Appendix 15: 60-day Notice Comments & Response Summary

Requirements Related to Surprise Billing; Part II

CMS-10791

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.

The following responses are based on requirements outlined in the *Requirements Related to Surprise Billing; Part II* interim final rule (IFR).[1] Some policy issues raised by commenters on this PRA package overlap with those raised by commenters on the IFR, and we will take those under advisement as we work to finalize 45 CFR 149.610-620.

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, includes physician and/or dental office-based settings.

***Response*:**

All providers and facilities that schedule items or services for an uninsured (or self-pay) individual or receive a request for a good faith estimate (GFE) from an uninsured (or self-pay) individual must provide such individual with a GFE. The GFE requirement's applicability to facilities is not limited to those facilities that are included in the definition of "health care facility" used for purposes of the balance billing protections, as defined at 45 CFR 149.30.

Instead, the terms "health care provider (provider)," "health care facility (facility)," and "Items or services" are defined in the IFR at 45 CFR 149.610(a)(2) for purposes of the GFE requirements for uninsured (or self-pay) individuals as:

"Health care provider (provider)" means a physician or other health care provider who is acting within the scope of practice of that provider's license or certification under applicable State law, including a provider of air ambulance services;

"Health care facility (facility)" means 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

[1] 86 FR 56080 (October 7, 2021).

local law provides for the licensing of 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.

“Items or services” includes all encounters, procedures, medical tests, supplies, prescription drugs, durable medical equipment, and fees (including facility fees), provided or assessed in connection with the provision of health care. The definition of items or services in 45 CFR 147.210(a)(2) encompasses and accurately defines the types of items or services that are expected to be reported in the GFE including items or services such as those related to dental health, vision, substance use disorders and mental health.

There may be variations in practice patterns, such as whether a specific provider or facility furnishes services to uninsured (or self-pay) individuals, along with the types of items or services provided. There are some items or services that may not be included in a GFE because they are not typically scheduled in advance and not typically the subject of a requested GFE (such as urgent, emergent trauma, or emergency items or services); however, to the extent that such care is scheduled at least 3 days in advance, a provider or facility would be required to provide a GFE.

For example, individuals will likely not be able to obtain GFEs for emergency air ambulance services, as these are not generally scheduled in advance. However, the applicability of these requirements to providers of air ambulance services helps to ensure that individuals can obtain a GFE upon request or at the time of scheduling non-emergency air ambulance services, for which coverage is often not provided by a plan or issuer and thus even individuals with coverage must self-pay.

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 enforcement of the advanced explanation of benefits (AEOB) requirements under section 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.

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*:**

HHS appreciates that furnishing GFEs to uninsured (or self-pay) individuals will require most providers and facilities to incur some level of administrative burden. HHS is of the view that this burden will likely vary based on the number of uninsured (or self-pay) individuals served by a particular provider or facility, and variations in practice patterns, such as the types of items or services provided. However, HHS believes the requirements related to providing a GFE for uninsured (or self-pay) individuals appropriately balance this burden against the importance of providing consumers with the appropriate information to make informed decisions related to their healthcare needs and could provide protection for vulnerable consumers and those unable to obtain coverage.

The Departments have worked to minimize the burden of implementing the GFE requirements under section 112 of division BB of the CAA. In response to stakeholder feedback, the Departments have delayed enforcement of the requirement that providers and facilities provide GFE information for individuals enrolled in a plan or coverage and who are seeking to submit a claim for scheduled items or services to their plan or coverage, as well as the related AEOB provisions under section 111 of division BB of the CAA. At this time, the Departments have not issued a specific enforcement deadline and will not enforce these provisions until rulemaking to fully implement this requirement to provide a GFE to an individual in order to give plans, issuers and providers and facilities enough time to develop and build the infrastructure necessary to support the transfers of information needed to provide the GFE.

Additionally, the Departments have delayed enforcement of the requirements related to co-providers and co-facilities until January 1, 2023, discussed in detail below.

We appreciate the comment 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. We will take that into consideration for potential future rulemaking. We note, however, that providers and facilities must comply with the timing requirements specified in section 2799B-6 of the PHS Act and codified in 45 CFR 149.610.

Finally, we confirm that the requirement to provide a GFE to an uninsured (or self-pay) individual under 45 CFR 149.610 is not triggered if that item or service is being scheduled fewer than 3 business days before the date the item or service is to be furnished (i.e., a provider or facility is not required to provide a GFE to uninsured (or-self-pay) individuals who schedule an

item or service the same day as, or 1 or 2 days before, the item or service is to be furnished; or to reschedule the appointment in such a case to allow for the provision of a GFE).

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.

1.3 Coordination with the Hospital Price Transparency Final Rule

***Comment*:**

In the IFR, HHS sought comment on how the Hospital Price Transparency[2] 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 GFE 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 GFE 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 machine-readable files could have any utility in meeting the uninsured (or self-pay) GFE 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 agree with commenters that GFEs are more individualized, and contain more specificity, than the standard charges that hospitals are required to display under the Hospital Price Transparency Final Rule. We acknowledge the burden on hospitals to comply with both sets of requirements, but believe they each serve distinctly important purposes. Therefore, we do not believe at this time that one can serve as a substitute for the other.

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 GFE information between providers and facilities. HHS also expressed interest in whether

[2] 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.

publicly available standardized processes exist or could be developed that would facilitate and support efficient and timely transmission of GFE 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 GFEs.

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

HHS recognizes that some providers or facilities may need to establish efficient and secure communication channels for transmission of GFE information between convening providers or facilities and co-providers and co-facilities. HHS understands that it may take time for providers and facilities to develop systems and processes for transmitting and receiving the required information to and from co-providers and co-facilities. Therefore, for GFEs provided to uninsured (or self-pay) individuals from January 1, 2022 through December 31, 2022, HHS will exercise its enforcement discretion in situations where a GFE provided to an uninsured (or self-pay) individual does not include expected charges from co-providers or co-facilities.

HHS notes that nothing prohibits a co-provider or co-facility from furnishing the GFE information to the convening provider or facility prior to December 31, 2022, and an uninsured (or self-pay) individual from separately requesting a GFE directly from the co-provider or co-facility, in which case the co-provider or co-facility would be required to provide the GFE for such items or services. Otherwise, during this period (January 1, 2022 through December 31, 2022), HHS encourages convening providers and facilities to include a range of expected charges anticipated to be provided and billed by co-providers and co-facilities.

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 GFE, 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*:**

HHS appreciates the feedback regarding the amount of time we estimate will be needed for a provider or facility to complete a GFE. While we understand that some providers or facilities may have to generate GFE information manually, we do not expect that manually gathering and generating the content required under 45 CFR 149.610(c) will take more than 30 minutes. Many of the content elements will be standard for each GFE, such as the provider or facility's identifying information and the disclaimers, and therefore should take a negligible amount of time to gather and input into the GFE. We expect that the information needed to complete the other requirement elements is easily accessible, such as the patient's name and date of birth; the list of items or services reasonably expected to be furnished by the convening provider or convening facility for the period of care; and applicable diagnosis codes, expected service codes, and expected charges associated with each listed item or service. Therefore, we believe that 30 minutes is sufficient time for a convening provider or facility to complete the GFE. Likewise, we expect that an additional 30 minutes allows sufficient time for a provider or facility to complete a GFE with expected charges from co-providers or co-facilities.

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,[3] 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 GFEs, 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. Comments on these topics will be taken into consideration as we finalize the rule.

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

***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*:**

In instances where multiple providers might be responsible for furnishing care in conjunction with a primary item or service, the "convening provider or facility" must provide a GFE to the uninsured (or self-pay) individual, which includes items or services reasonably expected to be furnished by the convening provider or facility, and items or services reasonably expected to be furnished by co-providers or co-facilities.

The convening provider or facility is the provider or facility that is responsible for scheduling the primary items or services. Other providers or facilities that furnish items or services in conjunction with the primary item or service furnished by the convening provider or facility are considered "co-providers" and "co-facilities."

No later than one business day after scheduling the primary item or service or receiving a request for a GFE, the convening provider or facility must contact all co-providers and/or co-facilities that will provide items or services in conjunction with the primary items or services and request GFE information including the expected charges for these items or services expected to be provided by the co-provider or co-facility.

1.7 Scheduled or requested

[3] 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*:**

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

Because providers and facilities are required to provide GFEs to uninsured (or self-pay) individuals in connection with items or services scheduled, and not just upon the request of the uninsured (or self-pay) individual, whether the uninsured (or self-pay) individual wants the GFE does not affect the requirement to provide it.

We require providers and facilities to provide GFEs to uninsured (or self-pay) individuals both upon scheduling and upon request to help as many uninsured (or self-pay) individuals as possible understand their potential health care costs in advance of receiving care and incurring charges. This information helps financially vulnerable individuals to compare costs across providers and facilities, and to engage in informed health care decision-making so they can best meet their needs and the needs of their families.

Finally, to help ensure that uninsured (or self-pay) individuals do not mistake a GFE for a bill, HHS requires at 45 CFR 149.610(c)(1)(ix) that a GFE must include 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 estimate.

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 GFE is not a contract and does not

require the patient to obtain the item/service from the providers/facilities listed on the GFE; and requested that HHS correct these omissions.

***Response*:**

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 GFE is not a contract and does not require the patient to obtain the item/service from the providers/facilities listed on the GFE. We have made the appropriate changes to the GFE Template.

Comment:

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.

***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 GFEs 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 superseded Template to be minimal. Therefore, we do not believe enforcement discretion is necessary or appropriate here.

***Comment*:**

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*:**

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 GFE 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,[4] Title VI of the Civil Rights Act of 1964,[5] and Section 504 of the Rehabilitation Act of 1973.[6]

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

When an individual schedules an appointment with a provider or facility, or upon request, the provider or facility must inquire if the individual is uninsured (or self-pay). If the individual is uninsured (or-self pay) at that time, the provider or facility must provide a GFE to the individual consistent with the requirements in 45 CFR 149.610. In situations where a provider or facility who has previously determined that an individual was not uninsured (or self-pay) becomes aware that an individual is uninsured (or self-pay) fewer than 3 business days in advance of the scheduled furnishing of items or services, nothing in the GFE regulations at 45 CFR 149.610 require that the provider or facility provide a GFE to such an individual, or reschedule an appointment to allow for the provision of a GFE to such an individual.

For individuals who, at the time of scheduling or request, are not uninsured (or self-pay), HHS has indicated in guidance that it will defer enforcement of the requirement under PHS Act section 2799B–6, as added by section 112 of division BB of the CAA, that providers and facilities provide a GFE to such individual's plan or coverage, until rulemaking to implement this requirement is adopted and applicable.[7] This means that until further rulemaking to

[4] 42 U.S.C. 18116.
[5] 42 U.S.C. 2000d et seq.
[6] 29 U.S.C. 794.
[7] FAQs about Affordable Care Act and Consolidated Appropriations Act, 2021 Implementation Part 49 (August 20, 2021), available at: https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/FAQs-Part-49.pdf.

implement this requirement is adopted and applicable, HHS will not enforce against providers and facilities that do not provide GFEs to plans and issuers for individuals who are not uninsured (or self-pay), as defined in 45 CFR 149.610(a)(2)(xiii), at the time the individual schedules or requests the GFE for the items or services expected to be furnished.

We encourage 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.

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 and evaluating the individual (in person or virtually) 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 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

The interim final rules do not require the GFE to include charges for items or services that could not have been reasonably expected. A GFE provided to uninsured (or self-pay) individuals must

include an itemized list of items or services that are reasonably expected to be furnished, grouped by each provider or facility, for that period of care.

If a provider or facility does furnish an item or service that was not included in the original GFE, and the difference between the billed charges and the GFE from the provider or facility is $400 or more, the uninsured or (self-pay) individual may initiate the patient-provider dispute resolution (PPDR) process. In such an instance, the provider or facility will have an opportunity to present evidence to an independent third party (a selected dispute resolution entity) to demonstrate why the additional charges were for items or services that were medically necessary and that could not have reasonably been expected by the provider or facility when the GFE was provided.

If a provider or facility expects or is notified of any changes to the scope of a GFE that was provided at the time of scheduling (such as expected changes to the expected charges, items, services, frequency, recurrences, duration, providers, or facilities), the provider or facility must provide a new GFE to the uninsured (or self-pay) individual no later than 1 business day before the items or services are scheduled to be furnished. Providers and facilities are encouraged to review any changes to a GFE with patients, to help them understand what has changed between the initial GFE and the new GFE.

For these reasons, we do not believe it is necessary or appropriate to require providers and facilities to include the individual's stated reasons for the visit in the GFE, for the purposes of dispute resolution. Also for these reasons, 45 CFR 149.610 does not require providers and facilities to obtain a comprehensive list of an individual's conditions, history, and symptoms of their lifetime, or a prior relationship with an individual, before producing an accurate estimate of expected costs.

Additionally, 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, such as for certain dental screenings or procedures, providers and facilities are not required to include diagnosis codes on a GFE. However, the provider or facility must include the expected charges and service codes for the items and services to be furnished during that visit, even when no diagnosis code is available.[8]

Finally, direct primary care (DPC) practices fall with the definitions "health care provider" and "health care facility" under § 149.610 and therefore must provide GFE to uninsured (or self-pay) individuals consistent with those requirements. However, we encourage DPC providers and facilities to tailor the GFE to meet the needs of their practice, within the parameters outlined in § 149.610. For example, in situations where all the items and services that are reasonably expected to be provided are already paid for by the flat fee paid by the individual, DPC providers and facilities may note that in the GFE, and list the expected charges as $0.

[8] FAQs about Affordable Care Act and Consolidated Appropriations Act, 2021 Implementation Part 49 (August 20, 2021), available at: https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/FAQs-Part-49.pdf.

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

Among additional requirements, a GFE issued to an uninsured (or self-pay) individual must include the following: Name, National Provider Identifier, and Tax Identification Number of each provider or facility represented in the GFE, and the State(s) and office or facility location(s) where the items or services are expected to be furnished by such provider or facility. If the provider who will furnish the scheduled (or requested) items or services is not known at the time of scheduling (or at the time an individual requests a GFE), providers or facilities may include a group NPI, where applicable, as an alternative. We understand that the requirement to provide either a group or an individual NPI may reduce some flexibility to provide team-based care and rely on flexible scheduling arrangements. We encourage providers and facilities to make any needed adaptations consistent with GFE requirements.

As a reminder, under 45 CFR 149.610(b)(1)(vii) a convening provider or convening facility must provide an uninsured (or self-pay) individual who has scheduled an item or service with a new GFE if a convening provider, convening facility, co-provider, or co-facility anticipates or is notified of any changes to the scope of a GFE (such as anticipated changes to the expected charges, items, services, frequency, recurrences, duration, providers, or facilities) previously furnished at the time of scheduling; a new GFE must be issued to the uninsured (or self-pay) individual no later than 1 business day before the items or services are scheduled to be furnished.

Specific provider or facility identifiers, such as the NPI and tax identification number of each provider or facility represented in the GFE, are required for purposes of the patient-provider dispute resolution (PPDR) process. Determinations of whether the total billed charges are substantially in excess of the total expected charges in the GFE, and determinations made by selected dispute resolution entities, are made separately for each specific provider or facility listed on the GFE.

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 recognize that providing a GFE upon an individual's scheduling an item or service, or upon request, is a challenge in situations where income-based discounts are not or cannot be applied until after the item or service has been furnished. We are considering how best to address these situations. Providers and facilities that use income-based sliding fee schedules or other income-based discounts should work within the current regulatory parameters pending future guidance or 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 GFEs. 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.