CORPORATE SYNERGIES®

compliance ALERT

Agencies Issue Interim Final Rule Implementing the No Surprises Act

July 9, 2021

Action Required:

- Review the new rule.
- **Plan sponsors:** Work with your carrier/ administrator to ensure compliance.
- **Plan sponsors:** Certain insurers must disclose the prohibition on surprise billing and the entities to contact in the event of a violation.

On July 1, the U.S. Departments of Health and Human Services (HHS), Labor (DOL) and Treasury (IRS), along with the Office of Personnel Management (OPM) issued a much anticipated Interim Final Rule (IFR) implementing certain provisions of the No Surprises Act (NSA). The NSA was adopted as part of the Consolidated Appropriations Act, 2021 (CAA) in December 2020 (see our eAlert here) and was designed to prevent surprise medical bills and increase healthcare price transparency in both group and individual health plans.

The new IFR was issued in conjunction with a press release, two fact sheets (here and here), and other new related guidance materials.

Among other provisions, this rule:

- Bans surprise billing for emergency services.
- Bans high out-of-network cost-sharing for emergency and non-emergency services with some exceptions.
- Bans out-of-network charges for ancillary care (like an anesthesiologist or assistant surgeon) at an in-network facility in all circumstances.
- Bans other out-of-network charges without advance notice.

This rule was designed to protect patients from the most pervasive and costly types of balance bills for emergency services, and by reducing these surprise bills, it seeks to, in turn, reduce patients' out-of-pocket costs and medical debt (and, of course, resulting financial anxiety and stress).

The new IFR applies to health insurance issuers offering group or individual health insurance coverage (including grandfathered plans) and applicable healthcare facilities and providers. The new IFR does not apply to health reimbursement arrangements (HRAs), short-term limited-duration insurance (STLDI) or retiree-only plans.

As far as next steps, employers and plan sponsors will have until plan years beginning on or after January 1, 2022 to make sure that their plans comply with these new rules, but given that much of the heavy lifting necessary to implement these changes will be done by insurance carriers, third-party administrators (TPAs) and healthcare providers, employers and plan sponsors should work closely with their carrier and TPA partners to ensure compliance and lower the number of surprise medical bills received by plan participants.■

↓ Full Explanation Follows ↓

Agencies Issue Interim Final Rule Implementing the No Surprises Act

On July 1, the U.S. Departments of Health and Human Services (HHS), Labor (DOL), Treasury (IRS) and the Office of Personnel Management (OPM) (the "Agencies") issued a much-anticipated **Interim Final Rule** (IFR) implementing certain provisions of the No Surprises Act (NSA). The NSA, adopted as part of the Consolidated Appropriations Act, 2021 (CAA) in December 2020 (see our eAlert **here**), was designed to prevent surprise medical bills and increase healthcare price transparency in both group and individual health plans. The new IFR was issued in conjunction with a **press release**, two fact sheets (**here** and **here**), a **model notice** and other new related **guidance materials**.

How Does this IFR Change the Law?

The IFR doesn't change the law, but rather, clarifies and implements the rules necessary to enforce the law.[1] The new IFR focuses on eliminating, or significantly reducing the cost of, most types of surprise medical bills by specifying many new patient protections and healthcare provider prohibitions, and by defining the "qualifying payment amount" (QPA), a central component of the NSA (discussed in more detail below).

The Agencies will issue the NSA regulations in phases. After this first IFR, a second regulation implementing the NSA is expected by October 1, 2021, which will establish an audit process, and a third regulation is expected by December 27, 2021, which will detail the NSA's independent dispute resolution (IDR) process.

Background on Surprise Medical Bills and NSA:

For many years before the NSA was enacted, legislators sought to eliminate or limit out-of-network surprise medical bills (also known as "balance bills"), which are bills that arise when a patient unknowingly receives care from a healthcare provider (for example, a treating physician) or at a medical facility (such as a hospital) that is not within their insurance plan's network. This typically occurs when a patient is taken to the closest emergency room to receive care, and it turns out to be in an out-of-network facility, or even where the patient obtains care at an in-network hospital, but is then treated by an out-of-network physician.

Out-of-network healthcare providers and facilities typically charge a higher rate to insurers than in-network providers, resulting in higher cost sharing for patients and plan participants. Additionally, if the insurer refuses to pay the out-of-network provider's billed charge, the provider may seek to recover its fees by "balance billing" the patients and plan participants, which can lead to extremely high out-of-pocket costs, financial anxiety and stress.

The NSA was designed to protect patients from the most pervasive and costly types of balance bills for emergency services by eliminating or reducing surprise bills, and in turn, reducing patients' out-of-pocket costs and medical debt.

Under the NSA, when an insured patient receives emergency care and certain non-emergency services from an out-of-network provider, the patient's cost sharing obligation will be capped at amounts that would apply if the services had been furnished by a participating provider. The nonparticipating provider is prohibited from balance billing the patient above in-network cost sharing thresholds.

The NSA statute provides that the patient's cost sharing liability will be: an amount determined by an applicable All-Payer Model Agreement[2]; an amount defined under state law; or the QPA, which generally is the median contracted rate recognized by the plan or issuer as provided in 2019 for the same or a similar item or service, by a similar provider in the same geographic region.[3]

Under the NSA statute, the agencies were tasked with further defining and shaping the QPA through regulation. The question of how the QPA is defined is significant to plan sponsors, insurers and providers because it influences consumers' cost sharing, influences payments to providers, and will be considered by arbiters in determining the final payment amount during billing disputes.

Who is Affected by the IFR's New Rules? Who do they Apply to?

The new IFR applies to health insurance issuers offering group or individual health insurance coverage and applicable healthcare facilities and providers.

[1] Specifically, the new IFR is the first regulation implementing provisions of Title I of Division BB of the CAA, which are provisions of the CAA containing the NSA.
[2] Some states (including Maryland, Vermont and Pennsylvania) have adopted an All-Payer Model Agreement under § 1115A of the Social Security Act, which is a system that limits a medical service's out-of-pocket cost to a designated amount approved under that system.
[3] This amount will be increased annually based on the Consumer Price Index for All Urban Consumers (CPI-U).

Group health plans subject to the IFR include both fully-insured and self-insured plans, private employment-based group health plans subject to ERISA and the ACA (including both grandfathered and non-grandfathered group health plans), non-federal governmental plans (for example, plans sponsored by states and local governments), church plans and traditional indemnity plans.

Individual health insurance coverage subject to the IFR includes Exchange and non-Exchange plans and student health insurance coverage.

The new IFR does not apply to health reimbursement arrangements (HRAs), short-term limited-duration insurance (STLDI) or retiree-only plans. Applicable healthcare facilities include hospitals, hospital outpatient departments, critical access hospitals and ambulatory surgical centers.

What types of medical services are covered by the new IFR and how does the IFR limit surprise bills for these services?

The IFR covers the following medical services: (A) emergency services[4]; (B) non-emergency services furnished by a nonparticipating provider (*i.e.*, an out-of-network provider that does not have a contractual relationship with the plan) at a participating facility in certain circumstances; and (C) air ambulance services furnished by a nonparticipating provider.

- The new IFR prohibits balance billing and limits the total amount paid to the provider or facility, including any cost-sharing, to (in order of priority):
  - (1) an amount determined by an applicable All-Payer Model Agreement, or
  - (2) an amount determined by specified state law,[5] or
  - (3) an amount agreed upon by the plan/issuer and provider/facility, or
  - (4) (if none apply) an amount determined by an IDR entity.
- For the medical services described in (A) and (B) above, the IFR limits cost-sharing to an amount determined by the applicable All-Payer Model Agreement, or (if none) an amount determined by specified state law, or (if neither applies) the lesser of the billed charge or median contracted rate, *i.e.*, the QPA.
- For the medical services described in (C) above, the IFR limits cost-sharing to the lesser of the billed charge or the QPA and in-network cost-sharing.

What are the new rules in the IFR that are the most important for employers and plan sponsors to be aware of?

What follows is a summary of the key provisions of the new IFR for employers and plan sponsors.

- **Ban on surprise billing for emergency services.** Regardless of where they are provided, emergency services must be treated on an in-network basis without requirements for prior authorization.
- **Ban on high out-of-network cost sharing for emergency services and non-emergency services (with some exceptions).** The IFR clarifies that, with some exceptions (discussed below), patient cost-sharing, such as co-insurance or a deductible, at a nonparticipating provider cannot be higher than if such services were provided by an in-network doctor, and any co-insurance or deductible must be based on in-network provider rates.
- **Ban on balance billing for certain non-emergency services, including ancillary care.** The IFR clarifies that the NSA bans balance billing for care provided during a "visit" to an in-network health facility for certain non-emergency services. The visit may include equipment and devices, telemedicine services, imaging services, laboratory services, and preoperative and postoperative services. This protection applies even if the provider that furnished those items or services is not physically located at the in-network facility (e.g., by providing care via telemedicine). The IFR also bans out-of-network charges for ancillary care (e.g., an assistant surgeon or anesthesiologist) at an in-network facility in all circumstances.
- **Bans other out-of-network charges without advance notice and patient consent; Exception applies if patient gives consent.** Healthcare providers and facilities must provide patients with a "plain English" consumer notice explaining that patient consent is required to receive care on an out-of-network basis before that provider can bill at the higher out-of-network rate. The IFR further clarifies that the cost sharing and balance billing protections of the NSA do not apply to certain post-stabilization services, or to certain non-emergency services performed by nonparticipating providers at participating health care facilities, if the provider or facility provides notice to the patient, and obtains the patient's consent to waive the balance billing protections.

[4]The definition of "emergency services" includes pre-stabilization services provided after the patient is moved out of the emergency department (ED) and admitted to a hospital, post-stabilization services and emergency services provided at an independent, freestanding ED.
[5]There are currently 18 states that have implemented broad-based surprise billing laws, while others have state laws that address specific elements of surprise billing practices.

- **Methodology for Calculating the QPA.** The IFR explains how the QPA will be determined, which is the basis on which the patient's share of the bill is calculated. The IFR builds on the above-described definition of QPA in the NSA statute, but clarifies the following:
    - Under the law, patients can't be billed for any amount other than what they would pay for in-network emergency care when they receive services from out-of-network providers at their health plan's in-network facilities.
    - The QPA also must be considered by arbitrators if the health plan and the providers can't agree on how much the doctor or hospital should be paid.
    - A health plan issuer is deemed to have sufficient information to calculate the QPA so long as there are at least three provider contracts for a given service in a given geographic region (with some exceptions).
    - The IFR also covers how to determine if services are similar and what is considered insurers' normal practices in contracting with providers.
- **Provider/Facility Disclosure Requirements.** For each item or service furnished by a nonparticipating provider or facility, the provider/facility must timely notify the plan or issuer as to whether balance billing and in-network cost-sharing protections apply and provide a copy of any signed written notice and consent documents. Plans and issuers must make certain disclosures with each initial payment or notice of denial of payment and provide additional information upon request. Additionally, plans/issuers must provide the QPA for each item/service and a statement certifying that the applicable QPA was determined in compliance with the methodology outlined in the IFR. They must also notify providers/facilities to initiate a 30-day open negotiation period and provide relevant contact information. If that does not result in a determination, the provider or facility may initiate the IDR process within four days of the end of the negotiation period. In addition, upon request, a plan/issuer must provide, promptly, information about QPA pricing, including whether it includes non-fee-for-service (FFS) rates, was based on a derived amount, which related service codes were used to price new codes, what database was used (if relevant), and any All-Payer Model-based rates that were not included in calculating the QPA.
- **Public Disclosure Requirement and Model Notice.** Certain healthcare facilities/providers and plans/insurers must post in a prominent location within the facility and on a public website, and provide to patients and participants in each explanation of benefits, a notice with the following information:

  (1) applicable requirements and prohibitions under the NSA and implementing regulations;
  (2) any applicable state balance billing requirements; and
  (3) how to contact appropriate state and federal agencies if the individual believes that the provider or facility has violated any of these requirements.

  The Agencies issued a Model Notice that contains this required information. Use of the Model Notice will serve as good faith compliance with the NSA requirement that, beginning in 2022, a plan or insurer disclose the prohibition on surprise billing and the entities to contact in the event of a violation.
- **Time Frames for Settlement of Billing Disputes.** To ensure timely resolution of billing disputes, the new IFR establishes time frames for initial payment/notice of denial (within 30 days of a bill being submitted), making a final benefit determination and payment (with 30 days of initial response), payment negotiations and initiating the IDR process. Plans/issuers are expected to act "reasonably and in good faith" for additional information requests. These time frame requirements do not apply to non-emergency services (other than air ambulance), post stabilization services or patients who consent to out-of-network rates.
- **Complaint Process.** The CAA directs HHS to establish a process to receive consumer complaints regarding NSA violations and respond to such complaints within 60 business days. However, the new IFR does not specify a time period by which a complaint must be filed. The Agencies intend to create a central system to intake all complaints and intend to issue additional guidance on this process.
- **Audits.** For most employer-sponsored group health plans, audits for compliance with these new rules will be by the DOL and IRS, as these agencies have primary enforcement authority over these types of plans. The IRS also has jurisdiction over certain church plans. HHS has primary enforcement authority over nonfederal governmental plans, and OPM has jurisdiction over federal governmental plans. Additional guidance is expected from HHS on enforcement of these new rules.

What are the Penalties for Noncompliance?

Where a healthcare provider or facility does balance bill in violation of the NSA and this IFR, HHS may impose civil monetary penalties of up to $10,000 per violation in states where HHS is directly enforcing the balance billing provisions. However, it will waive penalties for providers/facilities that do not knowingly violate and could not have been expected to reasonably know, provided they withdraw

their bill and reimburse the plan or individual (plus interest) within 30 days. Additional guidance on penalties will likely be issued in the forthcoming HHS enforcement guidance discussed above.

When will these Surprise Medical Billing Rules Go into Effect?

The new IFR will go into effect 60 days after it is published in the Federal Register. However, most of the provisions will not be applicable until January 1, 2022. The rule will take effect for healthcare providers and medical facilities on January 1, 2022. For group health plans and health insurance issuers, the provisions will take effect for plan, policy or contract years beginning on or after January 1, 2022. The consumer protections in the rule will take effect starting January 1, 2022.

Will the Agencies be accepting comments on the new IFR?

Yes. Written comments must be received by 5 p.m. on Sept. 7, 2021, to be considered by the Agencies.

How do the new rules affect employers and plan sponsors?

The new rules in the IFR will help employers and plan sponsors from a practical standpoint by creating an organized, methodical system for handling billing disputes. More specifically, the NSA and IFR establish a clear process or roadmap for determining reasonable prices for out-of-network services and resolving payment disputes between insurers and out-of-network healthcare providers—this includes an open negotiation process with independent dispute resolution if negotiations fail, and strong guardrails to prevent abuse of this process.

Currently, employers and plan sponsors often find themselves stuck in the middle of complicated disputes between healthcare providers, insurers and participants, and in some cases, particularly those involving very large bills on self-insured plans, these disputes can result in costly and time-consuming litigation. These new processes created under the NSA, and clarified further by this IFR, significantly reduce the likelihood that these billing disputes turn into court cases.

Employers and plan sponsors should also be aware that not all balance billing is prohibited, for example, if patient consent to out-of-network charges is obtained by a nonparticipating provider prior to the patient receiving certain post-stabilization or non-emergency services and all of the IFR's other requirements are followed by the provider for such consent. Additionally, the IFR does not apply to bills for non-emergency items or services provided at facilities that are not included within the definition of "health care facility" in the IFR; nor does the IFR apply to circumstances where a participant gets a surprise medical bill because the participant is enrolled in a group health plan that provides little or no coverage for their particular health condition or the items and services necessary to treat that condition.

What should employers and plan sponsors do next?

As far as next steps, employers and plan sponsors will have until plan years beginning on or after January 1, 2022 to make sure that their plans comply with these new rules, but given that much of the heavy lifting necessary to implement these changes will be done by insurance carriers, third-party administrators (TPAs) and healthcare providers, employers and plan sponsors should work closely with their carrier and TPA partners to ensure compliance and lower the number of surprise medical bills received by plan participants.

If you have any additional questions, please call your Corporate Synergies Account Manager or 866.CSG.1719.

Upcoming: July 14, 2021
Benefits Compliance Briefing Call