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Don't let the No Surprises Act surprise you

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After years of deliberation, the federal government enacted the No Surprises Act[1] (the act) into law as part of the Consolidated Appropriations Act of 2021 (Omnibus legislation). The act is a consumer protection law that seeks to prevent unanticipated medical bills for patients who lack meaningful choice in providers for certain services. Out-of-network providers and facilities generally charge higher rates for items and services than in-network providers/facilities. As such, the cost-sharing obligations of patients for out-of-network items and services increase accordingly. Balance billing (sometimes called surprise billing) is a medical bill from a healthcare provider billing a patient for the difference between the total cost of services being charged and the amount the insurance pays. Balance billing by out-of-network providers occurs in both emergency and nonemergency settings, and it can have an immense financial impact on patients. The act aims to protect patients from the most prevalent types of items/services that patients receive balance bills for by reducing these out-of-network bills. The law mandates the coverage of certain out-of-network bills, limits the cost-sharing amount that individuals can be held liable for for out-of-network items and services, and details requirements for providers and health plans to promote charge rate transparency.

The act has broad application to both health plans and providers. The law requires healthcare providers, facilities, and insurers to take affirmative steps to ensure compliance with the act's provisions. The legislation has extensive compliance, operational, and financial impact. The Departments of Health & Human Services, the Treasury, and Labor, and the Office of Personnel Management have been tasked with issuing more detailed regulations and guidance for the implementation of certain provisions of this law. The first interim final rule, in a series of anticipated rulemaking, was published in the *Federal Register* on July 13, 2021.[2] It became effective September 13 and is applicable to health plans, health benefit plans, providers, facilities, and providers of air ambulance services. As the regulations are published in a phased approach, organizations should prepare now to ensure meaningful compliance. Noncompliance with the act is subject to federal enforcement, starting January 1, 2022.

This article is intended to serve as a primer for compliance programs with respect to this reformative legislation with a particular focus on healthcare providers, facilities, and health plans. Here, we frame the discussion with the rationale for this consumer protection, then outline the key provisions that will affect healthcare providers, facilities, and health plans and the essential actions that they should take to promote compliance and manage their risks.

Whom and what the law covers

The act prohibits nonparticipating providers, certain healthcare facilities, and providers of air ambulance services from balance billing in emergency situations and in certain nonemergency situations, with certain exceptions. It limits the cost-sharing amount for out-of-network emergency services and nonemergency

services provided by nonparticipating providers at participating facilities to those of in-network levels, requires cost sharing to count toward any in-network deductibles/out-of-pocket maximums, and prohibits balance billing for services covered under the act.[3] The act also requires certain healthcare facilities and providers to disclose protections over balance billing, establishes a complaint process for violations of balance billing protections, and details the cost-sharing calculation amount for emergency services and nonparticipating providers at participating facilities.

Emergency services

Group health plans and health insurance issuers must cover services in emergency departments of hospitals or in freestanding emergency departments pursuant to the act. The act requires that the emergency services be covered:

1) without prior authorization;

2) regardless of whether the provider and the facility are in-network; and

3) regardless of any other plan term/condition, waiting period, or cost-sharing requirements.

The act expands the scope of emergency services in hospital emergency departments beyond the previous interpretation (ending when a patient is formally admitted) to include pre-stabilization services after the patient is moved out of the emergency department, regardless of the department in which the additional medical examination is furnished. The act also expands the scope of emergency services outside of hospital emergency departments (services provided at independent emergency departments) to include facilities licensed as freestanding emergency departments. Emergency services now include any facility that provides emergency services that is geographically separate and distinct from a hospital that is licensed by a state to provide emergency services. While regulations vary widely from state to state, urgent care centers fall under the act's purview with respect to covered emergency services in certain states per the expanded definition of freestanding emergency department as defined by the act.

The act also expands the definition of an emergency medical condition beyond the diagnosis code(s). It requires the coverage decision to be based on a prudent layperson standard (i.e., would a reasonable layperson consider the situation to be an emergency based on all pertinent documentation and the presenting symptoms?).[4]

The act's protections over emergency services also apply to air ambulances. The regulations require that plans/issuers base the coinsurance/deductibles for services provided by a nonparticipating provider on the lesser of the qualified payment amount (QPA), as defined later, or the amount billed.

The cost-sharing and balance billing protections pursuant to the act do not apply to certain post-stabilization and nonemergency services when the nonparticipating provider at a participating healthcare facility obtains the individual's consent to waive the balance billing protections.[5] In certain scenarios where surprise/balance billing is likely to occur, providers may not provide notice or seek to obtain the individual's consent to waive balance billing protections.

Nonemergency services

The act prohibits out-of-network providers from balance billing patients for nonemergency services provided by nonparticipating providers at an in-network facility unless the patients provide their written consent.[6] The act limits these out-of-network providers from billing these patients more than the in-network amount that would

be charged. The notice and consent requirements are outlined below. Notably, the notice and consent exception is not permitted in certain circumstances, as defined later, where surprise bills are likely to occur (e.g., ancillary services).

The following is a potentially problematic example of the profound impact the act's balance billing protections may have on healthcare operations. The balance billing protections for nonemergency services provided by a nonparticipating provider at a participating healthcare facility apply only to services that are provided by the plan/coverage. In many instances, a nonparticipating provider will not have sufficient information to determine coverage for the items/services rendered. To avoid billing the individuals and violating these balance billing protections, the nonparticipating provider would need to bill the health plan/insurer directly (rather than the patient). This is a divergence from how providers and facilities commonly directly bill individuals for out-of-network services.[7]

Notice and consent process

In some circumstances, a patient may wish to pay the out-of-network amount to receive care from a nonparticipating provider, such as a highly rated specialist for a complex medical condition. Therefore, the act and the regulations have established a process wherein providers provide a notice to the patient stating the services will be billed at out-of-network rates and the patient must provide prior consent.

The Department of Health & Human Services (HHS) will issue guidance that will include the standard notice document, which all providers must use for this process.[8] The regulations require that the notice be provided with the corresponding consent document. These documents must be separate from, and not be attached to or incorporated into, any other document. The notice may be written and provided on paper or electronically.

The required notice and consent must be received from the patient at least 72 hours prior to the item being delivered or service being performed, or at the time the appointment is made if the appointment is scheduled in a shorter time frame.[9] Additionally, in situations where the notice is provided on the same day as the service, notice must be provided no later than three hours prior to furnishing the items or services. This is an attempt to avoid a situation where a patient may feel pressured or compelled to consent immediately prior to the service (e.g., a nonparticipating specialist providing an unexpected consultation).

The notice has several requirements from the act and the regulations. Many of these will be accounted for within the standard HHS notice. However, the notice must be adjusted to include a few additional pieces of information:

- The name of the provider or facility;
- A good faith estimated amount of the charges, including items or services that are reasonably expected to be provided in conjunction with the items and services;
- Information on prior authorization and care management requirements, if they can be provided; and
- For post-stabilization services from a nonparticipating provider at a participating emergency facility, the notice must include a list of any alternative participating providers at the participating emergency facility.

The notice and consent process may be used by nonparticipating providers in many circumstances. Nevertheless, if patients are generally unable to select their specific provider, such as in the cases of ancillary services (i.e., emergency medicine, anesthesiology, pathology, radiology, and neonatology services; items provided by assistant surgeons, hospitalists, and intensivists; diagnostic services; and items provided by a nonparticipating provider if there is no participating provider that is able to furnish the items/services at the facility) and when

items/services are furnished as the result of unforeseen medical needs (i.e., regardless of whether the notice and consent process was satisfied), then the notice and consent process does not apply and providers must bill in-network rates.[10] The act defines the full categories of services that fit into this group, but it also gives the HHS authority to expand the list as necessary.[11]

The HHS has stated that if an individual receives the proper notice but does not provide (or revokes) consent, then the cost-sharing and balance billing protections remain in effect. In these circumstances, a provider may refuse to treat the individual when permissible by other state or federal laws.[12]

Qualified payment, payer audit, and independent dispute resolution

The regulations have established a methodology that group health plans or health insurance issuers offering group or individual health insurance must use to determine the QPA. States that have surprise billing legislation that set or have a process to determine the payment amount for out-of-network services will continue to use the state law process instead of the act's process.[13]

A provider may negotiate with a health plan for a period of 30 days (i.e., the "open negotiation" process) after receiving a denial or what the provider believes to be an insufficient amount. If an agreement cannot be reached, either party may trigger the independent dispute resolution (IDR) process within four days of the end of the open negotiation period to resolve the conflict.[14]

The act's IDR process follows the so-called baseball-style rules. Each party must submit a final offer to the IDR entity or the arbitrator. The arbitrator will choose the offer that the arbitrator considers the most reasonable. To determine the reasonability, the arbitrator can consider a range of factors, including:

- The median in-network rate the insurer pays for similarly situated items or services;
- Any good faith efforts (or lack thereof) to join the insurer's network;
- If existent, any contracted rates between the parties over the previous four years;
- The market shares of both parties;
- Patient acuity and complexity of services; and
- Details regarding the provider or facility, including training, experience, quality, teaching status, case mix, and scope of services.

The arbitrator may not consider the provider's usual and customary charges, nor may the arbitrator consider any rates of public payers, such as Medicare and Medicaid.

The losing party is required to pay the arbitrator fee, which is a considerable incentive for the parties to negotiate a settled payment amount rather than risk the extra cost. Additionally, the party that initiated the IDR must wait 90 days before initiating new arbitration for similar services with the same party. Each quarter, HHS will post macro-level information on the IDR process and micro-level data (e.g., parties, items/services at issue, location of care delivered, and more).

Provider and facility disclosure requirements

The act details disclosure requirements[15] (e.g., content, methods of disclosure, and timing of the disclosure) for

healthcare providers and facilities to post on their website, make publicly available, and provide the following information to individual participants, beneficiaries, or enrollees of a group health plan or individual health plan that the provider/facility furnishes services:

- A statement explaining the facility and provider requirements/prohibitions of the No Surprises Act,
- A statement explaining the facility/provider's state law requirements with respect to the amounts a provider/facility may charge an out-of-network individual, and
- Contact information for state and federal agencies in the event of a suspected violation of these requirements.

Healthcare facilities and providers are required to include the notice on the home page of their public website, post the notice on a sign in a prominent location, and send the notice to individuals (via mail or email) prior to or at the time of request for payment.[16] The act outlines an exception where healthcare providers are not required to make these disclosures if the provider does not furnish the items/services at a healthcare facility or in connection with a healthcare facility. The regulations specify that when a provider furnishes items/services under a plan/coverage at a facility, the provider satisfies the notice requirements if the facility makes the required information available.[17] The regulations further allow for a provider and facility to enter into a written agreement for the facility to provide the required notice. Notably, failure to provide the notice will be considered a violation of the disclosure requirements by the facility and not the provider.

Complaint process and enforcement

The regulations establish a complaint process to receive and resolve any complaints related to these balance billing protections. The HHS issued its own process to receive complaints from consumers related to violations by healthcare providers. When resolving a consumer complaint, a resolution may include referring the complainant to a state or federal regulatory authority with enforcement jurisdiction or initiating an investigation for enforcement action.[18]

The statute and the regulations authorize HHS to impose civil money penalties on facilities and providers who violate the requirements. The act provides that HHS shall waive penalties for a provider that does not knowingly violate, and should not have reasonably known it violated, the provisions. The provider must withdraw the bill and reimburse any amount improperly billed to the health plan or individual within 30 days of the violation.[19] With a short 30-day time frame, it will be important that providers have a process in place to identify these violations early and correct them.