process for claims subject to the NSA. In most cases, Third Party Administrators (TPAs) administering grandfathered plans will also be administering non-grandfathered plans and should be able to assist employers in making changes to comply. Employers with self-insured medical plans will want to discuss the additional services that will be needed and cost with their TPAs. Gallagher's *Claims and Appeals Toolkit* contains more detailed information on the ACA external review process and may be helpful as a starting point for employers who have grandfathered medical plans.

Interaction with State Surprise Billing Laws

The NSA is intended to supplement state "surprise billing" laws. In cases where a Specified State Law applies, the state law will be used to determine both the individual's cost-sharing amount and the out-of-network payment rate. Under an insured plan, the applicable state's surprise billing law would determine these values. In contrast, under a self-insured plan not subject to a state's surprise billing law (e.g., a self-insured plan where ERISA preemption is available), these dollar amounts would be determined by the NSA rules. In some states, self-insured plans that are not subject to a state surprise billing law are permitted to "opt-in" to the state's law. Plans that opt into a state surprise billing requirement would use the Specified State Law to determining both patient cost-sharing and the out-of-network payment amount rather than the NSA rules and process. Our Technical Bulletin – *No Surprises Act Guidance – Part 1* – provides more information including four example from the July 2021 regulations.

The ACA rules for external claim review would also apply. In general, under the ACA non-grandfathered group health plans (and grandfathered plans under the NSA) and health insurance coverage (including grandfathered coverage) must comply with any applicable state external review process, if that process meets the federal ACA standards. If the state process dos not meet the federal ACA standard of if the plan or insurer is not subject to state insurance regulations (for example, a self-insured ERISA plan), then the Federal ACA external review process applies.

In addition, some states with surprise billing laws may have their own requirements for consumer protections such as rules governing appeals. The Part 2 regulations do not provide guidance on how the ACA claim review requirements and state consumer protection laws will apply to items and services covered by the NSA and state surprise billing laws. Presumably both sets of requirements would apply unless application of the state law would prevent compliance with the NSA. In that case, federal preemption should apply, and the NSA rules would be used. Similarly, states may also have privacy laws under their Surprise Billing laws, and plans subject to those state laws would need to comply with both the state and the federal HIPAA privacy requirements (unless the state laws prevent compliance with HIPAA).

Unfortunately, determining how to comply with both NSA and state requirements will need to be a state-specific analysis since there is considerable variation among state surprise billing laws.

What's Next?

Checking with insurers and TPAs. Unless an employer is adjudicating its own medical claims, the IDR process will be handled by the insurer or TPA that processes the employer's medical claims. The primary impact on the employer will be financial in two ways. First, the payment amount selected by the IDR entity

will be reflected in the claims paid by the employer's plan (or the premium levels set under insured plans). Second, administrative fees and IDR service fees will likely be passed on to the employer either directly or when premium levels are established.

Although the ink is barely dry on the IDR rules, the effective date is less than three months away. Employers thus will want to confirm soon that their insurers and/or TPAs will be prepared to comply with the new rules on time. Employers with self-insured plans may also want to ask their TPAs about how the new process will impact the fees charged by their TPA.

Considering state opt in rules. Employers who have already opted into a state surprise billing law in any state may want to compare the new NSA rules with the relevant state law(s). Some employers may have opted into a state requirement because there was no Federal law available when they made that decision. If, upon review, the employer who opted into a state law would prefer to use the Federal law in the future, that employer will need to determine if and how it can opt out of the state law and how it will communicate the change to participants. There are likely state specific requirements and time frames attached to an opt-out decision. Perhaps less likely now that there is a federal law, employers who did not opt into a state surprise billing law may still be able to do so. In that case, the employer would want to compare the NSA and state requirements to determine how both would impact the employer's plan and if the decision is made to opt into a state surprise billing law, the employer would need to determine what timing and requirements apply to that state's opt-in process. Our article – *With the New NSA: Should Employers Opt in (or Out) of State Surprise Billing Laws?* – discusses issues an employer will want to consider.

Be on the lookout for advance EOB regulations. In the preamble to the Part 2 regulations, the Departments confirm that the requirement that group health plans and health insurers provide advance Explanations of Benefits (EOBs) upon request is delayed until guidance has been provided. Although providers will be required to provide an estimate of charges to individuals who intend to self-pay in January, providers will not be required to provide that information to plans or insurers. The Departments agree with stakeholders who pointed out that plans, insurers, and providers will need time to build the infrastructure needed to enable the transfer of information required for plans and insurers to create advance EOBs. Further, the Departments state that the guidance, when issued, will include a prospective applicability date that is intended to give plans, providers, and facilities a reasonable amount of time to comply.

Waiting for additional guidance on pharmacy benefit and prescription drug cost reporting. The Departments state in the preamble that they do intend to undertake rulemaking to implement reporting requirements related to pharmacy benefits and prescription drug cost later this year.

Stay tuned for more. Employers will want to be on the lookout for additional guidance during the coming months. Although these regulations and the prior regulations issued in July 2021 contain a lot of information that will be helpful in complying with the NSA, it is likely that additional questions will soon arise and we may see some additional assistance. Gallagher will, of course, be on the alert and will provide more information on any new guidance that becomes available.

Appendix

Definitions

Batched items and services means multiple qualified IDR items or services that are considered jointly as part of one payment determination by a certified IDR entity for purposes of the Federal IDR process.

Certified IDR entity means an entity responsible for conducting determinations that meets the certification criteria and has been certified by the Departments. (We refer to such entities simply as IDR entities in this Technical Bulletin.)

Conflict of interest means, with respect to a party to a payment determination, or certified IDR entity, a material relationship, status, or condition of the party, or certified IDR entity that impacts the ability of the certified IDR entity to make an unbiased and impartial payment determination. For purposes of this section, a conflict of interest exists when a certified IDR entity is:

(A) A group health plan, a health insurance issuer, a provider, a facility, or a provider of air ambulance services.

(B) An affiliate or a subsidiary of a health insurance issuer, a provider, a facility, or a provider of air ambulance services.

(C) An affiliate or subsidiary of a professional or trade association representing group health plans, health insurance issuers, providers, facilities, or providers of air ambulance services.

(D) A certified IDR entity that has a material familial, financial, or professional relationship with a party to the payment determination being disputed.

Material difference means a substantial likelihood that a reasonable person with the training and qualifications of a certified IDR entity making a payment determination would consider the submitted information significant in determining the out of network rate and would view the information as showing that the Qualifying Payment Amount (QPA) is not the appropriate out-of-network rate.

Qualifying payment amount is the lesser of the billed amount or the median of the plan's or insurer's contract rate for the service as of January 31, 2019 (as indexed).

Specified State Law means a State law that provides for a method for determining the total amount payable under a group health plan or group or individual health insurance coverage.

State All Payer-Model Agreement means an agreement under section 1115A of the Social Security Act between a State and CMS that applies with respect to the plan or insurer, the nonparticipating provider or nonparticipating emergency, and the item or service provided.

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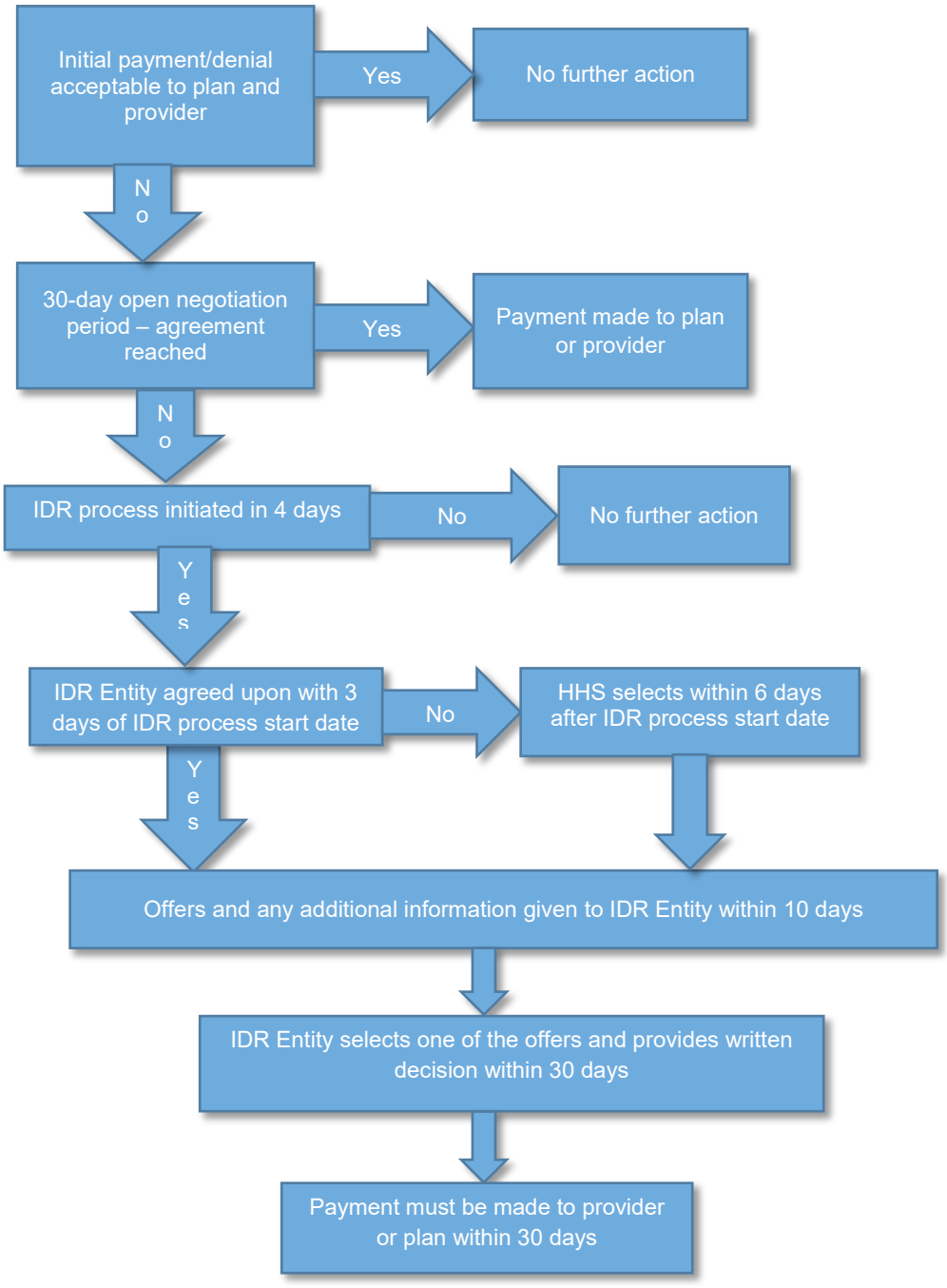
Steps in the Independent Dispute Resolution Process



The intent of this analysis is to provide general information regarding the provisions of current federal laws and regulation. It does not necessarily fully address all your organization's specific issues. It should not be construed as, nor is it intended to provide, legal advice. Your organization's general counsel or an attorney who specializes in this practice area should address questions regarding specific issues.