Federal Agencies Release Interim Final Rule to Implement the No Surprises Act

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Tuesday, July 13, 2021

Today, the Departments of Health and Human Services (HHS), Labor, and Treasury (the Departments) published an interim final rule (the Interim Final Rule) implementing certain provisions of the No Surprises Act,[1] which aims to address balance bills on a national scale. Effective for health insurance plan years beginning January 1, 2022, the legislation limits patient payment responsibility for certain unavoidable out-of-network services, prohibits providers and facilities from balance billing patients for those services, establishes price transparency disclosure requirements for providers and insurers, and mandates creation of dispute resolution processes for patients, providers, and insurers to address unanticipated
The Interim Final Rule provides critical details regarding some, but not all, aspects of the law, including the scope of the law’s balance billing prohibition, methodologies for patient cost-sharing responsibility and provider payment, requirements and limitations of the law’s notice and consent exception, and standards for required provider and facility disclosures. Notably, the No Surprises Act applies to self-funded employer insurance plans formed under the Employee Retirement Income Security Act (ERISA plans) and air ambulance services, two key areas states have been unable to address as they are governed by federal law. Both of these areas are addressed throughout the Interim Final Rule.

The Interim Final Rule represents a major development in the complicated and rapidly developing regulatory landscape applicable to balance billing. Healthcare providers and payors must take note of this rulemaking and move quickly to effectively respond to its requirements.

**Scope of Balance Billing Prohibition**

Balance billing occurs in situations when patients receive medical services from a provider that has not agreed to participate in their health insurance plan’s provider network. Because the out-of-network provider has not agreed on a payment amount with the insurer, the health insurance plan often does not pay the provider’s full charges, and the out-of-network provider bills the patient for the balance. Balance bills most commonly arise in connection with two types of services: emergency services, which are often rendered when a patient cannot select an in-network facility or provider, and non-emergency services furnished by an out-of-network provider during a visit to an in-network facility (the classic “surprise medical bill” scenario). The No Surprises Act targets both scenarios, and the Interim Final Rule addresses the scope of the law’s patient protections.

**Emergency Services**

For several years, the Affordable Care Act (ACA) has required all non-grandfathered health insurance plans that offer emergency services coverage to do so without prior authorization and without regard to whether the relevant services are provided by an in-network or out-of-network provider. The ACA also prohibits insurers from imposing administrative requirements or limitations on benefits for out-of-network emergency services that are more restrictive than those in place for in-network emergency services. However, while the ACA requires insurers to pay providers a minimum reasonable amount for emergency services, it does not prevent out-of-network providers from balance billing patients for any amount not paid by their health insurance plan, leaving patients vulnerable to significant charges.

The No Surprises Act fills this gap and adds more robust protections regarding emergency services, prohibiting an out-of-network provider of emergency services from balance billing the patient for any amount above the corresponding in-network cost-sharing responsibility (i.e., the patient’s in-network deductible, copayment, or coinsurance amounts) under the patient’s health insurance plan. The Interim Final Rule explains that the No Surprises Act expands the definition of “emergency
services” beyond the oft-used Emergency Medical Treatment and Labor Act (EMTALA) definition. Thus, the new law’s protections apply to a broader range of services, facilities, and situations.

Under EMTALA, emergency services include a medical screening examination to determine whether an emergency medical condition exists, as well as such further medical examination and treatment as is necessary to stabilize the patient. Under the No Surprises Act, emergency services subject to the law’s protections include pre-stabilization services that are provided after a patient is moved out of the emergency department and admitted to a hospital, as well as any additional services rendered after a patient is stabilized as part of outpatient observation or an inpatient or outpatient stay with respect to the visit in which the other emergency services are furnished. Such post-stabilization services will be categorized as emergency services under the No Surprises Act unless four conditions are met: (1) the patient is able to travel using non-medical transportation or non-emergency medical transportation to an available in-network provider or facility located within a reasonable travel distance (protecting patients receiving emergency care far from their plan’s provider network); (2) the provider or facility furnishing the post-stabilization services satisfies the notice and consent criteria set forth in the Interim Final Rule; (3) the patient is in a condition to understand the notice and provide informed consent; and (4) the provider or facility satisfies any additional requirements or prohibitions under applicable state law (for example, some state laws do not permit patients to waive protections in any circumstance).

The Interim Final Rule also provides that “emergency services” include those provided at an independent freestanding emergency department, a description that broadly includes any healthcare facility that provides emergency services, is geographically separate and distinct from a hospital, and is separately licensed by a state. Thus, independent freestanding emergency departments subject to the law may include urgent care centers if they are licensed by the state to provide emergency services.

The Interim Final Rule also addresses a practice among some insurers to summarily deny coverage for emergency services based solely on the final diagnosis codes in the resulting claim for payment. That is, after the episode of care, the insurers make a determination that the situation was not a covered “emergency” based solely on the ultimate diagnosis, then wait until a patient appeals denial of coverage to conduct a more complete consideration of the claim. The Interim Final Rule makes clear that an insurer must cover emergency services in the first instance without limiting what constitutes an emergency medical condition solely on the basis of the ultimate diagnosis; rather, the determination must take into account whether a prudent layperson (rather than a medical professional) would reasonably consider the situation to be an emergency in seeking services. If so, the episode of care falls within the definition of emergency services protected under the law, regardless of any clinical determination made in hindsight.

**Surprise Medical Bills**

The No Surprises Act prohibits balance billing in the case of surprise medical bills — those for non-emergency services furnished by out-of-network providers during a
visit by the patient at an in-network facility — unless the law’s notice and consent requirements are met. As with the emergency services rule, out-of-network providers may only bill the patient the cost-sharing responsibility they would bear for similar covered services from an in-network provider.

The Interim Final Rule develops the parameters of this requirement in detail. The rule limits these protections to services provided at in-network hospitals (including critical access hospitals), hospital outpatient departments, and ambulatory surgical centers. Of note, urgent care centers are not included among the facilities covered for the purposes of non-emergency care. The Departments explain that a “visit” to an in-network facility does not require the patient to set foot in the facility; rather, a visit includes furnishing of equipment and devices, telemedicine services, imaging services, laboratory services, and pre- and post-operative services, regardless of whether these items are physically provided to the patient at the in-network facility. The Interim Final Rule also clarifies that the available notice and consent exception that might otherwise permit an out-of-network provider to balance bill the patient is not available in the context of certain ancillary services.

**Air Ambulance Services**

The Interim Final Rule reiterates the No Surprises Act’s application to air ambulance services. Where a health insurance plan generally covers any air ambulance services, the patient’s cost-sharing responsibility is limited to the corresponding in-network amounts, and the out-of-network air ambulance services provider may not balance bill the patient. The Departments also note that air ambulance services will be subject to the law’s dispute resolution programs still to be developed in future rulemaking.

**Cost Sharing and Payment Methodologies**

The No Surprises Act provides that out-of-network providers of emergency services, non-emergency services furnished at certain in-network facilities, and air ambulance services may not bill the patient for more than his or her cost-sharing responsibility for the corresponding in-network services. The law generally states the amount the out-of-network provider will be paid in such circumstances; the Interim Final Rule specifies how insurers must calculate these amounts.

**Patient Cost-Sharing Responsibilities**

The No Surprises Act generally limits the patient’s cost-sharing responsibility — that is, the patient’s deductible, copayment, or coinsurance payments for services — to the corresponding in-network amount. Specifically, in the case of emergency services and in surprise bill scenarios, the law states that the patient’s cost-sharing responsibility will be calculated based on the total amount that would have been charged for the services by an in-network provider or facility, an amount the law terms the “recognized amount.”

The recognized amount is defined as:

(1) an amount determined by an All-Payer Model Agreement under the Social Security
(2) if there is no applicable All-Payer Model Agreement, an amount determined by a specified state law; or

(3) if neither of the above apply, the lesser of

(a) the amount billed by the provider or facility or

(b) the qualified payment amount (QPA).

In the case of air ambulance services, the Interim Final Rule provides that the recognized amount will be the lesser of the billed amount or the QPA.

**All-Payer Model Agreement.** An All-Payer Model Agreement is an advanced alternative payment model agreement between a state and the Centers for Medicare and Medicaid Services that permits the state to establish rates for all services provided by a particular provider or facility regardless of payer. Currently, only Maryland and Vermont hold such agreements.

**Specified State Law.** A specified state law is one that sets an out-of-network provider’s rate and is applicable to the relevant insurer — including any ERISA plans that have opted to be subject to the state law — as well as the relevant provider and services at issue. The state law must apply to all three aspects of the claim for the out-of-network rate to serve as the recognized amount under the No Surprises Act. Additionally, the Departments caution that the interplay between federal and state law regarding ERISA plans will require all parties to navigate the out-of-network rate determination carefully. The Interim Final Rule provides several examples of how such an analysis may be undertaken.

**Qualified Payment Amount (QPA).** The Departments explain in detail that the QPA will generally be an insurer’s median in-network rate for (a) the same or similar services; (b) furnished in the same or a similar facility; (c) by a provider of the same or similar specialty; (d) in the same or similar geographic area. Calculation of the median rate will be pegged to insurer rates as of January 31, 2019, and then adjusted for inflation going forward. The Interim Final Rule sets forth definitions for each element of the median rate calculation, as well as how insurers will be expected to apply the relevant definitions to calculate the QPA for air ambulance services. The Departments also provide guidance for how insurers must incorporate non-fee-for-service rates, such as capitation or bundled rates, in their existing plans. In the event an insurer does not have sufficient data to calculate the QPA for a service, the Interim Final Rule outlines the requirements for eligible databases on which the insurer may rely (though the Departments expect such situations to be rare).

Recognizing the importance of transparency regarding how insurers calculate the QPA, the No Surprises Act also requires insurers to make certain information available in writing to providers or facilities when the QPA serves as the recognized amount. With each initial payment or denial, an insurer must provide the QPA for the relevant item or service, a certification that the QPA applies for the purposes of the recognized amount and was determined in accordance with the Interim Final Rule,
and a statement that the provider may initiate a 30-day negotiation period and then proceed to the independent dispute resolution process if the provider chooses. Upon request by the provider or facility, the insurer must also provide information regarding any non-fee-for-service rates or database information included in the insurer’s QPA calculations, as well as clarification regarding whether the insurer’s QPA calculation included payment adjustments such as incentive-based or retrospective payments.

Notably, the cost-sharing determination approach set forth in the Interim Final Rule means that calculation of the patient’s cost-sharing responsibility will remain separate from calculations of and negotiations between the insurer and provider regarding the provider’s payment amount. The law also provides that any patient cost-sharing responsibility under these provisions must count toward his or her deductible and out-of-pocket maximums in the same way payment of any cost-sharing responsibility for in-network services is counted, regardless of the difference between the determined recognized amount and the ultimate amount paid to the provider.

**Out-of-Network Provider Payment**

The No Surprises Act and the Interim Final Rule also prescribe the amount out-of-network providers will receive from insurers for the relevant services under the law (the “out-of-network rate”). Under the law, an insurer must make a total payment to the out-of-network provider equal to the following (less the patient’s cost-sharing responsibility):

1. an amount determined by an applicable All-Payer Model Agreement under the Social Security Act;
2. if there is no applicable All-Payer Model Agreement, an amount determined by a specified state law;
3. if neither of the above apply, an amount agreed upon by the insurer and the provider or facility; or
4. if none of the above apply and the parties do not settle prior to completion of the independent dispute resolution process established in the law, the amount determined by the independent dispute resolution entity.

The Departments note that, despite the No Surprises Act’s application of this standard to air ambulance services providers, they are unaware of any state laws that apply to air ambulance services and therefore could feasibly serve as a specified state law in order to calculate payment. Accordingly, most air ambulance services payment will be left to insurers and providers to negotiate, either privately or through the established independent dispute resolution program.

**Notice and Consent Exception**

Recognizing that there are instances in which a patient may wish to obtain services from an out-of-network provider in spite of the potentially higher cost of those
services, the No Surprises Act included an exception under which a patient may knowingly waive the protections of the law in certain circumstances. Accordingly, the cost-sharing limitations and balance billing prohibitions do not apply to (a) post-stabilization services that meet the four criteria set forth above removing them from the definition of emergency services under the law or (b) certain non-emergency services provided by an out-of-network provider at an in-network facility if the out-of-network provider or facility timely provides the patient a prescribed notice regarding such services, the patient acknowledges receipt of the information in the notice, and the patient consents to waive the protections under the law. The Interim Final Rule sets forth detailed requirements for the form and content of the notice, as well as when and how it must be provided to the patient to be effective under the law.

**Required HHS Model Notice and Consent**

The No Surprises Act requires providers and facilities to use a written notice “specified by HHS” in guidance. Accordingly, providers and facilities seeking to avail themselves of the exception must use the notice and consent forms issued by HHS. The notice and consent forms contain the elements required by the law and Interim Final Rule; however, the forms must be tailored to include information specific to the relevant provider or facility, patient, and contemplated items and services.

The Interim Final Rule explains that the notice must be provided with the consent, and together these documents must be given physically separate from, and not attached to or incorporated into, any other documents. The notice must be provided within the required timeframe on paper or electronically, as selected by the patient. An in-network facility may provide the notice on behalf of an out-of-network provider; however, if the resulting consent is flawed, the waiver of the protections under the No Surprises Act will not be effective.

**Timing**

If a patient schedules an appointment for items or services subject to the exception at least 72 hours before the appointment, the provider or facility must provide the notice and consent no later than 72 hours before the appointment. If the patient schedules the appointment within 72 hours before the appointment, the provider or facility must provide the notice and consent on the day the appointment is made. If the notice and consent are provided to the patient on the same day the relevant items or services are furnished, they must be provided no later than three hours prior to furnishing the items or services to ensure any consent received is truly voluntary.

**Content of Notice**

As outlined in HHS’s forms, the notice must identify by name the provider or facility furnishing the items or services, and it must state that the provider or facility is out-of-network with regard to the patient’s health insurance plan. The notice must also contain information regarding whether prior authorization or other management limitations may be required by a patient’s health insurance plan prior to receiving
the anticipated items or services, though providers and facilities may fulfill this requirement by providing general information on this point.

The notice must include a good-faith estimate of the amount the provider or facility may charge the patient for the contemplated items or services. In keeping with the principle that the good-faith estimate should provide the patient a meaningful picture of their total payment responsibility, the good-faith estimate should include any items or services the provider or facility reasonably expects to provide in conjunction with the contemplated items or services. Similarly, out-of-network emergency facilities that pursue the notice and consent exception in connection with post-stabilization services must include in the good-faith estimate the amounts that may be charged by both the facility and any out-of-network providers with respect to the same visit.

In the context of non-emergency services, each provider must obtain his or her own consent. Thus, a provider is only required to include items and services he or she would be furnishing and is not required to include other providers’ items and services in his or her estimate. Further, one provider may not rely on a consent obtained by another provider for the same visit to satisfy the notice and consent provisions.

The notice must expressly state that the patient is not required to consent to receive the contemplated items or services from the out-of-network provider or facility and may instead seek care from an in-network provider or facility. In the case of qualifying post-stabilization services being rendered at an in-network facility, the notice must include a list of any in-network providers available at the facility and advise the patient that he or she may request a referral to such a provider. Despite the many requirements placed on the content of the notice, the Interim Final Rule makes clear that neither it nor the accompanying consent constitute an agreement regarding the amount of final payment.

Standards for Consent

A patient’s consent to waive his or her protections under the No Surprises Act must be knowing and voluntary. As discussed, providers and facilities are required to use HHS’s prescribed consent form. This document must contain all required information in the identified fields and must be signed (including by electronic signature), dated, and time-stamped. Importantly, the consent will only be effective regarding the provider, facility, and items and services identified by name in the document.

The consent document must acknowledge that the patient has received the written notice and been informed that payment for the contemplated items and services may not be counted toward the in-network deductible or out-of-pocket maximum under his or her health insurance plan. The document must also state that, by signing the consent, the patient agrees to be treated by the out-of-network provider or, in the case of qualifying post-stabilization services, by the out-of-network emergency facility, and that he or she understands that he or she may be balance billed and subject to any cost-sharing requirements in connection with the items and services.

To comply with language access requirements, the consent must be made available in any of the 15 most common languages in the geographic region in which the
relevant facility is located. Upon signature of the document, the provider or facility must provide the patient a copy of the notice and consent in person or via mail or email, as selected by the patient. The facility or provider must retain a copy of the signed notice and consent documents for seven years following the date the items or services are rendered. A provider or facility that pursues the notice and consent exception must timely notify the insurer regarding whether balance billing and in-network cost-sharing protections apply to the item or service and provide a copy of the signed notice and consent documents. Additionally, where the notice and consent procedure is followed in connection with qualifying post-stabilization services, the provider or facility must specifically inform the insurer whether all four of the required criteria set forth in the law have been met.

**Exception Not Available in Certain Circumstances**

The notice and consent exception is not available — and thus, the cost-sharing and balance billing protections remain in place — in connection with emergency services other than qualifying post-stabilization services and air ambulance services. In the context of non-emergency services, the exception does not apply to ancillary services, which include 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; and items and services provided by an out-of-network provider in circumstances where there is no in-network provider who can furnish the item or service at the relevant facility. Moreover, the exception does not apply to items or services furnished as a result of unforeseen, urgent medical needs that arise during provision of items and services for which the out-of-network provider has satisfied the notice and consent requirement.

The Interim Final Rule clarifies that if a patient receives the notice but does not consent as outlined above, the balance billing and cost-sharing provisions remain in place. A patient may also revoke consent in writing at any time prior to receiving the relevant items or services.

**Facility and Provider Disclosure Requirements**

Among other provisions designed to increase transparency regarding the costs of medical care, the No Surprises Act requires providers and facilities to distribute to patients a one-page disclosure notice regarding the billing requirements that apply to the provider or facility under the law, as well as information regarding any applicable state requirements. Similarly, insurers must provide information to their enrollees regarding the billing provisions in the law. While HHS has published a model disclosure notice for providers, facilities, and insurers to adapt for these purposes, use of the model disclosure notice is not required by the No Surprises Act or the Interim Final Rule.

The disclosure requirements do not apply to air ambulance services providers under the law, but HHS urges such providers in the Interim Final Rule to make available clear and understandable information regarding the requirements and prohibitions applicable to their services.
Content and Form

Per the Interim Final Rule, the required disclosure must include a clear and understandable statement that explains the requirements and prohibitions applicable to the provider or facility under the No Surprises Act, including the cost-sharing limitations and balance billing prohibitions applicable to emergency services and non-emergency services provided by an out-of-network provider at an in-network facility. The disclosure must also explain any applicable state law requirements regarding the amounts the provider or facility may charge the patient once it has billed the insurer for services rendered. Where a state law is more restrictive than the No Surprises Act, the disclosure need not include language regarding the inapplicable provisions of the federal law. The disclosure must also contain contact information for the appropriate state and federal agencies should the patient encounter a suspected violation of the laws. The disclosure must be limited to one page, though it may be double-sided, and it may not be in any print smaller than 12-point font.

Methods of Disclosure

The Interim Final Rule sets forth detailed requirements for how and when providers, facilities, and insurers must provide the required notice. Providers and facilities must make the disclosure readily available on their public website. Possibly in response to compliance issues with its recently implemented hospital price transparency rule, HHS warns providers that “the disclosure or a link to the disclosure must be searchable on the provider’s or facility’s website” and requires that it be “easily accessible, without barriers, to the general public,” including that it be “findable through public search engines.” If a provider or facility does not have a website, it is exempt from the online aspect of the disclosure requirement.

Providers and facilities must also display the required disclosure on a sign posted prominently at the provider or facility’s location. The Interim Final Rule provides that the sign must be posted in a central location, such as where patients schedule care, check-in for appointments, or pay bills. As with the online requirement, providers that do not have a publicly accessible location are not required to post the sign.

Finally, providers and facilities must furnish the required disclosure to patients in person or through mail or email, as selected by the patient.

Timing

Providers and facilities must provide the required disclosure to patients no later than the date and time on which the provider or facility requests payment from the patient (including requesting a copayment at the time of a visit to the provider or facility). In cases where the facility or provider does not request payment from the patient, the disclosure must be provided no later than the date on which the provider or facility submits a claim for payment to the insurer.

Exceptions
While not expressly set forth in the No Surprises Act, the Interim Final Rule clarifies that providers are not required to make the disclosure described above if they do not furnish items or services at a health facility covered by the law (i.e., hospitals, hospital outpatient departments, or ambulatory surgical centers) or in connection with visits at such facilities. Additionally, providers must be careful to provide the disclosure only to patients to whom they render items or services that may be subject to the law, and then only if such items or services are rendered at a healthcare facility covered by the law. In short, the Interim Final Rule aims to ensure that providers required to furnish the disclosure in circumstances covered by the No Surprises Act do not inadvertently furnish the disclosure in situations that are not covered by the law, which could suggest to the patient that they may have protection from balance billing when they do not. For example, a provider that sometimes renders out-of-network services in a hospital may not provide a patient the disclosure in connection with services rendered in his or her clinic.

Additionally, the Interim Final Rule provides that, to the extent a provider furnishes an item or service covered by the law in a healthcare facility (including an emergency department of a hospital or independent freestanding emergency facility), 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.

Complaints

The No Surprises Act requires the Departments to establish processes to receive complaints regarding potential violations of the law by the insurers and providers under their respective governance. However, in the Interim Final Rule, the Departments announce their intention to create one system to intake all complaints related to the various components of the law and direct them to the relevant department to be addressed. The Interim Final Rule clarifies that there will be no time limit in which a complaint must be filed, and that the relevant department(s) must respond or in writing no later than 60 business days after a complaint is received. Such response may be to request further information, refer the complaint to an appropriate dispute resolution process, refer the complaint to a more appropriate state or federal regulatory authority, or to initiate an investigation for enforcement action.

In light of the short timeframe before the No Surprises Act’s January 1, 2022, effective date, the Departments availed themselves of an exception in the Administrative Procedure Act to issue the Interim Final Rule without implementing the usual notice-and-comment rulemaking process. However, the Interim Final Rule contains several requests for comment and identifies several areas on which the Departments will collect additional data to inform further implementation of the law. The regulations contained in the Interim Final Rule are set to be effective September 13, 2021 (60 days after its publication in the Federal Register). Comments will be due on the same date.

As explained in the Interim Final Rule, the Departments intend to issue additional rules promulgating the law in several phases. Still to come are rules regarding the patient-provider and insurer-provider dispute resolution processes, price
transparency and comparison tools, reporting requirements for insurers and providers (including air ambulance services providers), and — perhaps most importantly — enforcement mechanisms under the law. The No Surprises Act authorizes HHS to impose civil monetary penalties when a provider or facility violates the law, though there is an exception for a provider or facility that did not know and should not have reasonably known it violated the provisions if the provider withdraws the offending bill within 30 days of the violation and reimburses the patient. Until these additional rules are released, the Departments urge all parties to abide by a reasonable, good-faith interpretation of the law’s requirements.

The federal and state laws that govern whether and how providers may balance bill patients are complex and can have a profound impact on a provider or facility’s ability to obtain payment for services. If you have any questions regarding the No Surprises Act, its implementation under the Interim Final Rule, or its state law counterparts, please reach out to our attorneys for assistance.

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[1] The No Surprises Act was enacted December 27, 2020, as part of the Consolidated Appropriations Act, 2021 (Pub. L. 116-260)

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National Law Review, Volume XI, Number 194