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Office of Personnel Management; Department of the Treasury; Department of Labor; Department of Health and Human Services: Interim Final Rules with Requests for Comments - Requirements Related to Surprise Billing; Part I

July 15, 2021

Background & Summary

On July 1, 2021, the Office of Personnel Management (OPM), Department of the Treasury (Treasury), Department of Labor (DoL), and Department of Health and Human Services (HHS) (the Departments) issued an interim final rule with request for comments, "Requirements Related to Surprise Billing; Part I" (hereinafter IFC). The IFC provides regulations to implement various provisions of the No Surprises Act (NSA), which was enacted as part of the Consolidated Appropriations Act, 2021 (Pub. L. 116-260). The NSA aimed to protect patients receiving group or individual health insurance coverage from surprise medical bills (e.g., balance billing for out-of-network services) and outlines how patient cost-sharing must be determined, among other provisions.

While many of the NSA's provisions, which this IFC implements, apply to group health plans and certain health insurance issuers, they are relevant to health care providers because they clarify payment processes (including methodology) to providers or facilities when a surprise billing circumstance arises, which is critical in resolving billing disputes. In addition, the IFC provides HHS-only regulations, which apply to hospitals and freestanding emergency departments, other health care providers and facilities and air ambulance providers. These HHS-only regulations include information on how balance billing protections may be waived through notice and consent, and disclosure requirements, among other information directly relevant to hospitals and other providers.

Comments are due September 7, 2021 by 5pm. In addition, the IFC is effective September 13, 2021, however, the HHS-only regulations are applicable beginning on January 1, 2022, along with other key provisions. Later this year, additional regulations regarding the audit process and independent dispute resolution (IDR) process are expected.

Preventing Surprise Medical Bills

The IFC includes provisions applicable to group health plans and health insurance issuers[1] (collectively "plans and issuers" for purposes of this summary) and HHS-only provisions applicable to health care providers, facilities, and providers of air ambulance services. These regulations detail the new patient protections from surprise medical bills and how payments between plans and issuers and providers and facilities will now be handled should a circumstance arise that previously would have caused a patient to receive a surprise medical bill.

[1] The IFC also includes information regarding regulations for Federal Employees Health Benefits (FEHB) Program carriers are also provided in the IFC (p. 163-167).

The new surprise billing protections address a range of emergency and non-emergency circumstances in which a surprise bill (e.g., balance billing or out-of-network cost sharing) commonly occurs. Specifically, the services addressed are:

- Emergency services (including post-stabilization services) provided by a nonparticipating provider or nonparticipating emergency facility (i.e., out-of-network providers or out-of-network emergency facilities)
- Non-emergency services performed by nonparticipating providers at participating health care facilities (i.e., out-of-network clinicians at in-network health care facilities), and
- Air ambulance services.

Patient Protections and Requirements Related to Emergency Services Provided by a Nonparticipating Provider or Nonparticipating Emergency Facility

In the IFC, the Departments provide that a plan or issuer providing coverage of emergency services must do so without the individual or the health care provider having to obtain prior authorization (including when the emergency services are provided out-of-network) and without regard to whether the health care provider furnishing the emergency services is a participating provider or a participating emergency facility with respect to the services.

In addition, the plan or issuer providing such coverage must comply with different requirements in the IFC regarding cost sharing, payment amounts and processes for resolving disputes.

Alternatively, nonparticipating providers and nonparticipating emergency facilities are required to communicate expeditiously with plans and issuers regarding when the surprise billing protections do not apply because the IFC's notice and consent criteria have been satisfied. Also, the IFC provides the steps providers and facilities must take to ensure balance billing and cost-sharing protections are appropriately applied.

Key Terms

In the IFC, the Departments clarify several key terms and provide numerous definitions. For example, "emergency medical condition", and "to stabilize", generally have the meaning provided under the Emergency Medical Treatment and Labor Act (EMTALA). However, two key differences are that the "emergency services", with respect to an emergency medical condition, under the IFC is broader than EMTALA's "emergency services" definition because it includes those services provided in both an emergency department of a hospital or an independent freestanding emergency department[2]. In addition, post-stabilization services, except under certain conditions, are included in the definition of "emergency services".

The Departments seek comment on any additional conditions that would be appropriate to include under the definition of emergency services.

Post-stabilization services are those services provided after a beneficiary is stabilized and as part of outpatient observation or an inpatient or outpatient stay with respect to the visit in which the other emergency services are furnished. Although post-stabilization services are generally subject to surprise billing protections, the IFC provides an exception to this rule which is detailed below.

[2] The definition of "independent freestanding emergency department" is intended to include any health care facility that is geographically separate and distinct from a hospital, and that is licensed by a state to provide emergency services, even if the facility is not licensed under the term "independent freestanding emergency department."

Cost-Sharing

For emergency services, the IFC prohibits nonparticipating providers and nonparticipating facilities (also referred to as an out-of-network provider and out-of-network facility) from balance billing patients. As a result, patients will not be responsible for more than their in-network cost sharing requirement (e.g., deductible, co-payment or coinsurance) for those emergency services provided. For example, if a plan or issuer imposes a 20 percent coinsurance rate for emergency services from participating providers or participating emergency facilities, the plan or issuer may not impose a coinsurance rate on emergency services from nonparticipating providers or facilities that exceeds 20 percent. In addition, due to the balance billing restrictions, the provider could not bill the patient the difference between the provider's billed charges and the amount collected (i.e., from the plan or patient). The cost-sharing requirements must be counted toward any in-network deductible or out-of-pocket maximums applied under the plan or coverage.

In addition, the IFC details how plans and issuers are to apply and calculate the cost-sharing amount (e.g., deductible, coinsurance, copayments). Specifically, the patient's cost-sharing is to be treated as if the emergency services were provided by an in-network provider or emergency facility. Also, the charge for such items and services is based on a "recognized amount" which is determined as follows:

1. An amount determined by an applicable All-Payer Model Agreement under section 1115A of the Social Security Act (SSA)[3];
2. If there is no applicable All-Payer Model Agreement, an amount determined by a specified state law; or
    - In the IFC (p. 55-59), the Departments further detail how specified state laws may interact with the IFC's requirements. As discussed in the IFC, a specified state law is a state law that provides a method for determining the total amount to pay an out-of-network provider by a plan or issuer.
3. If there is no applicable All-Payer Model Agreement or specified state law, the lesser of the amount billed by the provider or facility or the Qualifying Payment Amount (QPA).
    - Under the IFC, the QPA is the median of the contracted rates of the plan or issuer for the item or service in the geographic region. See below for "Methodology for Calculating the Qualifying Payment Amount" for more information.

Non-Emergency Services Performed by Nonparticipating Providers at Participating Health Care Facilities

The NSA and IFC ban balance bills when, during a "visit" (as defined in the IFC), non-emergency services are performed by nonparticipating providers at participating health care facilities (i.e., a hospital, a hospital outpatient department, a critical access hospital or ambulatory surgical center). **The Departments solicit comments on other facilities (e.g., urgent care centers[4] or retail clinics) that would be appropriate to designate as health care facilities.**

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[3] An All-Payer Model Agreement is an agreement between the Centers for Medicare & Medicaid Services (CMS) and a state to test and operate systems of all-payer payment reform for the medical care of residents of the state, under the authority granted under section 1115A the Social Security Act. All-Payer Model Agreements can vary significantly by state, including in using different approaches for approving payment amounts for items or services covered by the Agreements. These interim final rules defer to the state to determine the circumstances under which, and how, it will approve an amount for an item or service under a payment system established by an All-Payer Model Agreement.

[4] IFC at 41. The Departments notes that emergency services provided at urgent care centers that are licensed in a manner that brings them within the definition of independent freestanding emergency department would be subject to cost-sharing and balance billing protections,

In the IFC, items and services are included within the scope of a visit. In addition, a visit to a participating health care facility may also include the furnishing of equipment and devices, telemedicine services, imaging services, laboratory services, and preoperative and postoperative services, regardless of whether the provider furnishing such items or services is at the facility. **The Departments solicit comments regarding other items and services that would be appropriate to include within the scope of a visit.**

Cost-Sharing

As previously noted, to prevent balance billing under the IFC, out-of-network providers are generally not permitted to bill patients more than the patient's in-network cost-sharing amount. Assuming no exceptions apply, if a plan or issuer covers benefits for non-emergency items and services furnished by a nonparticipating provider at a participating health care facility, then the plan or issuer may not impose a cost-sharing requirement that is greater than if such items or services had been furnished by a participating provider. For example, if a plan imposes a 20 percent coinsurance rate for non-emergency services from participating providers, the plan may not impose a coinsurance rate on non-emergency services from nonparticipating providers that exceeds 20 percent. Such cost-sharing must also be counted towards the patient's in-network deductible and out-of-pocket maximum.

Regarding the process to determine cost-sharing amount for non-emergency services provided by a nonparticipating emergency facility, the IFC provide the same process for non-emergency services as emergency services, where cost-sharing is based on the "recognized amount" for such items services.

It is also important to note that cost-sharing and balance billing protections do not apply if the nonparticipating provider/facility provides the patient with notice and receives consent to waive the protections. Under these circumstances the patient would agree to out-of-network charges.

Air Ambulance Services

With respect to air ambulance services furnished by nonparticipating providers (including inter-facility transports), the IFC provides requirements for plans and issuers related to cost sharing, payment amounts, and processes for resolving billing disputes.

Cost-sharing

If a plan or issuer covers benefits for air ambulance services, the plan or issuer must cover those services from a nonparticipating provider so that the same requirements would apply if such services were provided by a participating provider. Any cost-sharing requirement for air ambulance services furnished by a nonparticipating provider must be counted toward any in-network deductible or out-of-pocket maximums.

The cost-sharing requirement (e.g., co-insurance percentage, deductible, copayment) for air ambulance services furnished by nonparticipating providers must be the same as would apply if such services were provided by a participating provider. However, the methodology to determine the cost-sharing amount for air ambulance services furnished by nonparticipating providers does not

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among others. But, due to variation in state law definitions, urgent care centers are not included within the definition of health care facilities, in the context of non-emergency services.

rely on the recognized amount (as provided in the IFC for certain emergency services and non-emergency service) as there are not specified state laws on air ambulance services.[5]Rather, the amount of any cost-sharing is based on the lesser of the QPA or the billed amount. **The Departments seek comment on any potential alternate approaches for calculating the cost-sharing amount for air ambulance services furnished by nonparticipating providers of air ambulance services.**

Methodology for Calculating the Qualifying Payment Amount (QPA)

As noted above, in some circumstances (e.g., whether there is a specified state law), the cost-sharing requirements imposed by plans for emergency services, non-emergency services or air ambulance services will be based on the QPA. In addition, IDR entities will consider the QPA when selecting between offers submitted during the IDR process. In the IFC, the Departments establish the methodology that must be used to determine the QPA.

Generally, for a given item or service, the QPA is the median of the contracted rates recognized by the plan or issuer on January 31, 2019 (adjusted for inflation), for the same or similar item or service that is provided by a provider in the same or similar specialty and provided in a geographic region in which the item or service is furnished. The median contracted rate is determined with respect to all group health plans of the plan sponsor or all group or individual health insurance coverage offered by the health insurance issuer that are offered in the same insurance market, consistent with the methodology established by the Departments and detailed further in the IFC.

Notably, regarding the median contracted rate that is used to determine the QPA, the Departments indicate "these interim final rules do not allow plans or issuers to separately calculate a median contracted rate based on other characteristics of facilities that might cause contracted rates to vary, such as whether a hospital is an academic medical center or teaching hospital."[6]

In addition to other QPA-related clarifications, the IFC notes that for items and services other than air ambulance services, a geographic region is generally defined as one region for each metropolitan statistical area (MSA) in a state and one region consisting of all other portions of the state. The Departments advanced this approach to minimize the instances in which a plan or issuer lacks sufficient information to calculate the median of contracted rates in any particular geographic region.

The NSA also provided an alternative methodology for determining the QPA in cases where a plan or issuer had insufficient information to calculate a median contracted rate for an item or service. In the IFC, the Departments provide the definition of "sufficient information", address the use of databases to determine the QPA and address new plans and coverage, along with new service codes. The Departments indicate their intent to minimize use of alternative methodologies whenever possible.

The IFC provides special rules for calculating the QPA for items or services for which a plan or issuer generally determines the reimbursement level for the same or similar items or services by multiplying the contracted rate by another unit, such as time or mileage. In addition, the IFC

[5] States are preempted from regulating air ambulance providers under the Airline Deregulation Act
[6] IFC at p. 75, available at: https://www.cms.gov/files/document/cms-9909-ifc-surprise-billing-disclaimer-50.pdf

provides specific instructions for calculating the QPA for anesthesia services (p. 84-85) and for certain service codes for air ambulance services (p. 85-86).

The Departments seek comment on the QPA methodology, including whether there are any considerations or factors that are not sufficiently accounted for in the methodology established in these interim final rules; the impact of the methodology on cost sharing, payment amounts, and provider network participation; and whether there are areas where commenters believe additional rulemaking or guidance is necessary.

Payer and Issuer Coverage Decisions in a Hospital's Emergency Department

In the IFC, the Departments indicate some plans and issuers currently deny coverage of certain services provided in an emergency department for various reasons (e.g., based solely on final diagnosis codes, imposing time limits between symptom onset and presentation at the emergency department). In the IFC, the Departments make clear that the determination of whether an episode of care involves an emergency medical condition should be based on whether the prudent layperson standard[7] is met, and must be made on a case-by-case basis before an initial denial of an emergency services claim. This clarification applies when a patient receives either in-network and out-of-network emergency services. In addition, the IFC indicates that in covering emergency services, plans and issuers must also ensure that they do not restrict coverage by imposing a time limit (including a requirement for a sudden onset) between the onset of symptoms and presentation of the enrollee at the emergency department.

Plan/Issuer and Provider/Facility Payment and Communications

Out-of-Network Rate

In addition to patient protections related to cost-sharing, the NSA and the IFC establish a process to determine the total amount a plan or issuer must pay an applicable provider when the IFC's surprise billing protections are triggered; this amount is referred to as the out-of-network rate. The IFC provides the following process to determine the out-of-network rate (less any cost sharing from the patient):

1. An amount determined by an applicable All-Payer Model Agreement under section 1115A of the SSA;
2. If there is no such applicable All-Payer Model Agreement, an amount determined by a specified state law;
3. In the absence of an applicable All-Payer Model Agreement or specified state law, if the plan or issuer and the provider or facility have agreed on a payment amount, the agreed upon amount; or
4. If none of those three conditions apply, and the parties enter into the independent dispute resolution (IDR) process and do not agree on a payment amount before the date when the IDR entity makes a determination of the amount, the amount determined by the IDR entity applies.

[7] IFC at p.31, *stating* "the determination of whether the prudent layperson standard has been met must be based on all pertinent documentation and be focused on the presenting symptoms (and not solely on the final diagnosis). This determination must take into account that the legal standard regarding the decision to seek emergency services is based on whether a prudent layperson (rather than a medical professional) would reasonably consider the situation to be an emergency."

While there are similarities in the process to determine the out-of-network rate and "recognized amount" (which is primarily relevant to determine the patient's cost-sharing), the IFC does not require that the QPA be used to determine the out-of-network rate. In addition, the IFC clarifies that where the surprise billing protections apply, and the out-of-network rate exceeds the amount upon which cost sharing is based, the plan or issuer must pay the provider or facility the difference between the out-of-network rate and the cost-sharing amount.

The IFC provides the following example: if an individual has a high deductible health plan ($1,500 deductible that has not yet accumulated any costs) and receives emergency services at an out-of-network facility, the plan may then determine the recognized amount for the services is $1,000. Since the deductible has not been satisfied, the individual's cost-sharing amount would be $1,000 (which would accumulate towards the deductible). After this occurs, the plan or issuer may determine that the out-of-network rate is $1,500. Based on the IFC, the plan would then pay $500 for the emergency services, which is the difference between the out-of-network rate ($1,500) and the cost-sharing amount ($1,000). Notably, the plan or issuer, under the IFC, is expected to make a payment to the provider or facility prior to the individual satisfying the deductible.

More information regarding the initial payment from the plan or issuer to the provider or facility is provided below.

Information to be Shared About the QPA

Although the QPA is not required to be used to determine the out-of-network rate, it will be relevant for arbitration and in determining the patient's cost sharing amount. As a result, providers and facilities may want details regarding how the plan or issuer determines the QPA. In the IFC, the Departments specify the information that a plan or issuer must share with a nonparticipating provider or nonparticipating emergency facility, as applicable, when determining the QPA.

The Departments require that plans and issuers make certain disclosures with each initial payment or notice of denial of payment. Also, plans and issuers must provide additional information upon request of the provider or facility. This information must be provided in writing, either on paper or electronically, to a nonparticipating provider, emergency facility or provider of air ambulance services, as applicable, when the QPA serves as the recognized amount.

A complete list of the disclosures required by the plan or issuer are provided in the IFC (p. 100-101). Notably, disclosures include the QPA for each item or service involved and information for the provider or facility to initiate negotiations. Additional information regarding the QPA can also be requested by the provider or facility from the plan or issuer.

The Departments seek comment on the disclosure requirements and what additional information a plan or issuer should be required to share with a provider or facility about the QPA, either in all cases or upon request. The Departments also seek comment on whether a specific definition or standard is needed to ensure that information provided upon request is disclosed in a timely manner.

Provider or Facility Notice to Plans or Issuers

For each item or service furnished by a nonparticipating provider or nonparticipating emergency facility, the provider (or participating facility on behalf of the nonparticipating provider) or nonparticipating emergency facility, as applicable, must provide timely notice to the plan or issuer as to whether either balance billing or in-network cost sharing protections apply to the item or service. If applicable, the provider or facility must provide to the plan or issuer a signed copy (by the patient or

their authorized representative) of any written notice and consent documents. This information sharing is required so the plan or issuer can process the claim appropriately.

With respect to post-stabilization services, the nonparticipating provider or nonparticipating emergency facility must notify the plan or issuer as to whether certain conditions are met with respect to each of the items and services for which the bill is submitted.

For non-emergency services only, in instances where the nonparticipating provider bills the patient directly (where permitted under the IFC), the provider (or participating health care facility on behalf of the provider) may satisfy the requirement for timely notification of the plan or issuer by including the notification with the bill to the individual.

HHS seeks comment on whether additional rulemaking would be helpful regarding the process and timing for such notification, including the definition of 'timely,' and what processes for conveying the notification would be most efficient, including existing processes that could be leveraged to convey the information. HHS is particularly interested in comments regarding the requirement that providers or facilities provide to the plan or issuer a copy of the signed written notice and consent document, including comments on barriers and burdens associated with such requirement, and recommendations on how best to ensure plans and issuers have information regarding the notice and consent documents without imposing undue burdens on providers and facilities.

In addition, HHS understands that currently, nonparticipating providers and facilities may bill individuals directly for out-of-network services, leaving the individual to submit the bill to the plan for coverage. HHS also recognizes that to comply with the IFC, nonparticipating providers would be required to communicate with the plan, rather than only the patient. **HHS seeks comment on the impact this change will have on nonparticipating providers and facilities**.

Additional Plan and Issuer Requirements Regarding Making Initial Payments or Providing a Notice of Denial

The NSA establishes procedural requirements to help resolve billing disputes in a timely fashion. These procedural requirements include timeframes for a plan or issuer to send a notice of denial of payment or make an initial payment; the length of any open negotiation period regarding payment; and initiating the IDR process following an open negotiation period. Additional regulations are expected to detail the IDR process.

However, these procedural requirements generally do not apply to post-stabilization services or to out-of-network non-emergency services (other than out-of-network air ambulance services) if the provider or facility provided notice and received consent from the patient (or their authorized representative), as described below.

Initial Payment of Notice of Denial of Payment

The IFC requires plans and issuers to send "an initial payment or notice of denial of payment" no later than 30 calendar days after a nonparticipating provider or facility submits a bill related to the items and services that fall within the scope of the new surprise billing protections (e.g., for emergency services, non-emergency services performed by nonparticipating providers at participating facilities, and air ambulance services furnished by nonparticipating providers of air ambulance services).

In addition, the Departments clarify that the "initial payment" does not refer to a first installment. Rather, this initial payment should be an amount that the plan or issuer reasonably intends to be paid in full based on the relevant facts and circumstances and as required under the terms of the plan or coverage, prior to the beginning of open negotiations or the IDR process. The IFC does not specify an amount for the initial payment but does indicate several state balance billing laws set standards for minimum initial payment amounts. **The Departments seek comment on whether to set a minimum payment rate or methodology for a minimum initial payment in future rulemaking, and if so, what that rate or methodology should be. The Departments also seek comment on whether a minimum payment rate should be defined as a commercially reasonable rate based on payments for the same or similar services in a similar area, without requiring any specific methodology. In addition, the Departments seek comment regarding the impact of these provisions on underserved and rural communities, and other communities facing a shortage of providers.**

Provider/Facility and Patient Communications, Including Balance Billing Exceptions

Post-Stabilization Services Exception

Post-stabilization services would not be subject to the surprise billing protections if the following conditions are met by both the provider and/or facility and patient (or their authorized representative).

1. The attending emergency physician or treating provider must determine that the beneficiary is able to travel using nonmedical transportation or nonemergency medical transportation to an available participating provider or facility located within a reasonable travel distance, taking into consideration the individual's medical condition and social risk. Should an individual be unable to travel using nonmedical or nonemergency transportation, the balance billing protections would continue to apply.
2. The provider or facility furnishing post-stabilization services provides notice and obtains the patient's consent to waive the balance billing protections. Additional detail regarding the notice and consent process are available in the section below detailing non-emergency services performed by nonparticipating providers at participating health care facilities.
3. The individual (or their authorized representative) must be in a condition to receive the notice and provide informed consent (in accordance with state law). In the IFC, the Departments anticipate that post-stabilization notice and consent procedures will generally be applied in limited circumstances, where the individual knowingly and purposefully seeks care from a nonparticipating provider or facility. **Note, the Departments solicit comments on what guidelines may be needed to determine when an individual is in a condition to receive notice and provide consent (more information is provided below).**
4. The provider or facility must satisfy any additional requirements or prohibitions under state law.

The IFC also provides that in cases where post-stabilization services are being furnished by a nonparticipating provider at a participating emergency facility, the notice must include a list of any participating providers at the participating emergency facility who are able to furnish the items or services involved. The notice must inform the individual that they may be referred, at their option, to such a participating provider. **HHS seeks comment regarding the format and content of the referral list to be included in the notice, including any challenges that providers may have in providing this information, and any further requirements that should be applied to providers when furnishing this information to the individual**.

Notice and Consent Exception to Prohibition on Balance Billing

Under the NSA and the IFC, the protections that limit cost sharing and prohibit balance billing do not apply to certain non-emergency services or to certain post-stabilization services provided in the context of emergency care if certain requirements related to notice and consent are met. In conjunction with the IFC's release, CMS provided a standard notice and consent form. Those requirements are:

1. The nonparticipating provider or nonparticipating emergency facility furnishing those items or services provides the participant, beneficiary, or enrollee, with notice (written or, as practicable electronic);
2. The individual acknowledges receipt of the information in the notice; and
3. The individual consents to waive the balance billing protections with respect to the nonparticipating emergency facility or nonparticipating providers named in the notice.

The IFC details the requirements related to the content, method, and timing of the notice and consent communications; requirements related to language access, exceptions to the applicability of the notice and consent process; requirements for the retention of the notice and consent documents; and requirements to notify the plan or issuer regarding consent provided by the participant, beneficiary, or enrollee. These factors are further discussed below.

The notice and consent exception to the prohibition on balance billing does not apply to emergency services (other than post-stabilization services, under certain circumstances) or air ambulance services.

Content of Notice

A provider or facility must provide the written notice using the form specified by HHS in guidance, customized to include certain information (e.g., provider or facility by name; good faith estimated amount that such nonparticipating provider or nonparticipating emergency facility may charge the individual for the items and services involved including any item or service that the nonparticipating provider reasonably expects to provide in conjunction with such items and services).

Since the notice must include the good faith estimate for such items or services that would reasonably be expected to be provided by the nonparticipating emergency facility or by nonparticipating providers as part of the visit at such facility, **HHS seeks comment regarding potential challenges that may occur in developing the good faith estimate. In addition, HHS seeks comment regarding the method by which this good faith estimate amount should be calculated and anticipates addressing this requirement in future rulemaking.**

In addition to other information, the notice must provide information about whether prior authorization or other care management limitations may be required in advance of receiving such items or services at the facility or from the provider. HHS recognizes that there may be challenges for nonparticipating providers or facilities to identify what prior authorization and other care management limitations may apply with respect to a plan or coverage in which they do not participate. Therefore, providers and facilities may provide general information in order to satisfy this requirement, but to the extent possible, HHS encourages them to contact the issuer or plan about any such limitations so that they can include specific information in the notice.

In cases where post-stabilization services are being furnished by a nonparticipating provider at a participating emergency facility, the notice must include a list of any participating providers at the participating emergency facility who are able to furnish the items or services involved.

Timing of Notice

To ensure there is sufficient opportunity to review the notice and provide consent, the IFC indicates the provider or facility must provide such a notice in the timeframe specified in the statute and the IFC. There are three relevant timeframes for providers and facilities to consider. First, if an individual schedules an appointment for items or services at least 72 hours before the appointment, the provider or facility must provide the notice at least 72 hours before the appointment. Second, if the individual schedules the appointment within 72 hours of the date of the appointment, notice must be provided on the day that the appointment is made. Third, if an individual receives notice on the same day as the items or services are provided, then the notice must be provided at least 3 hours before such items and services were provided. **HHS seeks comment on whether these time limits provide a reasonable approach, as well as whether the 3 hours' time requirement should be shorter or longer, in order to best ensure that consent is freely given while also facilitating timely access to care.**

Standards for Consent

To meet the consent requirements, the patient (or their authorized representative) must acknowledge that they consent to be treated and balance billed by the nonparticipating emergency facility or nonparticipating provider under circumstances where the individual elects to receive such items or services. An incomplete consent document will be treated as a lack of consent and balance billing protections will still apply.

As with the notice document, providers and facilities must use the standard consent document specified by HHS in guidance, and the consent document must be provided in accordance with such guidance. The nonparticipating provider, participating health care facility on behalf of the nonparticipating provider, or nonparticipating emergency facility must provide the individual with a copy of the signed notice and consent in-person, or through mail or email, as selected by the individual. The notice and consent documents must meet applicable language access requirements (e.g., notice available in the most 15 common languages in a state or geographic region in which the facility is located, compliance with other state and federal laws)[8], among other requirements.

HHS clarifies that consent obtained by the provider or facility under this notice and consent process in no way substitutes for or modifies requirements for informed medical consent otherwise required of the provider or facility, under state law or codes of medical ethics.

The participant, beneficiary, or enrollee may revoke consent by notifying the provider or facility in writing prior to the furnishing of the items or services. If an individual revokes consent, the balance billing protections apply to applicable items or services provided after the revocation as if consent was never provided. **HHS seeks comment on whether additional rulemaking or guidance is needed on how an individual can revoke consent.**

Authorized Representatives

The IFC indicates that the notice may be provided to the individual's authorized representative instead of the individual, and consent may be provided by the authorized representative on behalf of the individual. Although treating providers may be authorized under state law to provide consent to treatment, HHS believes that providers should generally not be permitted to receive notice or

[8] If the individual's preferred language is not among the 15 most common languages in which the documents are made available by the nonparticipating provider or nonparticipating emergency facility, or the individual cannot understand the language in which the notice and consent documents are provided, as self-reported by the individual, the notice and consent requirements described in these interim final rules are not met unless the provider or facility furnishes the individual with a qualified interpreter.

provide consent regarding treatment by a nonparticipating provider or facility because of the potential for an inherent financial or professional conflict of interest. These same concerns extend to employees of the facility at which the items or services are furnished.

HHS seeks comment on whether and how the term "family member" should be defined. HHS is sensitive to concerns that some individuals may not have a familial relation formally recognized under applicable state law, or other documented legal partnership with individuals whom they consider family. Therefore, when interpreting this requirement, HHS indicates it will construe "family member" broadly to include such individuals prior to the issuance of additional guidance.

Retention of Certain Documents

Nonparticipating emergency facilities, participating health care facilities and nonparticipating providers are required to retain written notice and consent documents for at least a 7-year period after the date on which the item or service in question was furnished.

Requirements to Notify the Plan or Issuer

As described above, the IFC requires the provider or facility to provide notice to the plan or issuer when notice and consent has been received so it can process the claim appropriately.

Exceptions to the Availability of Notice and Consent

With respect to non-emergency services, the notice and consent exception does not apply to items or services provided as a result of unforeseen, urgent medical needs that arise when an item or service is furnished or ancillary services.

Ancillary services means items and services related to emergency medicine, anesthesiology, pathology, radiology, and neonatology; items and services provided by assistant surgeons, hospitalists; and intensivists; diagnostic services, including radiology and laboratory services; and items and services provided by a nonparticipating provider, only if there is no participating provider who can furnish such item or service at such facility. **HHS seeks comment on other ancillary services that should be considered as ineligible for the notice and consent exception.**

The exception for notice and consent is not applicable with respect to emergency services, except for post-stabilization services, under certain conditions described above.

Provider and Facility Disclosure Requirements Regarding Patient Protections against Balance Billing

The NSA and IFC require providers and facilities to provide disclosures regarding patient protections against balance billing. The IFC outlines methods of disclosure and content. The notice must include information about any applicable state requirements, and about how to contact appropriate state and federal agencies if the individual believes the provider or facility has violated the balance billing rules.

To reduce burden and facilitate compliance with these disclosure requirements, the Departments are concurrently issuing a model disclosure notice that health care providers, facilities, group health plans, and health insurance issuers may, but are not required, to use to satisfy the disclosure requirements regarding the balance billing protections. The Departments will consider use of the model notice in accordance with the accompanying instructions to be good faith compliance with the disclosure requirements.

Methods of Disclosure

The NSA and the IFC require that each health care provider or facility make the required disclosure publicly available, and (if applicable) post it on a public website of such provider or facility. In addition, providers and facilities must provide a one-page notice to individuals who are participants, beneficiaries, or enrollees of a group health plan or individual health insurance coverage offered by a health insurance issuer.

Timing of Disclosure to Individuals

The IFC generally requires a health care provider or health care facility to provide the notice to participants, beneficiaries, or enrollees no later than the date and time on which the provider or facility requests payment from the individual (including requests for copayment made at the time of a visit to the provider or facility). In cases where the facility or provider does not request payment from the individual, the notice must be provided no later than the date on which the provider or facility submits a claim for payment to the plan or issuer. **HHS seeks comment on this timing requirement, and whether another timing requirement would be more appropriate.**

Disclosure Requirements

The IFC provides the following two circumstances to guide health care providers as to when disclosure regarding balance billing protections is needed:

1. Health care providers are not required to make the disclosures required under the IFC if they do not furnish items or services at a health care facility, or in connection with visits at health care facilities; and
2. Health care providers are required to provide the required disclosure only to individuals to whom they furnish items or services, and then only if such items or services are furnished at a health care facility, or in connection with a visit at a health care facility.

HHS seeks comment on these exceptions and whether there are other scenarios that should be considered.

Special Rule to Prevent Unnecessary Duplication with Respect to Providers

In the IFC, HHS notes there may be some instances where an individual may receive two disclosure notices – one from a provider furnishing items or services at a health care facility, and the other from the health care facility itself. To minimize duplication, the agency provided a special rule to prevent unnecessary duplication. The special rule provides that to the extent a provider furnishes an item or service covered under the plan or coverage at a health care facility (including an emergency department of a hospital or independent freestanding emergency department), the provider satisfies the disclosure requirements if the facility agrees to provide the information, in the required form and manner, pursuant to a written agreement.

Surprise Billing Complaints

The NSA directs HHS to establish a process to receive consumer complaints regarding violations by health care providers, facilities, and providers of air ambulance services regarding certain balance billing requirements and to respond to such complaints within 60 days. The IFC includes HHS-only rules to establish a process by which HHS will receive complaints regarding violations of these balance billing requirements by health care providers, facilities, and providers of air ambulance services. In addition, CMS provides additional detail regarding the complaints submission process.

To process complaints, the Departments intend to provide one system that will direct complaints to the appropriate Department for processing, investigation, and enforcement action, as necessary.

The Departments also seek comment on ways to ensure consumers are aware and know how to use this system.

The IFC clarifies that HHS will respond to complaints regarding violations of balance billing protections by health care providers, facilities, and providers of air ambulance services within 60 days of receipt. The next steps of the complaint resolution process may include referring the complainant to another appropriate state or federal resolution process, referring a complainant to the state or federal regulatory authority with enforcement jurisdiction or initiating an investigation for enforcement action. The Departments will make reasonable efforts to notify the complainant of the outcome of such investigations or enforcement actions. **Feedback is requested on this approach.**

Audits and Enforcement

The NSA requires rulemaking to establish a process under which group health plans and health insurance issuers offering group or individual health insurance coverage are audited by the applicable Secretary or applicable state authority to ensure compliance with the requirement of determining and applying the QPA. The IFC outlines enforcement authorities (e.g., states, HHS, DoL, Treasury, OPM) for different entities relative to different aspects of the IFC. Additionally, the IFC includes an audit provision establishing that HHS's existing enforcement procedures will apply with respect to ensuring that a plan or issuer complies with the requirement of determining and applying a QPA.

The IFC indicates that where a provider or facility engages in improper balance billing, the Secretary of HHS may impose civil money penalties in states where HHS is directly enforcing the balance billing provisions with respect to health care providers, facilities and providers of air ambulance services. However, the NSA provides that the Secretary shall waive the penalties with respect to a health care provider, facility or provider of air ambulance services who does not knowingly violate (and should not have reasonably known it violated) such provisions, if, within 30 days of the violation, the provider or facility withdraws the bill and reimburses the health plan or individual, as applicable. The amount reimbursed must be equal to the difference between the amount billed and the amount allowed to be billed under the provision, plus interest, at an interest rate determined by the Secretary. HHS intends to address enforcement of the NSA's requirements applicable to health care providers, facilities and providers of air ambulance services through future rulemaking.

What's Next?

Although the IFC is effective on September 13, 2021, most of the provisions are not applicable until January 1, 2022. The Departments are accepting comments on the IFC until September 7, 2021 at 5pm. Also, two additional regulations related to the No Surprises Act are anticipated in 2021. One regulation to establish an enforcement process and another that will detail the independent dispute resolution (IDR) process.

Vizient's Office of Public Policy and Government Relations looks forward to hearing member feedback on this IFC. Stakeholder input plays a major role in shaping future changes to policy. We encourage you to reach out to our office if you have any questions or regarding any aspects of this IFC – both positive reactions and provisions that cause you concern. Please direct your feedback to Jenna Stern, Sr. Regulatory Affairs and Public Policy Director in Vizient's Washington, D.C. office.