Key Requirements in Part 1 of the Surprise Billing Interim Final Rule

July 20, 2021

This memo outlines some key requirements contained in Part 1 of the Surprise Billing Interim Final Rule (IFR) published in the Federal Register on July 13, 2021. Click here for the published version. Comments are due no later than 5:00 PM ET on September 7, 2021. Click here to download an Excel chart (prepared by our intern Sean McDowell) identifying the comments requested.

Click here for our initial overview with links to the unpublished version, along with the HHS fact sheets and press release. Click here for the standard notice and consent document and here for the model disclosure. The regulations have an effective date of September 13, 2021 with an application date of January 1, 2022.

Additional regulations are coming. The No Surprises Act (NSA) requires the payer audit process to be published by October 1, with the provisions related to the independent dispute resolution process (IDR) and patient transparency provisions by December 27, 2021. HHS intends to promulgate additional rules on enforcement requirements.

The IFR begins with a lengthy preamble that seems to stretch some of the boundaries set forth in the requirements in the text of the rule. The IFR is also somewhat complicated, in part because of the various departments involved in promulgating it. These include HHS, Labor, Treasury and OPM which address different types of health insurance - health insurance coverage in the individual, small group and large group markets, as well as self-funded plans, and Federal Employees Health Benefit Program, among others. In general, the provider provisions are in the HHS section.

Emergency Services and Post-Stabilization Services

The NSA prohibits nonparticipating facilities and nonparticipating providers from balance billing patients for emergency services. The patient's cost-sharing is limited to what would have applied if the facility or treating provider were participating in the network. Patients cannot waive the NSA protections for emergency services, except in certain circumstances for post-stabilization services.

The IFR defines "emergency medical condition" to mean a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that a prudent layperson could reasonably expect the absence of immediate medical attention to result in (1) placing the health of the individual in serious jeopardy, (2) serious impairment to bodily functions, or (3) serious dysfunction of any bodily organ or part. This definition includes mental health conditions and substance use disorders.

The definition of emergency services includes pre-stabilization services that are provided after the patient is moved out of the emergency department and admitted to a hospital and these services are subject to the protections of the NSA.

Payers are prevented from placing certain restrictions on emergency care services, such as:

- Payers may not require prior authorization for emergency services;
- Payers must cover emergency services without limiting what constitutes an emergency medical condition solely on the basis of diagnosis codes; and
- Payers may not impose time limits between the onset of symptoms and when the patient sough emergency care.

Balance billing for post-stabilization services is prohibited unless the following conditions are met:

- The attending emergency physician or treating provider determines the patient is able to travel using nonmedical transportation or nonemergency transportation to an available participating provider or facility within a reasonable travel distance;
- The provider or facility furnishing post-stabilization services satisfies the notice and consent criteria; where the facility is participating and the provider is not, written notice must include a list of participating providers at the participating facility;
- The individual (or authorized representative) is in a condition to receive the information contained in the notice and gives informed consent to be billed for the out-of-network care; and
- The provider satisfies any additional requirements or prohibitions as may be imposed under state law where there is an applicable state law.

The preamble explains how the Departments intend to view what constitutes reasonable travel and informed consent and stresses that post-stabilization notice and consent procedures should be used sparingly and in limited circumstances.

Notice and consent are not applicable for certain services:

- Ancillary services –
    - items and services related to emergency medicine, anesthesiology, pathology, radiology and neonatology, whether provided by a physician or non-physician provider;
    - Items and services provided by assistant surgeons, hospitalists, and intensivists;
    - Diagnostic services, including radiology and laboratory services;

    - 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 or services furnished as a result of unforeseen, urgent medical needs that arise at the time an item or service is furnished.

The definition of emergency services includes items or services provided in:

- Emergency departments of a hospital, which includes a hospital outpatient department that provides emergency services;
- Independent freestanding emergency departments;
- Urgent care centers when licensed by the state to provide emergency care; and
- Additional entities may be added.

Non-Emergency Services

A health care facility in the context of non-emergency services includes:

- A hospital;
- A hospital outpatient department;
- A critical access hospital; and
- An ambulatory surgical center

Patients may not be balance billed for non-emergency services provided by a nonparticipating provider at a participating health care facility unless the notice and consent requirements are met.

Notice and consent are not applicable for certain services:

- Ancillary services –
    - items and services related to emergency medicine, anesthesiology, pathology, radiology and neonatology, whether provided by a physician or non-physician provider;
    - Items and services provided by assistant surgeons, hospitalists, and intensivists;
    - Diagnostic services, including radiology and laboratory services;
    - 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 or services furnished as a result of unforeseen, urgent medical needs that arise at the time an item or service is furnished.

Patient Cost Sharing Amount

Cost sharing for emergency services provided at a nonparticipating emergency facility and for non-emergency services provided by nonparticipating providers in a participating facility will be calculated as if the services were provided by participating facilities and providers. The cost sharing cannot be greater than the “recognized amount” which is based on:

- an amount determined by an applicable All-Payer Model Agreement under section 1115A of the Social Security Act;

- if there is no such applicable All-Payer Model Agreement, an amount determined under a specified state law; or
- if neither of the above apply, the lesser amount of either the billed charge or the qualifying payment amount (QPA), which is generally the payer's median contracted rate.

Qualifying Payment Amount (QPA)

In addition to being important for the patient cost-sharing amount, the QPA influences payments to providers and will be considered by arbitrators during the independent dispute resolution (IDR) process.

The QPA generally is the median contracted rate recognized by the plan or issuer as provided in 2019 for the same or a similar item or service, by a similar provider in the same geographic region.

- The IFR specifies the process for calculating the median rate and indexing it by the percentage increase in the CPI-U over 2019, 2020 and 2021 to derive the 2022 rate. It also addresses the process for 2023 and beyond.
- The IFR addresses the information required to be sufficient to calculate the median rate, addresses what constitutes new plans and new service codes.

Note that the QPA methodology is based on contracted amounts – it does not take into account actual paid claims amounts.

Payers are required to disclose to nonparticipating providers the QPA for each item or service involved. Providers may then request additional information regarding whether the QPA was based on an underlying fee schedule or derived amount, any alternative service codes or eligible databases, and whether any contracted rates were not set on a fee-for-service basis. Understanding how the QPA was determined will be important in determining whether to accept the payment, seek to negotiate payment or move to IDR.

The Departments are seeking comments on all aspects of the methodology.

Initial Payment or Notice of Denial

The IFR requires payers to send either an initial payment or notice of denial of payment not later than 30 days after the information necessary to decide a claim for payment for service is received. (However, in cases where the recognized amount is determined by a specified State law or All-Payer Model Agreement, such other timeframes as apply) Following this 30-day period, either party may initiate the negotiation phase and subsequently IDR. There is no mechanism in the IFR to enforce the 30-day requirement.

The preamble raises additional issues:

- Payers need clean claims and information on whether the provider gave and obtained proper notice and consent, where applicable. Providers are encouraged to include in their

claim forms information on whether the surprise billing protections apply. Payers are encouraged to act in good faith when requesting additional information for a claim determination.

- Initial payment amount should represent what the payer "reasonably believes" to be payment in full – not a first installment.
- There is a "significant distinction" between an adverse benefit determination, which may be disputed through a payer's internal appeals process, and a denial of payment or initial payment that is for less than the billed amount, which may be disputed through negotiation or IDR. Both processes may occur with respect to the same claim.

Notice and Consent Documents

Click here for the Standard Notice and Consent Documents for use by nonparticipating providers and nonparticipating emergency facilities beginning January 1, 2022 and here for additional information on the documents. These documents, along with the Model Disclosure notice below, have a 30-day comment period once they are published in the Federal Register. Use of these documents in accordance with the instructions will be considered evidence of good faith compliance with the notice and consent requirements provided that all other requirements are met. The documents must include a good-faith cost estimate of the patient's charges by service and other details.

Additional details regarding the notice and consent process are contained in the preamble and text of the IFR, addressing timing, content, language access, exceptions, retention requirements, and notice to payers. Note that where notice and consent are applicable, written notice must be given to the patient not later than 72 hours before the items or services are provided; for same day appointments, notice and consent is required at least 3 hours in advance. Consent may be revoked.

Disclosure Requirements

Click here for the Model Disclosure notice that is required to be posted in the facility, placed on the website and provided to patients. Use of this document will be considered evidence of good faith compliance with this requirement.

Interaction with State Laws

The IFR explains that the NSA is to supplement rather than supplant state balance billing laws. The federal law is the floor for consumer protections and will defer to states where a higher standard is imposed under state law. The IFR notes that 33 states have enacted legislation that provide some balance billing protections and that additional laws may be enacted.

In terms of payment amounts, the IFR defines a "specified state law" as one that provides "a method for determining the total amount payable under a group health plan to the extent such State law applies for an item or service furnished by a nonparticipating provider or nonparticipating emergency facility." The IFR notes that only 14 states have, to date, established such a method.

The NSA adopted the preemption framework first adopted under the Health Insurance Portability and Accountability Act and continued under the Affordable Care Act. Under this framework, state laws are preempted only when those state laws impose a requirement that "prevents the application" of the NSA. State laws can generally exceed standards in the NSA that are more protective of consumers, but state laws cannot impose requirements that undermine or prevent the operation of the NSA.

Deference to state law would only apply only to those entities governed by state law – certain providers or facilities may not be covered under a state's balance billing law, certain services may not be covered by state law and state law may not reach certain plans, such as self-funded plans that did not or could not opt into state law. In such cases, federal law would apply.

The preamble includes examples of the application of state law in certain scenarios.

Penalties

If a provider sends a bill to a patient that is subsequently determined to violate the NSA, HHS may impose civil monetary penalties of up to $10,000 per violation. Penalties may be waived if 1) the provider did not knowingly violate and should not have reasonably known it violated the Act; and 2) the provider withdraws the bill and reimburses the plan or individual, plus interest.

Conclusion

These are some of the important items contained in the IFR but there are others than may be equally important for your health care system. We encourage you to review the IFR carefully. As always, we will be happy to work with you to develop written comments.

For additional information, please contact our General Counsel Diane Turpin at diane.turpin@shcare.net or 202-578-5444