Appendix 15: 60-day Notice Comments & Response Summary

Requirements Related to Surprise Billing; Part II

(CMS-10791/OMB control number-1210-0169)[1]

HHS received several comments from industry advocacy organizations and individuals related to an information collection request (ICR) HHS released concerning CMS-10791, a Paperwork Reduction Act (PRA) document detailing requirements related to the good faith estimates and patient provider dispute resolution process. This is the summary of and response to the comments and the comments addressed the following broad categories: 1) concerns related to good faith estimates for uninsured (or self-pay) individuals; 2) concerns related patient provider dispute resolution process; 3) and concerns relating to burden estimates for this ICR.

1. Good Faith Estimates for Uninsured (or self-pay) Individuals

1.1 Definitions

***Comment*:**

One commenter sought clarification as to whether the term "health care facility," as outlined in Requirements Related to Surprise Billing; Part II,[2] includes physician and/or dental office-based settings.

***Response*:**

We appreciate the commenter's response and will take it into consideration for potential future rulemaking.

1.2 Administrative burden and timeframes

***Comment*:**

Several commenters expressed concern about the administrative burden the GFE requirements for uninsured (or self-pay) individuals place on providers and facilities. One commenter stated that small office-based practices generally lack the administrative framework necessary to comply with the requirements for providing GFEs to uninsured (or self-pay) individuals. Two commenters noted that administrative staff will require additional training, and organizations may need to hire new staff.

Several commenters asked HHS to delay enforcement of the uninsured (or self-pay) GFE requirements until practices have the appropriate time to understand and implement them. One commenter suggested that aligning enforcement of the GFE requirements for uninsured (or self-pay) individuals with the advanced explanation of benefits (AEOB) requirements under section

[1] Requirements Related to Surprise Billing; Part II , 86 FR 55980 (October 7, 2021), available at: https://www.govinfo.gov/content/pkg/FR-2021-10-07/pdf/2021-21441.pdf.
[2] *Id.*

111 of division BB of the CAA would enable practices to more fully develop and test workflows to provide accurate GFEs for both insured and uninsured (or self-pay) patients. One commenter suggested that there is a "proposed deadline" at the end of 2022 to expand estimates to all patients, coordinated with their insurance carriers, and indicated that this is impossible with the technology that exists today.

Several commenters expressed concern about the timeframes for providing GFEs. One commenter stated that requiring providers and facilities to provide a GFE according to the timeframes in the regulations creates unnecessary burdens on providers and facilities. These commenters recommended that HHS implement more flexible timelines for providers to furnish GFEs to individuals. One commenter shared their belief that although co-providers and co-facilities are required to respond to the convening provider and facilities within a 1-day time frame, it is inevitable that delays will happen. One commenter warned that practices may be forced to schedule appointments further out to provide adequate time to gather the necessary information to provide a GFE within the required timeframe. One commenter asked HHS to clarify that providers are not required to provide a GFE when patients schedule an appointment that is less than three full business days from the time of scheduling.

***Response*:**

We appreciate commenters' responses and will take them into consideration for potential future rulemaking.

1.3 Coordination with the hospital price transparency final rule

***Comment*:**

In the IFR, HHS sought comment on how the Hospital Price Transparency[3] requirements for hospitals to display standard charges in a consumer-friendly manner (45 CFR 180.60), and, specifically, the voluntary use of online price estimator tools (45 CFR 180.60(a)(2)), may be leveraged to provide a good faith estimate for uninsured (or self-pay) individuals.

HHS received three comments related to this information request. Two commenters indicated that providers outside of a hospital setting are not subject to these requirements, and therefore have no comparable data to leverage. One commenter encouraged HHS to deem hospitals with patient estimator tools that are compliant with the Hospital Price Transparency Final Rule to also be compliant with the good faith estimate requirements for patients shopping for care, while also acknowledging that GFEs require additional layers of specificity. The commenter also questioned the value of the machine-readable files and disagreed with HHS' suggestion that the machine-readable file could have any utility in meeting the uninsured (or self-pay) GFE

[3] See Medicare and Medicaid Programs: CY 2020 Hospital Outpatient PPS Policy Changes and Payment Rates and Ambulatory Surgical Center Payment System Policy Changes and Payment Rates. Price Transparency Requirements for Hospitals To Make Standard Charges Public (Hospital Price Transparency Final Rule) 84 FR 65524 (Nov. 27, 2019), available at https://www.federalregister.gov/documents/2019/11/27/2019-24931/medicare-and-medicaid-programs-cy-2020-hospital-outpatient-pps-policy-changes-and-payment-rates-and.

requirements since using the file would not eliminate the need to contact co-providers or co-facilities to understand what services are expected to be furnished.

***Response*:**

We appreciate commenters' responses and will take them into consideration for potential future rulemaking.

1.4 Communication between convening providers and facilities and co-providers and co-facilities

***Comment*:**

In the IFR, HHS sought comment on any existing challenges related to secure transmission of good faith estimate information between providers and facilities. HHS also expressed interest in whether publicly available standardized processes exist or could be developed that would facilitate and support efficient and timely transmission of good faith estimate information.

Several commenters were particularly concerned about the administrative requirements related to exchanging GFE data between convening providers and facilities and co-providers and co-facilities. One commenter explained that providers and facilities will likely need to invest in technology and new administrative processes to facilitate highly efficient communication among convening and co-providers and co-facilities and patients. Another commenter requested that HHS identify a standard technology or transaction that would enable convening providers and facilities to automate the creation of comprehensive good faith estimates.

Several commenters shared that electronic communication is not possible between these parties if they are unaffiliated because there is no technology at this time that is uniformly used by all of the parties involved in the preparation of good-faith estimates. Two commenters noted that the requirements related to co-providers and co-facilities will be particularly burdensome for certain providers, such as small, office-based practices, rural providers, and primary care physicians.

Response

We appreciate commenters' responses and will take them into consideration for potential future rulemaking.

1.5 Time for GFE compliance

***Comment*:**

One commenter explained that physician practices do not have automated systems for generating GFE data and another commenter stated that hospitals' systems gathering and generating this data may only be partially automated. These commenters stated that because the information will have to be assembled manually, it will require more time than the estimated 30 minutes. For situations involving multiple participants, both commenters agreed that an additional 30 minutes

would not cover the manual process. In addition, one commenter suggested that seeking and receiving itemized lists from multiple co-providers, and collating those lists, would take more along the lines of at least 45 minutes to over an hour of work, depending on the complexity of the service.

One commenter stated that it would take more than one hour to check a patient's insurance status, offer a good faith estimate, and provide the estimate. This commenter noted that this assumption fails to account for essential hospital patients' low health literacy rates, translation needs, and need for help with financial assistance applications. Essential hospitals will have to hire additional staff to comply with the estimate requirements in the time allotted.

***Response*:**

We note that nothing in 45 CFR 149.610 requires providers and facilities to check or confirm an individual's insurance status with anyone other than the individual themselves. Under 45 CFR 149.610(b)(1), a convening provider or convening facility must determine if an individual is an uninsured (or self-pay) individual by (1) inquiring if an individual is enrolled in a group health plan, group or individual health insurance coverage offered by a health insurance issuer, Federal health care program (as defined in section 1128B(f) of the Social Security Act), or a health benefits plan under chapter 89 of title 5, United States Code; and (2) inquiring whether an individual who is enrolled in a group health plan, or group or individual health insurance coverage offered by a health insurance issuer or a health benefits plan under chapter 89 of title 5, United States Code is seeking to have a claim submitted for the primary item or service with such plan or coverage. Therefore, we expect this step to require a negligible amount of time to complete.

As discussed in the IFR[4], HHS recognizes that uninsured (or self-pay) individuals in underserved and racial/ethnic minority communities, may face additional barriers to paying for high unexpected health care costs, understanding their rights related to good faith estimates, patient-provider dispute resolution, and how and when to initiate the dispute resolution process. HHS sought comment in the IFR from underserved and racial/ethnic minority communities on additional barriers individuals from these communities may face in understanding and exercising their rights related to these topics, and how to address them. HHS also sought feedback on outreach and education activities, efforts, and resources available for underserved and racial/ethnic minority communities, including individuals with vision, hearing, or language limitations, individuals with limited English proficiency, lesbian, gay, bisexual, transgender, and queer (LGBTQ+) individuals, and persons with health literacy needs, to help ensure that these rights and tools are available, accessible, and understood such that they can be used equitably by all uninsured (or self-pay) individuals in appropriate circumstances.

1.6 Determining the convening provider or facility and the co-provider or co-facility

[4] Requirements Related to Surprise Billing; Part II , 86 FR 55980 (October 7, 2021), available at: https://www.govinfo.gov/content/pkg/FR-2021-10-07/pdf/2021-21441.pdf.

***Comment*:**

One commenter asserted that one of the key challenges in implementing the requirements related to GFEs for uninsured (or self-pay) individuals is to determine who will be the convening provider. This commenter also questioned how the convening provider will determine which co-provider or co-facility from which to request a GFE, and asked for clear guidelines to determine these choices.

***Response*:**

We appreciate commenters' responses and will take them into consideration for potential future rulemaking.

1.7 Scheduled or requested

***Comment*:**

Two commenters highlighted the additional burden on providers and facilities to provide GFEs to uninsured (or self-pay) individuals who have scheduled an item or service to be furnished, but have not requested a GFE. One of these commenters recommended that implementation of the GFE be staged such that, initially, GFEs are provided at the specific request of the patient, rather than upon scheduling an item or service. This commenter argued that providing a GFE prior to furnishing an item or service, and without the individual having requested it, would increase administrative burden and may mislead an individual into thinking the estimate is a bill. The other commenter recommended that HHS provide an exception in cases where the patient chooses to forgo receiving a GFE.

One commenter opined that the provision of a GFE in cases in which the provider does not already have an established relationship with the individual requesting it for price comparison purposes places additional burden on the provider and calls the accuracy of the GFE it is able to provide into question.

Response

We appreciate commenters' responses and will take them into consideration for potential future rulemaking.

1.8 GFE Template

***Comment*:**

One commenter flagged that "Appendix 2: Standard Form, 'Good Faith Estimate for Health Care Items and Services' Under the No Surprises Act" appears to be missing a place for the convening provider or facility to include a list of items or services that the convening provider or facility anticipates will require separate scheduling (expected to occur before or after the primary episode of care); as well as the required disclaimer that the good faith estimate is not a contract

and does not require the patient to obtain the item/service from the providers/facilities listed on the good faith estimate; and requested that HHS correct these omissions.

One commenter asked that HHS exercise enforcement discretion with respect to providers who relied on the GFE Template published in 2021, which stated that GFEs must be provided within one business day, which is only accurate in certain circumstances. In January 25, 2022, HHS published an updated Template indicating that GFEs must be provided within 3 business days when an uninsured (or self-pay) individual schedules a primary item or service at least 10 business days before such item or service is to be furnished, or when such an individual requests a GFE.

One commenter encouraged HHS to publish the Template disclosures and the GFE Template Notice in common languages other than English, to ensure all practices can have these critical disclosures related to GFE policies available for patients.

***Response*:**

We appreciate the feedback regarding the different Template versions. Both the No Surprises Act (NSA) and the implementing regulations at 45 CFR 149.610 require that a convening provider or facility must provide a GFE within 3 business days when an uninsured (or self-pay) individual schedules a primary item or service at least 10 business days before such item or service is to be furnished, or when such an individual requests a GFE. Providers and facilities are bound by the NSA and its implementing regulations, and not by the GFE Template. The Template is a model notice for notifying uninsured (or self-pay) individuals of good faith estimates of their expected charges. However, HHS does not require the use of such model notice in order to allow providers or facilities flexibility to develop notices that would be most effective for their patient populations. Additionally, because these GFE requirements did not go into effect until January 1, 2022, HHS expects the number of providers and facilities that may have relied on the outdated Template to be minimal. Therefore, we do not believe enforcement discretion is necessary or appropriate here.

HHS agrees with the commenter's assessment regarding the lack of a place for the convening provider or facility to include a list of items or services that the convening provider or facility anticipates will require separate scheduling (expected to occur before or after the primary episode of care); as well as the required disclaimer that the good faith estimate is not a contract and does not require the patient to obtain the item/service from the providers/facilities listed on the good faith estimate. We have made the appropriate changes to the GFE Template.

HHS appreciates the commenter’s suggestion to provide the GFE Template in common languages other than English, and will take this into consideration. As a reminder, consistent with the regulatory requirements, providers and facilities are required to provide information regarding the availability of a good faith estimate available in a clear and understandable manner, and in accessible formats and languages spoken by individuals considering or scheduling items or services with such convening provider or convening facility. Providers and facilities are also required to comply with other applicable State or Federal laws, including those governing the accessibility, privacy, or security of information required to be disclosed under 45

CFR 149.610. Providers and facilities that are recipients of Federal financial assistance must comply with Federal civil rights laws that prohibit discrimination. These laws include Section 1557 of the Patient Protection and Affordable Care Act,[5] Title VI of the Civil Rights Act of 1964,[6] and Section 504 of the Rehabilitation Act of 1973.[7]

1.9 Changes in insurance status

***Comment*:**

One commenter was concerned that if an uninsured (or self-pay) individual arrives for a visit without having received a GFE at scheduling (for example, because the individual was insured at the time of scheduling), providers and facilities would be forced to reschedule the patient and turn them away.

Another commenter suggested HHS require that if a provider learns of a change in insurance status that would then lead to the patient being eligible to receive an uninsured (or self-pay) GFE after the patient schedules care, the provider should be permitted to issue a GFE to the patient at least one business day prior to the furnishing of services.

Response

We appreciate commenters' responses and will take them into consideration for potential future rulemaking.

1.10 Estimating diagnosis codes and reasonably expected items or services

***Comment*:**

Several commenters pointed out that in many cases, it is not possible for providers and facilities to accurately estimate a diagnosis or assess what services and are required without first seeing (in person or virtually) and evaluating the individual and potentially conducting radiologic or other diagnostic tests. One commenter maintained that it will not always be apparent at the time of scheduling which providers will be providing which services, especially for facility-based procedures. This commenter also requested guidance regarding when a provider makes medically necessary care changes while services are being provided that impact the estimates provided by co-providers/co-facilities.

One commenter explained that creating GFEs is particularly burdensome with respect to patients with no existing relationship with the provider, and recommended that HHS permit, but not require, providers and facilities to include a diagnosis code on GFEs. Two commenters urged HHS to permit providers and facilities to issue modified GFEs with a range of potential costs and

[5] 42 U.S.C. 18116.
[6] 42 U.S.C. 2000d et seq.
[7] 29 U.S.C. 794.

potential service codes for new patients or patients in situations in which a provider cannot reasonably determine the appropriate diagnostic or procedure codes.

One commenter indicated it is particularly difficult for administrative staff at primary care practices to obtain an individual's conditions, history, and symptoms over the phone when scheduling an appointment, and that many patients are uncomfortable with sharing their private health information with administrative and clinical staff with whom they do not have an established, trusting relationship. This commenter recommended that HHS exempt direct primary care practices from the GFE requirement when: (1) All the items and services that are reasonably expected to be provided are already included in the flat fee paid by the patient; or (2) In the event additional services are reasonably expected to be provided that are not included in the flat fee and the patient opts to submit a claim to their insurer for those services.

One commenter asked HHS, for the purposes of dispute resolution, to require providers and facilities to include the individual's stated reasons for the visit in the GFE.

Response

We appreciate commenters' responses and will take them into consideration for potential future rulemaking.

1.11 National Provider Identifier (NPI)

***Comment*:**

Two commenters recommended that HHS remove the requirement to provide a National Provider Identifier (NPI) on the GFE. These commenters were concerned that the requirement to specify which clinician will see the individual could undermine team-based care and flexible scheduling arrangements, which improve care for patients and can lessen physician burnout. One commenter reported that the requirement to provide a specific clinician's NPI on the GFE contributes to the burden imposed by the GFE requirements, and that this requirement may cause care delays and confusion if a different clinician from the same practice needs to see the patient due to unforeseen circumstances.

Response

We appreciate commenters' responses and will take them into consideration for potential future rulemaking.

1.12 Discounts

***Comment*:**

One commenter noted that it would be difficult for providers and facilities that are required under Federal and State law to apply discounts for financially disadvantaged patients prior to the patient's presenting certain financial information and supporting documentation and completing an application form. Typically, this commenter explained, patients apply for these discounts after being evaluated and scheduling the specific service. The commenter suggested that to provide a GFE that includes the application of all potential discounts, the existing regulatory timeframes may not be feasible in all cases.

Another commenter asked HHS to clarify that financial assistance eligibility determinations must only be done for those patients who request it or may be reasonably expected to meet the criteria, and that HHS assist in the development of tools to automate these determinations.

Response

We appreciate commenters' feedback and will take it into consideration for potential future rulemaking.

2. Burden Related Comments

Comment:

One commenter indicated that the number of cases that will go through the PPDR process annually is understated and therefore HHS under-calculated the cost of process. This commenter believes the process will be more costly to providers and facilities than HHS has estimated in the rule.

Response

While HHS appreciates this commenter's opinion, HHS believes that the number of cases and their associated burden on patients and providers is accurately estimated. For the purpose of creating PPDR estimates, HHS relied on the experiences of New York and North Carolina. The number of claims is estimated based on the total nonemergency elective procedures (surgical and non-surgical) performed in the U.S. each year while using realistic assumptions to estimate the number of uninsured (or self-pay) individuals that will engage in the Patient-Provider Dispute Resolution process. This results in 26,659 claims that are anticipated to end up in the process. Using data from Bureau of Labor Statistics, HHS believes that labor cost to process these claims is accurately estimated.

Comment:

Two commenters expressed their concern regarding the overall burden of the rule. They believe that the rule significantly understates the burden imposed on providers and facilities in connection with the provision of good faith estimates. Furthermore, they stated they are experiencing higher costs of compliance due to the need to allocate staff and resources to track, print and distribute estimates.

Response

HHS believes that the burden imposed on providers and facilities is estimated accurately based on data drawn from Bureau of Labor Statistics and other reliable sources to estimate number of respondents and labor costs. HHS invites comments if there are specific concerns regarding the accuracy of the time and labor cost estimates.