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Federal government publishes an Interim Final Rule (part 1) implementing the No Surprises Act

By C. Frederick Geilfuss, Esq., Alexandra (Allie) Shalom, Esq., Lawrence Vernaglia, Esq., and Nick Welle, Esq., Foley & Lardner LLP*

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Over the last several years, both the federal government and a number of state legislatures have sought to find a solution to the billing by out-of-network providers, referred to as "Out of Network Billing" (OON Billing) and often negatively as "surprise billing."

In a prior blog post,[1] we discussed a number of prior legislative attempts to address the issue, including the Executive Order on An America-First Healthcare Plan, issued on September 24, 2020, which highlighted the federal government's interest in the issue.

Since that time, the No Surprises Act was passed during the Trump Administration and was signed into law in December 2020, and the first set of implementing rules were released by the Biden Administration on July 1, 2021.

These bipartisan efforts aim to reduce the occurrences of OON Billing, which generally occur when a patient with health care coverage unexpectedly receives care from a provider or at a facility that is not within his or her health care network. Often, the patient only discovers the provider or facility's out-of-network status weeks later when they receive the out of pocket bill that far exceeds the patient's expectations.

Note that Medicare, Medicaid, Indian Health Services, Veterans Affairs Health Care, or TRICARE already either prohibit or severely limit OON Billing, so the No Surprises Act (the Act) and its regulations apply generally to group health plans and health insurance issuers that offer group or individual health insurance coverage, as well as carriers in the Federal Employees Health Benefit Program (collectively, "Covered Plans").

For a further primer on OON Billing, please see our October 6, 2020 blog post.

No Surprises Act

On December 11, 2020, several congressional committees collectively announced a bipartisan deal "to protect patients from out-of-network medical bills and promote fairness in payment disputes between insurers and providers, without increasing premiums for patients or interfering with strong, state-level solutions already on the books."[2]

The legislation was signed into law with a number of minor revisions on December 27, 2020 as the "No Surprises Act." The provisions put obligations in defined situations on Covered Plans to provide coverage for items and services furnished by non-participating providers and on providers to preclude balance billing and to accept specified reimbursement.

A nonparticipating hospital or independent freestanding emergency department providing Emergency Services under such circumstances is to be paid the out-of-network rate by the Covered Plan less any cost-sharing payments.

The provisions of the Act applicable to Covered Plans are to become effective for plan and policy years beginning on or after January 1, 2022, and the provisions applicable to health care providers, facilities and providers of air ambulance services become applicable on January 1, 2022. The Act also instructs agencies to promulgate implementing rules and regulations.

July interim rule

On July 1, 2021, the U.S. Departments of Health and Human Services (HHS), Labor, and Treasury, and the Office of Personnel Management, issued the first set of implementing regulations for the Act: "Requirements Related to Surprise Billing; Part I."

The July 1 rule (the IFR) is an interim final rule, with an opportunity to comment that aims to implement the Act in a number of ways. The principal components of the IFR include:

(1) Provisions applicable to coverage of Emergency Services provided by a hospital or independent freestanding emergency department.

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(2) Provisions applicable to non-emergency services performed by nonparticipating providers in certain participating facilities.

(3) Provider requirements concerning balance billing for emergency, non-emergency services and air ambulance services.

(4) Notices required of Providers and Facilities.

(5) Protections concerning selection of a primary care provider.

(6) Establishing complaint processes for out-of-network medical bills and balance billing.

1. Coverage of emergency services. The IFR requires Covered Plans that cover any benefits for emergency services, to provide coverage irrespective of whether the hospital or free-standing emergency provider is in-network (participating) or out-of-network (not participating). Such emergency services must also be covered:

- without regard to any prior authorization requirement; and
- if furnished by an out-of-network provider,
    - without imposing any administrative requirement or limitation that is more restrictive than those required of participating in-network providers and emergency facilities;
    - without imposing patient cost-shares (e.g., coinsurance or copay) that are greater than those for in-network items and services performed by participating providers and emergency facilities;
    - by specifying that any cost-share payments made count toward any in-network deductible or out-of-pocket maximum; and
    - without regard to any term or condition of the coverage other than the exclusion or coordination of benefits, an affiliation or waiting period permitted by law, or applicable cost-sharing requirements.

For purposes of the IFR, "Emergency Services" include services provided prior to stabilization of the patient and also post-stabilization services provided by an out-of-network provider with respect to an emergency visit unless

- the physician determines the patient is able to travel using non-medical transportation to a participating provider or facility within a reasonable distance,
- the provider or facility provides written notice that includes a list of participating providers who furnish the services,
- a notice is furnished to the patients, including a good faith estimate of the amount that the patient may be charged,
- the patient is in a condition to provide informed consent, and
- all state law requirements are satisfied.

The requirement to limit cost-sharing to the in-network cost-sharing amount specifies that the provider or facility must determine whether the services are covered within 30 days of the date of the bill.

Further, the IFR requires Covered Plans to determine applicable cost-sharing based on the following amount: (i) if the State has an All-Payer Model Agreement, the amount under such agreement, (ii) if there is no such applicable All-Payer Model Agreement, an amount determined by state law, or (iii) if neither of the above apply, the lesser of the billed charge or the "**qualifying payment amount.**"

The **qualifying payment amount** is the Covered Plan's median contracted rate for the item or service adjusted for cost of living increases. (The IFR includes provisions for determining a Covered Plan's median contracted rate.)

A nonparticipating hospital or independent freestanding emergency department providing Emergency Services under such circumstances is to be paid the **out-of-network rate** by the Covered Plan less any cost-sharing payments.

The out-of-network rate for an item or services is (i) the amount determined by an applicable All-Payer Model Agreement, (ii) if there is no such applicable All-Payer Model Agreement, the amount specified by State law, (iii) if there is no State law determined rate, the amount agreed upon between the Covered Plan and the provider, or (iv) if no agreement is reached, an amount determined pursuant to an independent dispute resolution (IDR) entity for which regulations are still to be published.

The regulations leave the critical issue if the ultimate calculation of payment rates to a second round of rulemaking.

2. Coverage of non-emergency services performed in certain participating facilities and air ambulance services. The IFR also imposes requirements for non-emergency items or services provided by non-participating providers at a participating health care facility (including hospitals, critical access hospitals, ambulatory surgery centers and other facilities included in regulations).

Such provisions are particularly (though not exclusively) directed at non-participating hospital-based physicians, such as but not limited to anesthesiologists and radiologists.

Essentially, the same provisions also apply to air ambulance services provided by non-participating providers, although the IFR technically creates a separate set of rules for out-of-network air ambulance services.

For non-emergency items and services provided by non-participating providers at participating health care facilities, Covered Plans must provide coverage and do so:

- without imposing a patient cost-sharing requirement greater than the cost-sharing requirement if the services were performed by a participating provider.
- calculating the cost-sharing requirement as if the amount charged were equal to the charge described above (that is, the charge under an applicable All-Payer Model Agreement, the State approved charge, or, if these do not apply, the lesser of the billed charge of the non-participating provider or the qualifying payment amount (described above)).

- paying the non-participating provider the out-of-network rate (also described above) for the involved items and services less the cost-share amounts.
- determining coverage within 30 days of sending the invoice for the services.
- counting any cost-sharing paid toward the patient's in-network deductible and in-network out-of-pocket maximums.

3. Balance billing; notice and consent exceptions. As a general matter, non-participating providers covered by the IFR (including non-participating emergency facilities and non-participating providers for emergency service, non-participating providers in participating facilities and non-participating air ambulance providers) may not balance bill patients/enrollees for a payment amount that exceeds the patient/enrollee's cost share.

Non-participating facilities and non-participating providers with respect to emergency services and non-participating providers performing non-emergency services in participating facilities may avoid the prohibition on balance billing and other provisions if it provides written notice and obtains written consent signed by the patient/enrollee, which notice and consent must meet specified criteria.

For emergency services, the notice and consent exception applies effectively to post-stabilization services.

The notice and consent criteria include

- a written notice in paper or electronic form if practical, as selected by the patient/enrollee, that is consistent with HHS guidance and form;
- a separate consent document that is provided to the patient/enrollee not later than 72 hours prior to date of the furnishing of the items and services (or on the date of appointment if the appointment is not scheduled within 72 hours prior to the date on which the items and services are to be furnished, but the notice in all events must be provided at least three hours prior to the furnishing of the items or services); and
- the patient/enrollee consents voluntarily to be treated by the nonparticipating provider.

The consent must be voluntarily provided, must be in form and manner specified by HHS, and must not be revoked prior to receipt of the items. The IFR specifies requirements for the form of notice and the consent and suggested language is provided. The provider must furnish the Covered Plan with the notice and signed consent.

The notice and consent to avoid in-network treatment will not be available or apply with respect to (A) for non-emergency services, Ancillary Services, namely

- items or services related to emergency medicine, anesthesiology, pathology, radiology and neonatology,
- items or services provided by assistant surgeons, hospitalists and internists,
- diagnostics services, including lab and radiology services, and
- items or services provided by a non-participating provider if there is no participating provider who can furnish the item or service at the facility)

Or (B) for emergency or non-emergency services, items or services furnished as a result of unforeseen medical needs that arise when the item or service is furnished.

4. Notice by provider/facility concerning balance billing. Each health care provider and health care facility must make publicly available and post on a public website and provide to an enrollee of a Covered Plan to whom the provider/facility furnishes items or services certain information. The information includes:

- a statement of the requirements and prohibitions concerning balanced billing;
- if applicable, a statement explaining any State law requirements concerning the amounts the provider/facility may charge an enrollee if the provider or facility does not participate in a Covered Plan; and
- a statement providing contact information for the State and Federal agencies who an individual may contact if an individual believes the provider or facility has violated a requirement described in the notice.

5. Selection of primary care provider. While not as directly related to the issue of OON Billing, the Act and the IFR mandate that a Covered Plan that requires a patient/enrollee to designate a participating primary care provider must permit the patient/enrollee to designate any participating primary provider of the Covered Plan meeting any reasonable applicable geographic location.

If the Covered Plan requires or provides for designation of a participating primary care provider for a child, the Covered Plan must permit the patient/enrollee to designate a pediatrician who participates in the network as the child's primary care provider.

Further, under the IFR, a Covered Plan may not require an authorization or referral for a female enrollee who seeks obstetrical or gynecological care by a participating professional who specializes in obstetrics or gynecology.

A Covered Plan must also provide a notice informing each enrollee of the provision regarding designation of a primary care provider, including the provisions concerning a pediatrician and direct access without authorization or referral to an obstetrician and gynecologist. The IFR provides a template form of notice.

6. Complaint processes for out-of-network medical bills regarding covered plans. The IFR establishes a complaint process by which individuals may file a complaint with HHS regarding Covered Plans for failing to comply with the IFR.

Within 60 days of the filing of the complaint HHS is required to respond concerning the next steps in the complaint resolution process. HHS may also request additional information needed to process the complaint. HHS will then review the complaint to make an outcome determination.

The resolution may include referral to another Federal or State enforcement authority, or referral of the Covered Plan for an enforcement action. HHS will provide the complainant with an explanation of the resolution of the matter and any action taken.

In addition, the IFR establishes a complaint process with respect to providers who violate the balance billing requirements.

Comments

Industry and consumer comments on the interim rule are due on September 7, 2021. You may submit comments electronically at https://www.regulations.gov by entering the "CMS-9909-IFC" in the search window and then clicking on "Comment."

Requirements related to OON billing; part II

The second set of rules that are yet-to-be-issued will define and outline the independent dispute resolution process related in setting the out-of-network rates.

Notes

[1] https://bit.ly/3fPHBnt

[2] https://bit.ly/3jKAZYn

About the authors




(L-R) **C. Frederick Geilfuss** is a partner and health care lawyer with **Foley & Lardner**, based in the firm's Milwaukee office. He can be reached at fgeilfuss@foley.com. **Alexandra (Allie) Shalom**, an associate and health care business lawyer based in the firm's Boston office, can be reached at ashalom@foley.com. **Lawrence Vernaglia**, a partner and health care lawyer based in the firm's Boston and New York offices, is the chair of the firm's Industry Teams Department. He can be reached at lvernaglia@foley.com. **Nick Welle** is a partner and business lawyer based in the firm's Milwaukee office. He can be reached at nwelle@foley.com. This article was originally published July 20, 2021, on the firm's website. Republished with permission.

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