Legal Issues: Navigating the Additional Surprises of Good Faith Estimates Under the No Surprises Act

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he No Surprises Act of the Consolidated Appropriations Act of 2021 (the "No Surprises Act"), which seeks to protect patients from "surprise medical bills" for out-of-network care and non-participating providers, became effective on January 1, 2022. In implementing the regulations under the No Surprises Act, the Department of Health and Human Services ("HHS"), the Department of Labor and the Department of Treasury, sought to protect patients against surprise billing in circumstances under which surprise billing or balance billing frequently arise. However, since the announcement of the No Surprises Act, providers have been the ones scrambling to look out for surprises. With the three federal agencies having just finalized interim rules with respect to health plan participants, more rules, guidance and adjustments are in the works. Timing is ripe to review where things currently stand with the No Surprises Act, focusing mainly on the requirements for providers, including nephrologists and nephrology practices, to provide a good faith estimate ("GFE") of medical costs to certain patients, as well as the associated GFE enforcement changes coming in 2023.

Good Faith Estimates

Effective as of January 1, 2022, all healthcare providers, including nephrologists and nephrology practices, as well as facilities operating under the scope of a state-issued license or certification, including hospitals, ambulatory surgical centers and dialysis facilities, must provide GFEs of the total expected charges for a planned medical service to every new and continuing patient who is either *uninsured* or will not submit a claim to their insurance for the services received (i.e., self-pay patients). The regulation does not identify any providers or facilities that are specifically exempt from the GFE requirements, and HHS has previously stated that "[n]o specific specialties, facility types, or sites of service are exempt from this requirement." 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 balance billing prohibitions (discussed further below).

Nephrologists' responsibilities for the GFE will differ in a circumstance where they serve as a "convening provider" or a "co-healthcare provider" or "co-provider" A nephrologist or a nephrology practice will be considered a convening health care provider when it receives an initial request for a GFE or is responsible for scheduling the primary service. In such a circumstance, the co-provider would be the provider, other than the convening provider, which furnishes items or services in conjunction with the primary service, such as a dialysis facility or an ASC providing vascular access services.

The convening provider must provide a GFE to the patient either upon a request from an uninsured (or self-pay) individual or at the time of scheduling a primary item or service for an uninsured or self-pay patient. The convening provider is also required to contact any other co-provider that will likely be involved in the patient's treatment to secure those providers' GFEs for their services to incorporate into the GFE to go to the patient. During the calendar year 2022, HHS exercised enforcement discretion and did not enforce this requirement. Patients were still able to request and receive estimates directly from such co-providers.

Who Must Receive The GFE?

A convening provider is required to inquire whether a patient is covered under commercial health coverage, Medicare, Medicaid or the Federal Employees Health Benefits Program ("FEHBP") and, if the patient is covered under commercial coverage or FEHBP, whether he or she intends to use that coverage. An individual covered only by short-term limited-duration insurance is considered uninsured for this purpose and is entitled to receive a GFE. There are separate requirements for GFEs for insured patients, however, HHS has indicated that it will defer enforcement of the No Surprises Act requirements that healthcare providers and facilities provide a GFE to an insured individual's plan or coverage, until rulemaking to implement such requirement is promulgated.

The GFE must be provided in written form either on paper or electronically, pursuant to the uninsured (or self-pay) individual's requested method of delivery. GFEs provided to uninsured (or self-pay) individuals that are transmitted electronically must be provided in a manner that the uninsured (or self-pay) individual can both save and print and must be provided and written using clear and understandable language and, in a manner, calculated to be understood by the average uninsured (or self-pay) individual. If a patient requests that the GFE information is provided in a format that is not paper or electronic delivery (e.g., orally over the phone or in person), the provider/facility may provide the GFE information orally but must follow-up with a written paper or electronic copy to meet the regulatory requirements.

Additionally, the GFE notice must be posted on the provider's website, at the office, and on-site where scheduling or cost questions arise. The GFE notice must be clear, understandable, prominently displayed and easily searchable.

Is There a Timeline For Providing The GFE?

The GFE must be provided within one business day of a service being scheduled or a GFE requested. When a service has been scheduled, the GFE is to be provided not later than one business day after the date of scheduling if the service is scheduled at least three business days before the service, and within three business days of scheduling if the service is scheduled at least ten business days in advance. If a GFE is requested before the service is scheduled, the GFE is due within three business days, provided that once the service is scheduled, a new GFE must be furnished. We also note that the most recent FAQs published by CMS 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."

The regulations also require providers to update the GFE for any changes to the scope of the original GFE, or upon changes in expected providers or facilities represented in the original GFE. Finally, for recurring services, the provider may issue a single GFE, provided that it meets content requirements and does not exceed a 12-month duration. For nephrology services, it may be appropriate to update the GFEs annually as the Medicare Fee Schedule is updated.

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What Is The Required Content Of The GFE?

The regulations require that the GFE include, at a minimum, the following information:

- 1. The patient's name and date of birth;
- 2. A description of the primary item or service and, if applicable, the scheduled date;
- 3. An itemized list of items or services reasonably expected to be furnished;
- 4. Applicable diagnosis and expected service codes, with expected charges listed for each item or service;
- 5. The FAQs published on April 5, 2022, clarify that a diagnosis code is not required for every GFE. Rather, a provider is required to provide a diagnosis code only when required for the calculation of the GFE. However, the expected charges and service codes for items to be furnished must still be included even when no diagnosis code is available. Additionally, the GFE does not have to include expected charges for future visits.
- 6. The name, National Provider Identifier (NPI), and Taxpayer Identification Number (TIN) of each provider and facility included in the GFE;
- 7. A list of items or services the convening provider anticipates will require separate scheduling before or after the primary service.
- 8. Mandatory regulatory disclaimers, which include:
 - a. 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;
 - b. a disclaimer informing 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;
 - c. a disclaimer regarding 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; and
 - d. 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.

CMS has provided a model GFE notice. Use of this specific document is not required, buensure that your GFE contains all the required information. The model GFE is available at www.cms.gov/regulations-and-guidancelegislationpaperworkreductionactof1995pra-listing/cms-10791.

Dispute Resolution Process

If the actual charges for services provided to the patient are in excess of \$400 from the estimated amount provided in the GFE or more, such patient has the right within 120 days after receiving the disputed bill to file a challenge through a dispute resolution process called a Patient-Provider Dispute Resolution process. Once the provider/facility receives notice, bills at issue may not be moved into collections nor may the threat of collections process be made for the items or services in dispute and accrual of all late payment fees must be suspended. However, once the dispute resolution process has started, parties can still negotiate a settlement amount.

The claim will be evaluated by an HHS selected dispute resolution ("SDR") entity, which will determine the amount owed by the patient within 30 business days after receiving all necessary information. Additionally, the SDR entity will rule on whether the provider or facility has provided credible information to demonstrate that the difference between the billed charges and the expected charges in the GFE reflect the costs of a medically necessary item or service and is based on unforeseen circumstances that could not have reasonably been anticipated by the provider or facility when the GFE was provided to the patient.

Accordingly, it is important for nephrologists and nephrology practices to take time to accurately reflect the estimated charges in their GFEs, and to update them should things change. Misstating the estimated costs may result in lost fees and additional administrative burdens on the practice, including potential down time for the nephrologists who may have to attend administrative hearings. We note that all GFEs must be made in "good faith." Consequently, practices and facilities should be careful not to intentionally overestimate charges to avoid such disputes, as this could be viewed as regulatory non-compliance with the GFE requirements.

No GFE Enforcement in 2023 for Related Providers

On December 2, 2022, CMS issued its third set of FAQs on GFEs, in which the agency clarified that HHS will not begin enforcing the co-provider GFE requirements as of January 1, 2023 as planned—unlike the convening provider requirements, which have been enforced since the start of 2022. HHS continued its enforcement discretion, pending future rulemaking, for situations where GFEs for uninsured individuals do not include expected charges from co-providers or co-facilities.

This additional extension of enforcement discretion aims to promote further interoperability across the health care industry and encourage providers, facilities, and other industry members to focus resources towards adopting interoperable processes for exchanging information. CMS noted that, once promulgated, rulemaking to fully implement the requirements for GFEs for related providers will include a prospective applicability date that gives providers and facilities a reasonable amount of time to comply with any new requirements.

In preparation for these additional obligations, nephrologists and nephrology practices should implement policies and procedures regarding coordination of estimated charges for related services with other providers whose services are ancillary to the services they provide. Stated differently, nephrologists and nephrology practices should coordinate the estimates with hospitals, dialysis providers, vascular access centers, and any other providers and facilities that generally support their practice.

GFEs for Insured Patients

In addition to reviewing comments on co-providers, the CMS is also requesting comments from stakeholders in response to its Request for Information ("RFI") regarding advanced explanation of benefits ("AEOBs") and GFEs for insured individuals. This next phase of the No Surprises Act would require providers to provide GFEs to the insurers, and in turn the insurers would prepare AEOBs using GFEs from providers, which would include the same above detailed information as required for un-insured (or self-pay) patients. CMS has delayed enforcement of these provisions until a standard industry process for such information exchange can be adopted via regulation to ensure that these estimates can be created as efficiently and accurately as possible. Currently, the rollout date for this phase of the GFE requirements is still to be determined, with no date having been scheduled to begin enforcement. However, this lack of enforcement is discretionary, and consequently enforcement could begin at any point.

Balance Billing Under The No Surprises Act

The No Surprises Act at its core prohibits balance billing for certain facilities that provide emergency and other related services, including ambulatory surgery centers. The Act defines balance billing as the practice of "out-of-network providers billing patients for the difference between: (1) the provider's billed charges, and (2) the amount collected from the plan or issuer plus the amount collected from the patient in the form of cost-sharing (such as a copayment, coinsurance, or amounts paid toward a deductible)." 87 FR 165, Aug. 26, 2022, p. 52618. The Act generally prohibits providers and facilities from balance billing patients or otherwise holding patients liable for cost-sharing amounts beyond what they would have paid for in-network care, including in circumstances where a patient receives non-emergency services from an out-of-network provider at an in-network facility, subject to limited exceptions. The No Surprises Act generally prohibits balance billing for (i) emergency services provided by out-of-network providers or emergency facilities; and (ii) non-emergency services by out-of-network providers at certain in-network healthcare facilities.

In addition to banning balance billing in these circumstances, the Act also requires providers and facilities to provide general public disclosures regarding patient protections against balance billing, including written disclosures to patients and postings both physically

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displayed in a prominent location at the location of the provider or facility and on a public website. The disclosure must include clear and understandable information about applicable state requirements and how to contact appropriate federal and state authorities if the patient believes the provider or facility has violated any applicable requirements for balance billing. This disclosure may be on a one-page form and should be provided no later than at the time the provider requests payment from the patient. HHS suggests that this disclosure may be given prior to providing services, such as when an individual schedules an appointment or when other standard notice disclosures, such as the Notice of Privacy Practices, are provided. These requirements went into effect at the start of 2022. While the CMS issued FAQs clarifying the balance billing prohibitions and notice requirements in the summer of 2022, there is nothing suggesting they will substantively change in 2023.

The Benesch Healthcare+ team monitors the development of this area of the law and may provide additional updates as they become available. For additional questions about the importance of the No Surprises Act and similar regulations, please contact the authors of this article.

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