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Compliance requirements for providers under surprise billing regulations: Part 1

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Editor's note: At press time for the November issue of Compliance Today, *the federal agencies issued Part 2 of the surprise billing regulations. This article outlines compliance obligations for healthcare providers under Part 1 of the regulations and references that Part 2 of the regulations are expected later this year.*

On July 13, the Departments of Health & Human Services (HHS), Labor, and the Treasury (the departments), along with the Office of Personnel Management, published an interim final rule with comment period (IFC) implementing portions of the federal ban on surprise medical bills enacted by Congress in December 2020.[1] The No Surprises Act (the act), part of the Consolidated Appropriations Act, 2021, included a ban on "balance billing," also referred to as "surprise medical bills," when a payer does not cover the entire cost of a patient's treatment by a nonparticipating (i.e., out-of-network, or OON) provider, and the patient receives a "surprise" bill to make up the difference.[2]

The departments are issuing regulations in phases to implement the act and refer to the IFC as "Part I" of requirements related to surprise billing. The IFC codifies a number of new compliance obligations, including requirements that will be applicable to healthcare providers as of January 1, 2022.[3] Although the departments issued the regulations as an interim final rule, and the effective date of the regulations is September 13, 2021, the departments are soliciting feedback from the public on the new requirements. Comments were due September 7, 2021.

Meanwhile, the HHS has published sample documents and instructions[4] to assist providers and facilities with meeting new disclosure obligations. Providers and facilities should review the IFC and accompanying guidance to prepare for meeting the new requirements by January 1, 2022.

Below is an outline of key compliance rules in the IFC applicable to providers and facilities.

Ban on balance billing and cost-sharing limitations

The IFC codifies in regulations a ban on balance billing at 45 C.F.R. § 149.410–420. The ban applies to emergency services, nonemergency services furnished by an OON provider at an in-network healthcare facility, and OON air ambulance services. The IFC also places limits on cost-sharing amounts that providers and facilities may charge for such services.

In general, the IFC requires OON providers or facilities furnishing emergency care and OON providers furnishing

certain nonemergency services at in-network facilities to charge patients no more than the amount that would apply for in-network care. Providers and facilities must calculate cost-sharing amounts based on:[5]

1. An amount determined by an all-payer model agreement in place in a given state (if applicable);
2. An amount determined under state law (if no all-payer model agreement is in place); or
3. The lesser amount of either the billed charge or the qualifying payment amount, which is generally the payer's median contracted rate (if no applicable state law).

The IFC requires OON air ambulance providers to calculate cost-sharing amounts based on the lesser of the billed charge or the payer's qualifying payment amount and the cost-sharing requirement that would apply if the services were rendered by an in-network provider.[6]

Notice and consent exception

In the case of certain nonemergency services and certain post-stabilization services provided in the context of emergency care, the IFC outlines an exception to the ban on balance billing that may allow higher cost sharing if the provider or facility gives notice to the patient and obtains the patient's consent to waive the balance billing protections.

Notice requirement

To satisfy the notice requirement and qualify for the exception to the ban on balance billing, an OON provider, or a facility on behalf of a provider, must provide a written notice to patients in paper or electronic form, as selected by the patient, that is consistent with guidance to be issued by the HHS and does the following:

- States that the provider is an OON provider with respect to the payer's coverage;
- Includes a good faith estimated amount that the OON provider may charge, along with notification that the information does not constitute a contract that binds the patient;
- Provides a statement that prior authorization or other care management limitations may be required; and
- States that their consent to receive the care is optional and that the patient may seek care from an available in-network provider.[7]

Providers/facilities must provide the written notice along with a consent document, and they must be provided physically separate from other documents that are not attached to or incorporated in any other document. When an appointment is scheduled at least 72 hours before a patient receives care, providers/facilities must provide the written notice no later than 72 hours before the care. When the appointment is scheduled within 72 hours of the care, notice must be provided on the date of the appointment. In cases where providers/facilities give notice on the same day as treatment, providers/facilities must provide notice no later than three hours before rendering the services subject to the notice and consent requirements.

An additional notice requirement applies when OON providers render post-stabilization services at an in-network emergency facility. In this case, the provider/facility must also include in the notice a list of in-network providers at the in-network emergency facility who are able to provide the services and must inform the patient that they have the option to be referred to an in-network provider.

Consent requirement

To satisfy the consent requirement, an OON provider/facility must document a patient's consent to be balance billed on a form specified by the HHS through guidance. The patient (or an authorized representative) must sign the form before services are furnished. The consent must be provided voluntarily, obtained in accordance with guidance issued by the HHS, and not be revoked before treatment is rendered. A provider/facility must also provide a copy of the signed written notice and consent to the patient in person or through mail or email, as selected by the patient.

Documentation of consent must:

- Acknowledge in clear and understandable language that the patient has been provided with the written notice in the form selected by the patient and that the patient has been informed that payment for the services may not count toward meeting payer limitations on cost sharing and that payment may not apply toward an in-network deductible or out-of-pocket cost maximum;
- State that, by signing the consent, the patient agrees to be treated by the OON provider and understands that the patient may be balance billed and may be subject to cost-sharing requirements applied by the OON provider; and
- Document the time and date on which the patient received the written notice and signed the consent form.

If an in-network facility obtains consent from a patient on behalf of an OON provider rendering services at the facility, the facility must retain the written notice and consent for at least a seven-year period after the care is provided. OON providers who obtain consent from a patient have the option of either coordinating with the in-network facility to retain the notice and consent for at least seven years or must retain the written notice and consent themselves for at least seven years.

OON providers, or in-network facilities on their behalf, must notify payers when care furnished by an OON provider is furnished in an in-network facility and must provide the signed written notice and consent document to the payer. If an OON provider bills the patient directly, the provider may meet this notification requirement through the bill submitted to the patient.

Exclusions to notice and consent exception

The notice and consent exception to the ban on balance billing does not apply to certain items and services rendered by OON providers at in-network facilities in cases where, according to the departments, surprise medical bills are likely to occur. Excluded items and services include the following ancillary services:

- "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 a nonparticipating provider if there is no participating provider who can furnish such item or service at such facility."

Items and services are also excluded if they are provided due to "unforeseen, urgent medical needs that arise at the time an item or service is furnished."

Notice and consent requirement compliance tips

In conjunction with publishing the IFC, the HHS published a standard notice and consent document for use by providers and facilities, along with accompanying instructions.[8] The HHS refers to the document as a "Surprise Billing Protection Form." The instructions indicate that the document constitutes the guidance referenced in the IFC, suggesting that there would be forthcoming guidance issued by the HHS that providers and facilities must follow to meet the notice and consent requirements under 45 C.F.R. § 149.410–420. The HHS specifies that the agency will view use of the document consistent with the instructions to be "good faith compliance" with the notice and consent requirements. Providers and facilities that may wish to meet the notice and consent exception to the ban on balance billing should review the standard notice and consent document and accompanying instructions.

In a supporting statement accompanying the standard notice and consent document, the HHS indicates that the agency "assumes that emergency facilities and health care facilities will provide the notice and obtain consent on behalf of nonparticipating providers, retain records, and notify plans and issuers."[9] Providers and facilities should coordinate to determine whether the parties will be taking actions to meet the notice and consent requirements independently, or if a facility will be taking actions on behalf of a provider.

Consumer notification requirements

The IFC codifies in regulation disclosure requirements that apply to providers and facilities regarding patient protections against balance billing under 45 C.F.R. § 149.430. Providers and facilities, including hospital emergency departments and freestanding emergency departments, must make certain disclosures to the public and to patients through several methods. The disclosures must include the following:[10]

- An explanation of the requirements of and prohibitions applicable to providers and facilities under the act and its implementing regulations;
- An explanation of any state law requirements regarding balance billing and cost-sharing amounts for OON services, if applicable; and
- Contact information for state and federal agencies that patients may contact regarding concerns about violations of the requirements in the notice.

The IFC outlines the following requirements for the methods through which providers and facilities must make the above disclosures:

- The information (or a link to the information) must be on a "searchable homepage of the provider or facility's website" (does not apply if there is no website);
- The information must be made available "on a sign posted prominently at the location of the provider or facility" (does not apply if a provider does not have a publicly accessible location); and
- The information must be provided to patients in "a one-page (double-sided) notice, using print no smaller than 12-point font," either in person or through mail or email, as selected by the patient.

Providers and facilities must make the disclosures no later than when the provider/facility requests payment from the patient. If no payment is requested, disclosures must be made no later than when the provider/facility submits the claim to the payer.

Special rule to prevent duplication

To avoid duplication of efforts, the IFC allows in-network facilities to provide disclosure to patients on behalf of OON providers that furnish services at the facility. The special rule applies with respect to disclosure to the public and to patients, but providers must still make the disclosures available via their own website. Disclosure made on behalf of a provider by a facility must be pursuant to a written agreement. If a facility agrees to make disclosures on behalf of a provider via a written agreement and the facility fails to do so, the facility will be in noncompliance with the requirements, but not the provider. The HHS indicates that a "written agreement" may include either an existing contract that is amended to address this rule or a new written agreement that outlines the disclosure requirements.[11] The HHS encourages providers that enter into arrangements with facilities to monitor the facility's compliance.

Consumer disclosure requirement compliance tips

In conjunction with publishing the IFC, the HHS also published a model disclosure notice for use by providers and facilities, along with accompanying instructions.[12] The HHS titles the model notice: "Your Rights and Protections Against Surprise Medical Bills." The agency notes that providers and facilities may use the model notice to meet the disclosure requirements, but they are not required to do so. The HHS specifies that the agency will view use of the model notice consistent with the instructions to be in "good faith compliance" with the disclosure requirements under 45 C.F.R. § 149.430, if all other requirements are met.

In light of the special rule allowing in-network facilities to provide disclosure on behalf of OON providers, facilities and providers should coordinate their compliance efforts with respect to the disclosure rules. In particular, providers and facilities should consider whether amendments to existing agreements will be needed to address disclosure obligations or if new agreements will be needed. In a supporting statement accompanying the model disclosure notice, the HHS indicates that the agency assumes that providers and facilities will enter into agreements for facilities to provide disclosure on behalf of providers.[13] The HHS also suggests that providers and facilities that are able to renew their contracts prior to 2022 could address the compliance obligations during the renewal process.

Payment to OON providers and future regulations implementing arbitration process

In addition to codifying the prohibition on balance billing and associated disclosure requirements, the IFC also outlines payment amounts to OON providers/facilities and previews future regulations to implement an arbitration process when there are disputes over OON payment rates. When an OON provider disputes a payment amount, or if the payer denies payment, the parties may attempt to negotiate an agreed upon rate. In cases where negotiation fails, the act calls for implementation of a binding independent dispute resolution (IDR) process to determine payment rates. The IFC is Part 1 of the regulations to implement the act and does not address the IDR process in detail. However, the departments indicate that they will issue regulations regarding the IDR process and IDR entities later this year.

Takeaways

- Healthcare providers and facilities will be subject to new requirements as of January 1, 2022, related to a federal ban on "balance billing."
- Some services are exempted from the ban on balance billing if a provider/facility meets a notice and consent requirement.
- Providers and facilities will be subject to consumer disclosure requirements.

- The Department of Health & Human Services has prepared sample documents and instructions to help providers/facilities meet the notice and consent and disclosure requirements.
- Federal agencies will issue Part 2 of the surprise billing regulations later this year, which will address payment to providers/facilities and an arbitration process.

1 Requirements Related to Surprise Billing; Part I, 86 Fed. Reg. 36,872 (July 13, 2021), https://bit.ly/3970Nco.
2 Consolidated Appropriations Act, 2021, Pub. L. No. 116-260, Division BB (2020).
3 Requirements Related to Surprise Billing; Part I, 86 Fed. Reg. 36,872.
4 "CMS-10780: Requirements Related to Surprise Billing: Qualifying Payment Amount, Notice and Consent, Disclosure on Patient Protections Against Balance Billing, and State Law Opt-in," Centers for Medicare & Medicaid Services, July 1, 2021, https://go.cms.gov/3nxUM0M.
5 Requirements Related to Surprise Billing; Part I, 86 Fed. Reg. 36,877.
6 Requirements Related to Surprise Billing; Part I, 86 Fed. Reg. 36,985.
7 Requirements Related to Surprise Billing; Part I, 86 Fed. Reg. 36,982–984.
8 "CMS-10780: Requirements Related to Surprise Billing."
9 Centers for Medicare & Medicaid Services, "Supporting Statement – Part A: Requirements Related to Surprise Billing: Qualifying Payment Amount, Notice and Consent, Disclosure on Patient Protections Against Balance Billing, and State Law Opt-in (CMS-10780/OMB control number: 0938-NEW)," July 1, 2021, https://go.cms.gov/3nxUM0M.
10 Requirements Related to Surprise Billing; Part I, 86 Fed. Reg. 36,984–985.
11 Requirements Related to Surprise Billing; Part I, 86 Fed. Reg. at 36,915.
12 Centers for Medicare & Medicaid Services, "Model Disclosure Notice Regarding Patient Protections Against Balance Billing: Instructions for Providers and Facilities (For use beginning January 1, 2022)," July 1, 2021, https://go.cms.gov/3nxUM0M.
13 Centers for Medicare & Medicaid Services, "Supporting Statement – Part A."