First Installment of Surprise Billing Regulations Released

By Richard Eiler, Catherine N. Simpson, Danielle M. Sloane and David A. Thornton | August 6, 2021

On July 1, the Department of Health and Human Services (HHS), Department of Labor, and Department of the Treasury (Departments) jointly issued interim final rules (IFR) implementing certain aspects of the No Surprises Act (Act), which was signed into law on December 27, 2020, as part of the Consolidated Appropriations Act, 2021. The purpose of the Act is largely to prevent balance billing related to emergency services, non-emergency services provided by out-of-network providers in certain in-network facilities such as hospitals and ambulatory surgical centers, and out-of-network air ambulance providers. Read our previous alert on the Act here.

The recently published IFR implement portions of the Act addressing surprise billing, corresponding rate and payment determinations, and provider notice obligations. The IFR include substantially parallel provisions that apply to or in connection with group health plans (generally under the Employee Retirement Income Security Act or ERISA and the Internal Revenue Code) and health insurance issuers (issuers) in the group and individual insurance markets (under the Public Health Service Act), along with additional HHS rules that apply to emergency departments, healthcare providers and facilities, and air ambulance service providers.

The IFR take effect September 13, 2021; however, because the joint regulations apply for group health plan (plan) or insurance policy (policy) years beginning on or after January 1, 2022, most of the provisions, including the HHS-only rules, do not apply until January 1, 2022. Comments are due by 5:00 p.m. ET on September 7, 2021.

IFR Scope: Emergency Services, Certain Non-Emergency Services, and Air Ambulance Services

The IFR protect individuals from surprise medical bills and limit cost-sharing obligations for the following services:

1. Emergency services provided by non-participating (i.e., out-of-network) emergency facilities or non-participating providers at participating (i.e., in-network) facilities, including certain post-stabilization services.
2. Non-emergency services furnished by non-participating providers at participating facilities.
3. Air ambulance services furnished by non-participating providers.

While the Act and IFR do not universally protect individuals from every high or unexpected medical bill, they do provide relief from some of the most common scenarios where a patient may face high and unexpected medical costs.

Emergency Services and Post-Stabilization Services

In general, the IFR require plans and issuers (payers) to cover "emergency services" without regard to the participation status of the provider or emergency facility and prohibit payers (and providers) from charging patients cost-sharing amounts greater than they would have paid for a participating provider. The surprise billing limitations apply to emergency services provided in a hospital or independent freestanding emergency department, which includes an urgent care center if it is licensed by the state to provide emergency services.

The term "emergency services" generally has the same meaning as under the Emergency Medical Treatment and Labor Act, including (1) an appropriate medical screening to evaluate whether an emergency medical condition exists and (2) medical treatment required to stabilize the individual. In addition, emergency services include pre-stabilization services provided after the patient is moved out of the emergency department and admitted to the hospital.

After a patient receives emergency services, the protections that limit cost-sharing and prohibit balance billing will continue to apply to covered services provided after the patient has been stabilized (post-stabilization services) unless the following four criteria are met:

1. An attending emergency physician or treating provider determines the patient can travel using nonmedical or non-emergency transportation to an available participating provider or facility located within a reasonable travel distance based on the individual's medical condition,
2. The provider or facility furnishing the post-stabilization services meets the notice and consent requirements described further below,
3. The individual (or the individual's authorized representative) is in a condition to receive such information and provide informed consent; and
4. Satisfaction of any additional requirements or restrictions under applicable state law.

Non-Emergency Services

The scope of services covered by the surprise billing protections is even broader in the context of non-emergency services provided by a non-participating provider during a "visit" to a participating "health care facility" unless the patient receives an appropriate notice and gives informed consent. Although the Departments may add additional types of facilities in the future (and are seeking comments in that regard), initially "health care facilities" to which these rules apply include hospitals, hospital outpatient departments, critical access hospitals, and ambulatory surgery centers.

A "visit" to one of these types of facilities broadly captures all 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 physically located at the facility. For example, covered services provided by an off-site non-participating laboratory fall within the purview of these rules if the sample is collected during an individual's visit to a participating healthcare facility.

The notice and consent exception does not apply to some non-emergency items or services such that the cost-sharing and balance billing protections will always apply to the following:

- "Ancillary services," such as the following:
    - Items and services related to emergency medicine, anesthesiology, pathology, radiology, and neonatology, whether provided by a physician or non-physician practitioner.
    - Items and services provided by assistant surgeons, hospitalists, and intensivists.

    - Diagnostic services, including radiology and laboratory services (excluding advanced diagnostic laboratory tests).
    - Items and services provided by a non-participating provider when there is no participating provider who can furnish such item or service at such facility.
- Items or services furnished as a result of unforeseen, urgent medical needs that arise at the time an item or service is furnished for which a non-participating provider satisfied the notice and consent criteria.

HHS is seeking comment on whether to expand the types of ancillary services that are ineligible for the notice and consent exception, particularly with respect to other services for which individuals have little control over the choice of provider. The Act also authorizes HHS to specify a list of advanced diagnostic laboratory tests for which the notice and comment exception can apply. To develop that list, HHS is seeking comment on what criteria should be considered in developing that list and on any specific laboratory tests that should be included on that list.

Air Ambulance Services

The IFR also codify Act protections from patients receiving surprise bills from non-participating providers of air ambulance services if the payer has a network of participating providers (even if that network doesn't include any air ambulance service providers) and covers any benefits for air ambulance services.

Payer (Plan and Issuer) Obligation: Calculating Cost-sharing Amount and Payments to Providers and Facilities

As required by the Act, the IFR implement limitations on cost-sharing for out-of-network services to in-network levels, require cost-sharing to count toward any in-network deductibles and out-of-pocket maximums, and prohibit balance billing.

Determining the Cost-Sharing Amount

Where the surprise billing limitations apply, the patient's cost-sharing obligation must be the same as if the services were provided by a participating provider. Except for air ambulance-related services, the payer must determine the "recognized amount" to calculate the patient's cost-sharing obligations. The "recognized amount" is effectively a proxy for what would have been the in-network rate, but it is not necessarily the reimbursement rate that the provider will receive. Most often, the "recognized amount" is likely to be the "qualifying payment amount" (QPA) – an amount determined using the methodology described further below – unless the state is participating in an all-payer payment reform model or the state otherwise specifies the payment rate.

Specifically, outside of contexts where there is an applicable "All-Payer Model Agreement" (currently only Vermont, Pennsylvania and Maryland) or a specified state law that determines the rate, "recognized amount" is the lesser of the billed charge or the QPA under the applicable plan or policy. In establishing this methodology, the Departments reasoned that not tying the cost-sharing payment amount to the amount ultimately paid by the payer to the non-participating provider or facility would reduce provider-payer disputes. Cost-sharing amounts for air ambulance services provided by non-participating providers must be calculated using the lesser of the billed charge or the QPA, and the cost-sharing requirement that would apply if such services were provided by a participating provider.

Determining the Out-of-Network Rate

The IFR also set forth requirements for determining the out-of-network rate due to the non-participating provider or facility. Specifically, the payer must pay the non-participating provider or facility one of the following amounts (less cost-sharing):

1. An amount determined by an applicable All-Payer Model Agreement.
2. If there is no applicable All-Payer Model Agreement, an amount determined by a "specified state law."
3. If there is no applicable All-Payer Model Agreement or specified state law, an amount agreed upon by the payer and the provider or facility.
4. If no agreement is reached, an amount is determined through the independent dispute resolution (IDR) process.

The payer must pay the provider or facility the amount by which the out-of-network rate exceeds the cost-sharing amount, even in cases where an individual has not satisfied their deductible.

Specified State Law

The Departments clarified that, in cases where specified state law applies (meaning the state law applies with respect to the plan or policy, the provider, *and* the services at issue), the recognized amount and out-of-network rate should—absent an applicable All-Payer Model Agreement—be calculated based on that state law.

Very generally stated with respect to group health plans, a state law likely would apply with respect to an insured plan but, for a self-insured (i.e., not insured) plan subject to ERISA, the state law likely would not apply because of ERISA preemption, though the IFR make clear that a state may implement an opt-in process for ERISA plans, in which case certain participant disclosures are required by plans that opt-in. The IFR (in the preamble) provide some examples illustrating how state law would apply to determine the out-of-network rate, including with respect to the interaction of state law and ERISA.

Qualifying Payment Amount

In general, the QPA for a given item or service furnished in 2022 is the median of the contracted rates on January 31, 2019, as applicable. The contracted rates include rates established, either: under all group health plans of the plan sponsor (or, at the option of the sponsor of a self-insured plan, of the "administering entity," such as the third-party administrator for the plan), or under all policies offered by the issuer in the same market, accounting for provider specialty, geographic region, and adjustments based on the consumer price index.

Among other things, the IFR also lay out methods for calculating the QPA in relation to alternative reimbursement models that are not standard fee-for-service arrangements and unit-based services that involve reimbursement tied to a contracted rate multiplied by another unit (e.g., anesthesia services and air ambulance services).

In general, the payer is to calculate the median contracted rate by taking the middle rate after arranging, from least to greatest, all of its contracted rates from all of its plans/policies in the same *insurance market* for the *same or similar item or service* that is with a *same or similar provider or facility* and provided in the *geographic region* in which the item or service is furnished; each of the italicized words being specifically defined terms.

"Contracted rate" is defined as the total amount (including cost-sharing) that a payer has contractually agreed to pay a participating provider, facility, or provider of air ambulance services for covered items and services, including through a third-party administrator or pharmacy benefit manager (PBM) (single case agreements do *not* constitute contractual agreements for this specific purpose).

Consistent with the Act, the IFR establish (and seek comments with respect to) alternative methodologies to determine the QPA for situations in which the payers do not have "sufficient information" to utilize the median contracted rate formula (e.g., when a does not have at least three contracted rates on January 31, 2019). The IFR also set forth the methodology for instances in which the payer later gains additional contracted rates based on the "first sufficient information year." Note that the "first sufficient information year" is defined as the following:

1. In the case of an item or service for which a payer does not have sufficient information to calculate the median of contracted rates in 2019, the first year after 2022 for which the payer has sufficient information to calculate the median of contracted rates in the year immediately preceding that first year after 2022.
2. In the case of a newly covered item or service, the first year after the first coverage year for such item or service with respect to such plan or coverage for which the payer has sufficient information to calculate the median of the contracted rates in the year immediately preceding that first year.

If there is insufficient information to determine the median contracted rate using 2019 or later contracted rates and thereby use those rates to calculate the QPA, payers are directed to use an eligible database, such as a state all-payer claims database or a third-party database that meets certain requirements described in the IFR. The IFR requirements for eligible third-party databases are aimed at ensuring the databases have sufficient information and do not present any conflict of interest.

Recognizing the need for transparency, payers are required to share certain information about the QPA calculation with a non-participating provider or facility. Specifically, the IFR require disclosures with each initial payment or notice of denial to an applicable provider or facility when the QPA is utilized as the recognized amount. The disclosure must include the QPA for each item or service involved and a statement certifying the following:

1. The QPA applies for purposes of the recognized amount (or, in the case of air ambulance services, for calculating the patient's cost-sharing).
2. Each QPA shared with the provider or facility was determined in compliance with the methodology outlined in the IFR.

The payer must provide a statement regarding the provider's/facility's right to initiate a 30-day open negotiation period to determine the total amount of payment (along with the contact information, including telephone number and email address, for initiating open negotiations); and, the right to initiate the IDR process within four days after the end of the open negotiation period if that open negotiation does not result in a determination of payment.

Upon request of the provider or facility, the payer must also provide:

1. Information about whether the QPA includes contracted rates that were not set on a fee-for-service basis for the items and services at issue and whether the QPA was determined using underlying fee schedule rates or a derived amount;
2. Information about any eligible database that was used in determining the QPA;
3. Information to identify any related service codes used in determining the QPA; and,
4. A statement that the contracted rates include risk-sharing, bonus, penalty, or other incentive-based or retrospective payments or adjustments for items and services (if applicable) that were excluded for purposes of calculating the QPA.

Provider and Facility Disclosure

Healthcare providers and facilities subject to the Act are required to provide general disclosures to patients and the public. The disclosures are aimed at ensuring that individuals are aware of the state and federal balance billing limitations and prohibitions applicable to the provider or facility. HHS also notes that these disclosures are important to ensure individuals can identify violations of the state and federal surprise billing laws and enable them, as applicable, to file complaints. The IFR codify the provider and facility disclosure requirements at 45 CFR § 149.430.

Each healthcare provider and facility must make a one-page disclosure in at least 12-point font that is easily readable and contains sufficient information publicly available, and post it on their public website. The Departments have released a model disclosure notice that providers, facilities, and payers may voluntarily rely on, which is available here. The Departments will consider the use of this model notice and the associated instructions to constitute good faith compliance with the disclosure requirements. HHS also encourages states to develop model language to assist in fulfilling any disclosure requirements related to applicable state law requirements.

To satisfy the requirement to post the disclosure on its public website, the provider/facility must ensure the disclosure or a link to the disclosure is searchable and accessible. In addition, providers and facilities must display the disclosure information on a prominently posted sign. Lastly, the facility/provider must distribute the one-page disclosure to individuals who are participants, beneficiaries, or enrollees of a group health plan or individual health insurance coverage offered by a health insurance issuer, and the distribution method, in-person or through mail or email, must be the option as selected by the individual.

Generally, the IFR require the disclosure be provided no later than the date and time when the provider or facility requests payment from the individual; or if no payment is requested, when a claim is submitted to the payer.

Importantly, the IFR include two exceptions to the general requirement to provide disclosures regarding balance billing protections:

- First, healthcare providers are not required to make the disclosures if they do not furnish items or services at a healthcare facility to which the surprise billing rules apply, or in connection with visits at such healthcare facilities. For example, office-based physician practices do not have to provide disclosures to their patients. HHS reasoned providing disclosures in contexts where the surprise billing rules do not apply would create confusion.
- Second, healthcare providers are only required to provide the disclosure to individuals to whom they furnish items or services at a healthcare facility or in connection with a visit at a healthcare facility.

In addition, recognizing some patients may interact with multiple providers during a visit, the IFR created a special rule to avoid unnecessary duplication. Specifically, if a provider furnishes an item or service at a healthcare facility (including an emergency department of a hospital or independent freestanding emergency department), the provider can satisfy the disclosure requirements by entering into a written agreement with the facility in which the facility agrees to provide the information in the required form and manner. In such instances, the disclosure must include information about the balance billing requirements and prohibitions applicable to *both* the facility and the provider. If such an agreement is in place and the facility fails to provide full or timely disclosure information, then the facility, but *not* the provider, would violate the provider disclosure requirements regarding balance billing protections. Note, however, the special rule does not provide an exemption to the required disclosure on a public website.

Providers and Facility Notice and Consent

Under the Act, the protections that limit cost-sharing and prohibit balance billing do not apply to certain services if appropriate notice is provided by the applicable provider or facility and the patient (or their authorized representative), consents to waive the balance billing protections. The IFR outline the requirements related to the content, method, and timing of the notice and consent communications, including exceptions to the applicability of the notice and consent process.

The IFR also implement requirements for non-participating providers and facilities to "timely" notify the payer regarding whether balance billing and in-network cost-sharing protections apply to the item or service, as well as to provide a signed copy of any signed written notice and consent documents. For non-emergency services, the non-participating provider or facility must timely notify the payer that the item or service was furnished during a visit at a participating healthcare facility. HHS has requested comment on whether additional rulemaking would be helpful regarding the process and timing for such notification, including the definition of "timely."

Standards for Notice

Pursuant to the IFR, providers and facilities must utilize a standard notice document provided by HHS, which is available here. Although providers and facilities will need to tailor the document to for their organization and the patient (e.g. identify the provider/facility), HHS believes a standard notice form will help ensure the content complies with the Act and is easy to read and comprehend. The notice must be provided separately from other documents and with the consent document in a written format on paper (or electronically if elected by the individual).

The content of the notice must state the following:

- The notice must identify the provider/facility by name and acknowledge the provider/facility is not a participating provider/facility under their plan/policy.
- The notice must contain a good faith estimated amount that such non-participating provider/facility may charge the individual for the items and services involved. Non-participating facilities are required to include not only an estimate for the facility's services but also any other non-participating providers' services. Whereas notices from non-participation providers are only required to address items/services they would be furnishing (as opposed to other providers at an applicable facility).
- Although HHS recognizes it may be challenging for non-participating facilities/providers to ascertain this information, information about whether prior authorization or other care management limitations may be required in advance of receiving the items or services at the facility/provider.
- The notice must clearly state that the individual does not have to consent to receive the services from the non-participating provider/facility and be balanced billed; and, that the individual may opt to obtain care from an available participating provider/facility.
- In cases where post-stabilization services are furnished, the notice must also include a list of participating providers at the participating emergency facility who can furnish the items or services involved.

An authorized representative may receive the notice and consent on behalf of the patient. An authorized representative is an individual authorized under state law to provide consent on behalf of the patient, excluding providers affiliated with the facility who are not "family members" of the patient. HHS seeks comment on how the term "family member" should be defined, but indicates that until it issues additional guidance it plans to interpret the term broadly to include individuals that may not be formally or legally recognized as familial relations but are considered family by the individuals involved.

To ensure the patient has an opportunity to properly review and consent to a notice and waive protections on balance billing, the IFR set out notice timeframes for providing notice consistent with the Act. The timeframes are as follows:

- If an individual schedules an appointment at least 72 hours before the date of the appointment, the provider/facility must provide the notice no later than 72 hours before the date of the appointment.
- If an individual schedules an appointment within 72 hours of the date of the appointment, the provider/facility must provide the notice on the day that the appointment is made.
- In a situation where an individual requires care the same day, notice must be provided no later than three hours prior to furnishing items or services to which the notice and consent requirements apply.

While HHS is seeking comment on whether the three-hour window is sufficient, it explained that it intends to ensure individuals can voluntarily provide informed consent without removing the option to provide same-day services.

Standards for Consent

To meet the Act notice and consent exception to the cost-sharing and balanced billing limitations, the non-participating provider/facility must obtain the individual's consent to be treated and acknowledgment that they

will be balanced billed by the facility/provider. The consent must be provided voluntarily and without duress; an incomplete consent document will be treated as a lack of consent.

Similar to the notice document, providers and facilities must use the standard consent document provided by HHS, which is available here. To be valid, the consent document must be tailored to include information specific to the individual and circumstances; be provided separately from any other documents (except for the notice); and, be signed (including, as applicable, electronically) by the individual or his or her authorized representative.

The provider/facility must give the individual a copy of the signed notice and consent. The signed consent document must:

- Acknowledge the individual has been provided with the written notice in the form selected by the individual (e.g., mail or email).
- Acknowledge the individual has been informed that his or her payment might not accrue toward meeting his or her cost-sharing or out-of-pocket obligations.
- State that, by signing the consent document, the individual agrees to be treated by the non-participating provider/facility and understands that he/she may be balance billed and subject to out-of-network cost-sharing obligations.
- In the case of a non-participating provider seeking consent, by signing the consent document, the individual agrees to waive balance billing and cost-sharing protections for only the items or services furnished by the provider or providers specifically named in the notice.
- Include the date on which the individual received the written notice and the date and time on which the individual signed such consent.

Consents may be revoked by notifying the provider or facility in writing prior to furnishing the items or services, and balance billing protections apply after the revocation as if the consent was never provided.

Notice and Consent Language Access and Retention

Providers must comply with requirements related to language access and retention of notice and consent documents. Specifically, notice and consent documents made available in any of the 15 most common languages in the geographic region in which the facility or provider is located. The provider and facility must also make a qualified interpreter available if an individual's preferred language is not among the 15 most common languages in which the notice and consent are available.

Further, non-participating facilities and providers are required to retain written notice and consent documents for at least seven years after the date the applicable item or service in question was furnished.

Comment Period and Future Rulemaking

While not addressed in this alert, the IFR also include regulations issued by the Office of Personnel Management that apply to the Federal Employees Health Benefits Program, which provides health benefits to federal employees and their families.

Regulators intend to issue additional proposed regulations in 2021 and 2022 on other aspects of the Act, including the federal IDR process, patient protections through transparency, the patient-provider dispute resolution process, price comparison tools, and how payers and providers of air ambulance services would report information regarding air ambulance services. Despite being required by the end of 2021, the Departments noted that regulations addressing some aspects of the Act will likely not be issued until 2022.

If you have any questions about the no surprise billing regulations, please contact the authors.

Authors

Richard Eiler
(865) 521-2039
reiler@bassberry.com

Catherine N. Simpson
(901) 543-5928
catherine.simpson@bassberry.com

Danielle M. Sloane
(615) 742-7763
dsloane@bassberry.com

David A. Thornton
(901) 543-5922
dthornton@bassberry.com

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