The Good Faith Estimate Requirement and Further Guidance from CMS

Insights

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PROFESSIONAL

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Last week, the Department of Health and Human Services ("HHS") provided additional guidance regarding health care provider compliance with the Good Faith Estimate ("GFE") requirements for uninsured and self-pay individuals. The GFE provisions of the No Surprises Act focus on price transparency across the health care delivery system and are separate and apart from the Act's "surprise billing" requirements related to out-of-network emergency services and out-of-network care furnished at in-network facilities. The recent guidance follows HHS's October 7, 2021 interim final rule with comment period ("IFR") implementing, among other things, the GFE requirement for uninsured and self-pay patients.

Beginning on January 1, 2022, all healthcare providers and facilities operating under the scope of a state-issued license or certification, must provide GFEs of the total expected charges for a planned medical service to every new and continuing client who is either uninsured or is not planning to submit a claim to their insurance for the services that they are seeking (i.e., self-pay patients). [1] Healthcare providers are also required to inform every uninsured or self-pay client of their right to receive a GFE, including both orally and by posting notice at their physical location(s) and on their website. GFEs must also be regularly updated by the healthcare provider as there are changes to the expected charges.

In addition the recent GFE FAQs posted on April 5, 2022, HHS previously released GFE FAQs on December 21, 2021 along with a number of fact sheets and templates to assist healthcare providers and facilities with compliance.

Which Providers and Facilities are subject to the GFE Requirement?

Healthcare providers and facilities are broadly subject to the GFE requirements for uninsured and self-pay patients. The terms "facility" and "provider" are each defined expansively by reference to state licensing and certification laws. In particular, the regulations define a facility as:

> … an institution (such as a hospital or hospital outpatient department, critical access hospital, ambulatory surgical center, rural health center, federally qualified health center, laboratory, or imaging center) in any State in which State or applicable local law provides for the licensing of such an institution, that is licensed as such an institution pursuant to such law or is approved by the agency of such State or locality responsible for licensing such institution as meeting the standards established for such licensing.

45 C.F.R. § 149.610(a)(2)(vii). While the regulations specifically identify hospitals, hospital outpatient departments, critical access hospitals, ambulatory surgery centers, rural health centers, federally qualified health centers, laboratories, and imaging centers as healthcare facilities potentially subject to the regulation, other institutions that are either licensed or approved as meeting the standards established for licensing may also be considered facilities under the definition. Likewise, the definition of "provider" extends beyond physicians to cover those providers licensed or certified under applicable state law, including a provider of air ambulance services. 45 C.F.R. § 149.610(a)(2)(viii).

Importantly, the IFR does not identify any providers or facilities that are categorically exempt from the GFE requirements, and in response to prior FAQs, HHS has stated that "[n]o specific specialties, facility types, or sites of service are exempt from this requirement."

What are the GFE Notice Requirements? Facilities and providers that receive requests for a GFE or are responsible for scheduling (known as "convening" providers and facilities) must provide notice of the availability of a GFE. This notice, must be prominently displayed (and easily searchable from a public search engine) on the convening provider's or facility's website, in the office, and on-site where scheduling or questions about the cost of items or services occur. The notice must also be provided orally to uninsured and self-pay individuals when scheduling or when questions about cost occur and must be made available in accessible formats and in the language(s) spoken by individual(s) considering or scheduling items or services with the convening provider or facility. HHS has made available a model notice, [2] the use of which is deemed to be good faith compliance with the notice requirement.

Which Patients are entitled to a GFE? Currently, under IFR, healthcare providers and facilities are broadly subject to the GFE and patient-provider dispute resolution requirements for *uninsured* and *self-pay* patients.

The recent FAQs clarified that no GFE is required, for now, if a provider determines that a patient is insured at the time of scheduling the service, but later becomes uninsured or chooses to self-pay at the service takes place. However, HHS "encourage[s] providers and facilities to inform patients when scheduling items or services or responding to a request for a GFE that they should contact their provider if any information related to their appointment, including their insurance status, changes in advance of the appointment, so that a new GFE can be provided, if necessary."

Although the statute includes a GFE requirement for insured patients, the Departments have delayed implementation of that requirement pending final rules. When this requirement is implemented, the GFE for an insured patient will be sent to the patient's insurer, who will furnish an Advance Explanation of Benefits.

How does the GFE work? The convening provider or health care facility, meaning the provider or facility that receives the initial request for a GFE from an uninsured or self-pay individual and that is, or, in the case of a request, would be responsible for scheduling the primary item or service must provide a GFE to the patient (1) upon a request from an uninsured or self-pay individual and (2) when scheduling a primary item or service for an uninsured or self-pay patient. This convening provider must also contact any other ancillary providers who may also be involved in the patient's treatment to secure those providers' GFEs for their services to incorporate into the GFE to go to the client. In many ways, the GFE functions like contractors and sub-contractors during a construction project.

The IFR does not define what constitutes the "scheduling" of an item or service, creating some potential uncertainty as providers and facilities determine which of them is the convening facility or provider for a particular service. While the most recent FAQs similarly do not address the definition of scheduling, there is the potential that HHS will provide more guidance in the future.

What is the timing for when providers must create a GFE? Once an item or service has been scheduled or a request for a GFE has been received, the GFE must be provided within three business days of the request or scheduling if it is scheduled at least 10 business days in advance. However, if the item or service is scheduled at least three but less than 10 business days in advance, the GFE must be provided within just one business day. The most recent FAQs clarify that a GFE is not required for same-day services and/or walk-in clients: "For example, if an uninsured (or self-pay) individual arrives to schedule same-day laboratory testing services, the laboratory testing provider or facility is not required to provide the individual with a GFE."

There are also requirements for updating GFE for any changes to the scope of the original GFE, or upon changes in expected providers or facilities represented in the original GFE.

For recurring services, the provider may issue a single GFE, provided that it meets additional content requirements (discussed below) and does not exceed a 12 month duration. However, if additional recurring services are expected beyond

12 months, or, similar to a GFE for non-recurring items or services, if there are any changes to the scope of the GFE, then the provider must provide a new GFE to the patient.

What does a GFE Need to Include? Under the IFR, the convening provider's GFE must include:

- The patient's name and date of birth;
- A description of the primary item or service and, if applicable, the scheduled date;
- An itemized list of items or services reasonably expected to be furnished;
- Applicable diagnosis and expected service codes, with expected charges listed for each item or service;
    - The recent FAQs note that a diagnosis code is not required for every GFE. Instead, a provider or facility is required to provide a diagnosis code only where one is required for the calculation of the GFE. For example, in situations in which a provider or facility has not determined a diagnosis, such as for initial screening visits or evaluation and management visits; or if there is not a relevant diagnosis code for an item or service, providers and facilities are not required to include diagnosis codes on a GFE. But, the expected charges and service codes for items to be furnished must still be included even when no diagnosis code is available.
    - The recent FAQs also provide that Providers and facilities are not required to provide expected charges for future visits in the same GFE provided for an initial visit.
- The name, National Provider Identifier (NPI), and Taxpayer Identification Number (TIN) of each provider and facility included in the GFE;
- A list of items or services the convening provider anticipates will require separate scheduling before or after the primary service.
- A series of disclaimers including: (1) a disclaimer that informs the uninsured (or self-pay) individual that there may be additional items or services the convening provider or convening facility recommends as part of the course of care that must be scheduled or requested separately and are not reflected in the GFE; (2) a disclaimer that informs the uninsured (or self-pay) individual that the information provided in the GFE is only an estimate regarding items or services reasonably expected to be furnished at the time the GFE is issued and that actual items, services, or charges may differ from the GFE; (3)a disclaimer that informs the uninsured (or self-pay) individual of that individual's right to initiate the Patient-Provider Dispute Resolution ("PPDR") process if the actual billed charges are substantially in excess of the expected charges included in the GFE. This disclaimer must include instructions for where the individual can find information about how to initiate the PPDR process and state that the initiation of the PPDR process will not adversely affect the quality of health care services furnished to the individual by a provider or facility; and (4) a disclaimer that the GFE is not a contract and does not require the uninsured (or self-pay) individual to obtain the items or services from any of the providers or facilities identified in the GFE.

For recurring services, there are additional GFE content requirements, including:

- The expected scope of the recurring primary items or services (such as timeframes, frequency, and total number of recurring items or services); and,
- Must not exceed 12 months.

Further, if additional recurring services are expected beyond 12 months, or, similar to a GFE for non-recurring items or services, if there are any changes to the scope of the GFE, then the provider must provide a new GFE.

Finally, the recent FAQs make clear that the IFR does not require the GFE to include charges for items or services that could not have been reasonably expected.

If you have any questions regarding the No Surprises Act or its GFE requirement, please reach out to attorneys at Hooper, Lundy, and Bookman to determine how best to proceed in this new, and rapidly changing, regulatory environment. Please contact Katrina Pagonis in San Francisco, Bridget Gordon, Alicia Macklin, or Sansan Lin in Los Angeles, Zachary Howard in Washington D.C., or any other member of our Hooper, Lundy & Bookman team.

[1] HHS has indicated that it will defer enforcement of the No Surprises Act requirement that healthcare providers and facilities provide a GFE to an *insured* individual's plan or coverage, until rulemaking to implement such requirement is promulgated.

[2] The model notice, titled "Right to Receive a Good Faith Estimate of Expected Charges Notice," is available for download here.

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