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Special Bulletin

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Agencies Issue Part One of Regulations Banning Surprise Medical Bills

The Office of Personnel Management, along with the departments of Health and Human Services (HHS), Labor, and Treasury July 1 released "Part 1" of regulations implementing the No Surprises Act. The interim final rule addresses several provisions in the law, including the ban on balance billing for certain out-of-network services (referred to as "surprise medical bills"); the notice and consent process that some providers may use to bill patients for out-of-network services; how patient cost-sharing must be calculated; and a complaint process for any potential violations of the provisions in the law. Notably, the regulations contain a strong rebuke of health plan actions to deny coverage of emergency services.

These regulations place a number of new requirements on hospitals, health systems and other providers, as well as group health plans and issuers serving the commercial market (generally referred to in this document as "health plans"). Consistent with the law, these regulations do not apply to the Medicare and Medicaid programs, as protections against balance billing already exist in those programs.

As expected, the regulations do not address significant portions of the No Surprises Act, which will be handled in future regulations. For example, these regulations do not address the independent dispute resolution process, the good faith estimates and advanced explanation of benefits, provider directories, or continuity of care, among other provisions.

The interim final regulations are effective 60 days after publication in the Federal Register; however, most provisions are applicable beginning Jan. 1, 2022.

Key Takeaways

The interim final regulations:

- Prohibit out-of-network providers from billing patients more than their in-network cost-sharing amount for emergency services and many ancillary services when provided during scheduled care at in-network facilities.
- Establish a formula to calculate the "qualifying payment amount," which is used to determine patient cost-sharing and will be a factor for consideration in the independent dispute resolution process.
- Establish a process for certain out-of-network providers to obtain patient consent to balance bill.
- Establish a complaint process for potential violations of any of these provisions.
- Clarify the interaction between state and federal laws.
- Do not address all provisions in the No Surprises Act, such as the independent dispute resolution process.

Stakeholders have 60 days to submit comments to the departments.

This Special Bulletin provides a summary of the key provisions. It does not address all elements in the regulations, such as how these provisions apply to air ambulances. The AHA will provide a more detailed analysis in the coming weeks, as well as provide ample opportunity for members to provide input on our comments to the departments.

AHA Take: America's hospitals and health systems strongly support protecting patients from unexpected medical bills that may arise from gaps in their health care coverage. We appreciate the departments acknowledging and ordering an end to abusive health plan practices that have subjected patients to unexpected and inappropriate medical bills for emergency services. However, we urge the departments to carefully reconsider some aspects of the rule that could create a financial windfall for insurers while financially destabilizing providers and thus removing access points for patients without any guarantee that the savings are passed on to consumers.

Highlights of provisions important to hospitals and health systems follow.

MAJOR PROVISIONS

Ban on Balance Billing in Certain Out-of-network Scenarios. The departments codify in regulations the scenarios in which out-of-network providers may not balance bill patients. These include emergency services and many ancillary services when provided at an in-network facility.

- **Definition of Emergency Services:** The regulations generally define emergency services consistent with the Emergency Medical Treatment and Labor Act (EMTALA) with two significant modifications. Specifically, consistent with EMTALA, emergency services include an appropriate medical screening examination and any such further examination and treatment as is required to stabilize the individual, including services provided after a patient has been moved from the emergency department and admitted to the hospital. For purposes of this regulation, the departments broaden the definition in two key ways: 1) the definition includes such services when provided by a freestanding emergency department, and 2) the definition includes services provided after stabilization unless certain conditions are met, as described below.

- **Treatment of Post-stabilization Services:** Services provided to a patient post-stabilization are subject to the balance billing protections until the point of discharge, transfer, or consent by the patient to be balance billed. Patients may only be transferred if they are sufficiently stable to travel using nonmedical transportation or nonemergency medical transportation, as is determined by the attending emergency physician or the treating provider. The departments direct providers to take into account all relevant facts and circumstances, and include the patient if possible in the decision-making process. More information on the notice and consent process can be found in a later section of this summary.

- **Reiteration of Requirements under Prudent Layperson Standard:** The departments note that they are aware that some commercial health plans have implemented policies that restrict coverage for emergency services that are inconsistent with the prudent layperson standard. For example, they note that some plans have implemented policies to deny coverage based on the patient's final diagnosis or using general plan coverage exclusions. The departments unequivocally state that these policies are inconsistent with the requirements of the No Surprises Act, as well as the prudent layperson standard established by the Affordable Care Act.

Interim Payment (or Notice of Denial) to Providers. The regulations establish requirements regarding health plans' initial payment (or notice of denial) to providers. Health plans have 30 calendar days to make an initial payment or issue a notice of denial. The 30-day window begins when the health plan determines it has received a "clean claim." The departments note that they expect health plans to act in good faith but will consider additional standards if they become aware of abuse or gaming by plans. The regulations do not establish any requirements related to how much plans must reimburse providers, and the departments seek comment on whether they should establish a minimum payment amount.

Notice and Consent Process. The law permits patients to waive balance billing protections if the out-of-network provider provides notice and obtains the patient's consent and directed the departments to establish such a process. This process, however, cannot be used for certain services, including emergency services (with the exception of certain post-stabilization services), certain ancillary services, and items or services that are delivered as a result of an unforeseen urgent medical need that arises during a procedure for which notice and consent was received. In addition, the law prescribes the timing, content and language accessibility of the notice as well as record retention requirements of the signed notice and consent form. The regulations provide further specification regarding these requirements.

The regulations require that providers use a standard notice in accordance with guidance HHS will be issuing at a later date. Providers and facilities will be able to tailor the document as applicable. The content of the notice must identify the provider or facility as being out-of-network and include a good faith estimate of charges for services that could reasonably be expected to be provided. With regard to good faith estimates, the regulation's preamble notes that the provider and facility are expected to apply the same process and considerations used to calculate the good faith estimate required by the law's transparency requirements, which will be addressed in future rulemaking. In addition, the notice must include information on prior authorization or utilization management limitations, and the notice and consent documents must be separate from other forms when presented to the patient. With regard to notices used for certain post-stabilization services, the regulations require that the notice must include a list of any participating (i.e., in-network) providers at the facility who are able to furnish the items or services involved. The notice must inform the individual that they may be referred, at

their option, to a participating provider. To ensure language accessibility, the notice is required to be available in the 15 most common languages in the provider's or facility's geographic region, as well as comply with other state and federal requirements regarding language access.

The law requires that providers and facilities provide notice and consent within 72 hours before the scheduled service. The rule further specifies that in the event of same-day-service, the notice must be provided at least three hours before the scheduled service. In addition, the regulations require that providers and facilities notify health plans when billing for services that they have met the notice and consent requirements of the law. Providers and facilities must retain records of the notice and consent for seven years. The regulations further specify that where the facility does not otherwise obtain the consent on behalf of the provider, the provider may either coordinate with the facility so that the facility retains the written notice and consent for a 7-year period, or the provider must retain the written notice and consent for a 7-year period.

Disclosure Requirements. Health care providers and facilities must make publicly available information on patients' rights with respect to balance billing. This notice is to be available on the providers' public websites. The notice must contain information on the requirements established under this law, information on any state-level protections if applicable, and contact information for state and federal agencies to report any potential violations. The regulations state that the departments will consider the use of a model notice to reduce burden.

Qualifying Payment Amount. The qualifying payment amount (QPA) has two purposes: to calculate patient cost-sharing (except in instances where billed charges are less than the QPA) and to act as one of the factors for consideration by the arbiter in the independent dispute resolution process (to be established in future regulation). The statute defines the QPA as the issuer's median in-network rate for 2019 trended forward. In the case of a self-insured group health plan, the administering entity is treated as the issuer for purposes of these provisions.

The law tasked the Secretary of HHS with determining the methodology for calculating the QPA, which is covered at length in the regulation. Specifically, the regulation addresses a number of factors that will determine which rates are included in the calculation. These include: the type of contract (e.g., single case agreement, rental networks), the insurance market (e.g., individual market versus large group), the geographic region, definition of "same or similar service," what constitutes a provider in the same or similar specialty, and facility type. Notably, with respect to facility type, the regulations only permit plans to distinguish between two types of facilities – freestanding emergency departments and hospital emergency departments.

The regulations also address other aspects of how the QPA will be calculated, as well as the process for determining cost sharing in unique circumstances. Specifically, the regulations address how the QPA will be trended forward and how to account for contracts using value-based payment methodologies or where services are reimbursed

on a per-unit basis, such as anesthesia. Issuers must have at least three contracted rates to complete the calculation. Where that is not possible, such as when an issuer does not have sufficient contract data for a given service or the plan is new, the regulations outline a process for using information from independent claims databases that meet certain standards to generate a calculation. The departments also address situations where entirely new service codes are created and for which neither the issuer nor an independent database would have adequate data to calculate the QPA. Finally, the departments address what information issuers must share with providers regarding calculation of the QPA.

Interaction with State Law. In general, the regulations state that these provisions apply to all forms of commercial coverage (e.g., individual market, self-insured, fully insured) except in instances where states have surprise medical billing protections in place for state-regulated plans. In those instances, the state law and processes would apply. The departments address the specific situation where a state has permitted a plan regulated under the Employee Retirement Income Security Act (ERISA) to opt in to the state's process and permit this practice to continue. They also address a number of different scenarios to help identify when state versus federal law would apply, such as when the health plan license and the provider are in different states.

Complaint Process. The regulations establish a process through which the departments can receive complaints about potential violations of all of the consumer protection and balance billing requirements included in the regulation. The single complaint process will apply to health plans, providers, facilities, and providers of air ambulance services. The process will allow for complaints to be made orally or in writing, and the departments will have 60 days to respond to the complaint. As part of their process, the departments may seek additional information from any of the stakeholders involved, including the person submitting the complaint, the health plan, or the provider/facility, and may engage other oversight bodies, including states, as determined necessary. There will be no statute of limitations on the time frame for submitting a complaint.

NEXT STEPS

Comments on the proposed rule are due 60 days after publication in the Federal Register. If you have questions, please contact AHA at 800-424-4301.