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Interim Final Rule with Comment Period Requirements Related to Surprise Billing; Part I

July 26, 2021

On July 13, 2021, the Centers for Medicare & Medicaid Services (CMS) distributed the above referenced [interim final rule with comment period \(CMS-9909-IFC\)](#). This sets forth interim final rules to implement certain provisions of the No Surprises Act, which was enacted as part of the [Consolidated Appropriations Act of 2021](#). The interim final rules amend and add provisions to existing rules under the Internal Revenue Code, the Employee Retirement Income Security Act (ERISA), the Public Health Service Act, and the Federal Employees Health Benefits Act. These interim final rules apply to group health plans and health insurance issuers offering group or individual health insurance coverage. Additionally, the Department of Health and Human Services has included interim final rules that apply to emergency departments of hospitals and independent freestanding emergency departments, health care providers and facilities, and providers of air ambulance services related to the protections against surprise billing. These rules are intended to protect enrollees in such plans from surprise medical bills when they receive emergency services, non-emergency services from nonparticipating providers at participating facilities, and air ambulance services from nonparticipating providers.

These rules are applicable beginning January 1, 2022.

CMS seeks comments on these interim final rules. Comments are due on or before September 7, 2021.

This summary highlights the interim final rules impacting health plans.

1. Applicability

(pgs. 105-107)

- A. These interim final rules impact:
 - i. Group health plans (including fully insured and self-insured and plans subject to ERISA)
 - ii. Individual health plans
 - iii. Carriers in the Federal Employees Health Benefits (FEHB) programThese health plans will hereafter be referred to as “Applicable Health Plan”.

- B. These interim final rules do not impact:
 - i. Medicare Advantage plans
 - ii. Medicare Advantage Prescription Drug plans
 - iii. Standalone Prescription Drug Plans
 - iv. Retiree-only group health plans

2. Scope of the New Surprise Billing Protections

A. Emergency Services

(pgs. 23-28)

- i. An Applicable Health Plan must cover emergency services without regard to whether the provider furnishing such services is a participating provider or facility.

- ii. An Applicable Health Plan must charge in-network cost-sharing for emergency services provided by a nonparticipating provider or nonparticipating emergency facility. Cost-sharing payments from an enrollee for these emergency services must be counted toward any in-network deductible or out-of-pocket maximum in the same manner as if such cost-sharing payments were for a participating provider or facility.
- iii. An Applicable Health Plan cannot require an individual or provider to obtain prior authorization for emergency services (including when the emergency services are provided out-of-network).
- iv. Broadens the definition of “emergency services” to include emergency services provided at an independent freestanding emergency department.
- v. If an Applicable Health Plan provides or covers any services in an emergency department of a hospital or emergency services in an independent freestanding emergency department, the Applicable Health Plan must cover emergency services without limiting what constitutes an emergency medical condition (as defined in these interim final rules) solely on the basis of diagnosis codes.
- vi. When an Applicable Plan denies coverage, in whole or in part, for emergency services, including services rendered during observation or surgical services, the determination of whether the prudent layperson standard has been met must be based on all pertinent documentation and be focused on the presenting symptoms (and not solely on the final diagnosis).
- vii. Applicable Plans cannot restrict the coverage of emergency services:
 - a. By imposing a time limit between the onset of symptoms and the presentation of the enrollee at the emergency department;
 - b. Because the enrollee did not experience a sudden onset of the condition.

B. Post-Stabilization Services

(pgs. 28-33)

- i. Clarifies that “emergency services” include any additional items and services covered under an Applicable Plan and furnished by a nonparticipating provider or facility after an enrollee is stabilized and as part of outpatient observation, inpatient stay, or outpatient stay – and are thus protected from surprise billing – unless all of the following conditions are met:
 - a. The provider who has evaluated the enrollee determines the enrollee is able to travel using nonmedical transportation or nonemergency medical transportation to an available participating provider or facility located within a reasonable travel distance, considering the enrollee’s condition and socioeconomic factors.
 - b. The provider or facility furnishing post-stabilization services satisfies specified notice and consent criteria.
 - c. The enrollee (or the enrollee’s authorized representative) is in a condition to receive the notice and provide informed consent.
 - d. The provider or facility satisfies any additional requirements or prohibitions imposed under applicable state law.

- C. Non-Emergency Services Performed by Non-Participating Providers at Participating Health Care Facilities**
(pgs. 33-34)
- i. An Applicable Health Plan must cover non-emergency items and services furnished to an enrollee by a non-participating provider during a visit to a participating health care facility at the in-network cost-sharing unless the provider has satisfied specified notice and consent criteria with respect to the items and services provided.
 - ii. Cost-sharing payments from an enrollee for these non-emergency services must be counted toward any in-network deductible or out-of-pocket maximum in the same manner as if such cost-sharing payments were for a participating provider or facility.
 - iii. Defines, in the context of non-emergency services, a “participating health care facility” as a health care facility that has a contractual relationship, directly or indirectly, with an Applicable Health Plan setting forth the terms and conditions on which a relevant item or service is provided to an enrollee under the plan. This includes single case agreements.
 - iv. Defines, in the context of non-emergency services, a “health care facility” as a hospital, hospital outpatient department, critical access hospital, or an ambulatory surgical center. This does not include urgent care facilities.
 - v. Defines a “visit” to include the furnishing of 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 at the facility).
- D. Air Ambulance Services**
(pgs. 37-38)
- i. Applicable Plans must cover air ambulance services furnished by a nonparticipating provider (including inter-facility transports) at the same cost sharing and using the same billing dispute resolution processes as if such services were provided by a participating provider.
 - ii. Cost-sharing payments from an enrollee for these air ambulance services must be counted toward any in-network deductible or out-of-pocket maximum in the same manner as if such cost-sharing payments were for a participating provider.
- 3. Determination of the Cost-Sharing Amount and Payment Amount to Providers and Facilities**
- A. Cost-Sharing Amount**
(pgs. 39-42)
- i. For emergency services furnished by a nonparticipating emergency facility or by a nonparticipating provider in a participating health care facility, an Applicable Health Plan must generally calculate cost sharing as if the total amount that would have been charged for the services by a participating emergency facility or participating provider were equal to the “recognized amount” for such services.
 - ii. The “recognized amount” is:
 - a. An amount determined by an applicable All-Payer Model Agreement (which is an agreement between CMS and a state to test and operate systems of all-payer payment reform for the medical care of residents of the state);

- b. If there is no applicable All-Payer Model Agreement, an amount determined by a specified state law; or
- c. If there is no applicable All-Payer Model Agreement or specified state law, the lesser of the amount billed by the provider or facility or the qualifying payment amount (QPA) (which is the median of the contracted rates of the plan or issuer for the item or service in the geographic region on January 31, 2019, increased for inflation).
- iii. The Applicable Health Plan separately determines the total payment amount for the furnished items or services, but that amount does not affect the cost-sharing amount the enrollee must pay.

B. Out-of-Network Rate

(pgs. 42-44)

- i. An Applicable Health Plan must make a total payment to a nonparticipating provider or facility equal to one of the following amounts, less any cost sharing from the enrollee:
 - a. An amount determined by an applicable All-Payer Model Agreement;
 - b. If there is no applicable All-Payer Model Agreement, an amount determined by a specified state law;
 - c. If there is no applicable All-Payer Model Agreement or specified state law, if the Applicable Health Plan and the provider or facility have agreed on a payment amount, the agreed-on amount; or
 - d. If none of these three conditions apply, and the parties enter into the independent dispute resolution (IDR) process and do not agree on a payment amount before the date when the IDR entity makes a determination of the amount, the amount is determined by the IDR entity.
- ii. Because the cost-sharing amount is calculated using the recognized amount, which is calculated separately from the determination of the out-of-network rate, these requirements may result in circumstances where an Applicable Health Plan must make payment prior to an enrollee meeting their deductible.
 - a. When the surprise billing protections apply, and the out-of-network rate exceeds the amount upon which cost sharing is based, an Applicable Health Plan must pay the provider or facility the difference between the out-of-network rate and the cost-sharing amount (the latter of which in this case would equal the recognized amount, or the lesser of the QPA or the billed amount), even if the enrollee has not satisfied their deductible

C. Specified State Law

(pgs. 44-52)

- i. A “specified state law” is a state law that provides a method for determining the total amount payable under an Applicable Health Plan to the extent state law applies.
- ii. When a specified state law applies, the recognized amount (i.e., the amount upon which cost-sharing is based) and out-of-network rate for emergency and non-emergency services subject to surprise billing protections is calculated based on such specified state law.
- iii. In order for a specified state law to determine the recognized amount or out-of-

network rate, any such law must apply to:

- a. The Applicable Health Plan or coverage involved, including where a state law applies because the state has allowed a plan that is not otherwise subject to applicable state law an opportunity to opt in, subject to section 514 of ERISA;
- b. The nonparticipating provider or nonparticipating emergency facility involved (and in the case of state out-of-network rate laws, the nonparticipating provider of air ambulance services involved); and
- c. The item or service involved.

D. Methodology for Calculating the Qualifying Payment Amount
(pgs. 55-91)

- i. Calculating median contracted rate
 - a. In general, the median contracted rate for an item or service is calculated by arranging in order from least to greatest the contracted rates of all plans of the Applicable Health Plan or all coverage offered by the Applicable Health Plan in the same insurance market for the same or similar item or service that is provided by a provider in the same or similar specialty or facility of the same or similar facility type and provided in the geographic region in which the item or service is furnished, and selecting the middle number.
 - b. If the same amount is paid under two or more separate contracts, each contract is counted separately.
 - c. If there are an even number of contracted rates, the median contracted rate is the average of the middle two contracted rates.
- ii. "Contracted rate" is the total amount (including cost-sharing) that an Applicable Health Plan has contractually and directly or indirectly agreed to pay a participating provider, facility, or provider of air ambulance services for covered items and services.
 - a. If an Applicable Health Plan rents its provider network or otherwise contracts with third parties to manage its provider network, the contracted rates between the between providers and the entity providing access to the network are used for purposes of calculating the QPA.
 - b. For the purpose of the definition of "contracted rate", a single case agreement, letter of agreement or other similar arrangement does not constitute a contract and the rate paid under such arrangement should not be counted among the Applicable Health Plan's contracted rates.
- iii. The No Surprises Act specifies an alternative methodology for calculating the QPS if an Applicable Health Plan has insufficient information to calculate it using the typical means (i.e., it is unable to calculate a median contracted rate for an item or service). However, CMS clarifies that such alternative methodology should be used only in limited circumstances.

E. Additional Applicable Health Plan Requirements Regarding Making Initial Payments or Providing a Notice of Denial
(pgs. 92-99)

- i. Requires Applicable Health Plans to send "an initial payment or notice of denial of payment" not later than 30 calendar days after a nonparticipating provider or facility

submits a bill related to the items and services that fall within the scope of the new surprise billing protections for emergency services, non-emergency services performed by nonparticipating providers at participating facilities, and air ambulance services furnished by nonparticipating providers of air ambulance services.

- a. Since Applicable Health Plans cannot comply with this requirement unless they first determine that the billed items and services are covered under the plan, these interim final rules require that Applicable Health Plans make such determination not later than 30 calendar days after a nonparticipating provider or facility submits a bill related to the items and services that fall within the scope of the new surprise billing protections for emergency services, non-emergency services performed by nonparticipating providers at participating facilities, and air ambulance services furnished by nonparticipating providers of air ambulance services.
 - b. The 30-calendar-day period begins on the date the Applicable Health Plan receives a clean claim.
- ii. Under these interim final rules, a “notice of denial of payment” means, with respect to an item or service for which benefits are subject to the surprise billing protections, a written notice from the Applicable Health Plan to the provider or facility that payment for the item or service will not be made and which explains the reason for denial.
- a. A notice of denial of payment could be provided, for example, if the item or service is covered but is subject to a deductible greater than the recognized amount.

4. Surprise Billing Complaints Regarding Group Health Plans and Health Insurance Issuers (pgs. 99-103)

- A. HHS will consider a complaint to be filed on the date on which HHS receive an oral or written statement with information about the complaint sufficient to identify the parties involved and the action or inaction that is the subject of the complaint. The information may also include the timing of the alleged violation, and the state where the alleged violation occurred.
- B. These interim final rules do not establish a timeframe in which a complaint must be filed.
- C. HHS must respond to complaints regarding violations of balance billing protections by providers and facilities within 60 business days of receipt.
 - i. Response may be verbal or written.