

Proposed Rules

Federal Register

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This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

OFFICE OF PERSONNEL MANAGEMENT

5 CFR Chapter I

RIN 3206-AO45

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Chapter I

RIN 1545-BQ37

DEPARTMENT OF LABOR

Employee Benefits Security Administration

29 CFR Chapter XXV

RIN 1210-AC14

DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Subchapter B

[CMS-9900-NC]

RIN 0938-AU98

Request for Information; Advanced Explanation of Benefits and Good Faith Estimate for Covered Individuals

AGENCY: Office of Personnel Management (OPM); Internal Revenue Service, Department of the Treasury; Employee Benefits Security Administration (EBSA), Department of Labor (DOL); and Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Request for information.

SUMMARY: This document is a request for information (RFI) to inform DOL, HHS, and the Treasury (collectively, the Departments) and OPM's rulemaking for advanced explanation of benefits (AEOB) and good faith estimate (GFE) requirements of the No Surprises Act, which was enacted as part of the Consolidated Appropriations Act, 2021 (CAA). This RFI seeks information and recommendations on transferring data

from providers and facilities to plans, issuers, and carriers; other policy approaches; and the economic impacts of implementing these requirements.

DATES: To be assured consideration, comments must be received at one of the addresses provided below by November 15, 2022.

ADDRESSES: In commenting, refer to file code CMS-9900-NC.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to <https://www.regulations.gov>. Follow the "Submit a comment" instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-9900-NC, P.O. Box 8013, Baltimore, MD 21244-8013.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-9900-NC, Mail Stop C4-26-05, 7500 Security Boulevard, Baltimore, MD 21244-1850.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT:

Padma Babubhai Shah, Office of Personnel Management (OPM), (202) 606-4056.

Emily Ames, Centers for Medicare & Medicaid Services (CMS), (301) 492-4246.

William Fischer, Internal Revenue Service (IRS), (202) 317-5500.

Elizabeth Schumacher or Frank Kolb, Employee Benefits Security Administration (EBSA), (202) 693-8335.

Customer Service Information: Information from OPM on health benefits plans offered under the FEHB Program can be found on the OPM website (www.opm.gov/healthcare-insurance/healthcare/). Individuals interested in obtaining information from the Department of Labor (DOL)

concerning employment-based health coverage laws may call the EBSA Toll-Free Hotline at 1-866-444-EBSA (3272) or visit DOL's website (www.dol.gov/ebsa). In addition, information from HHS on private health insurance for consumers can be found on the CMS website (www.cms.gov/cciio) and information on the No Surprises Act can be found at www.cms.gov/NoSurprises.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. The Departments and OPM post all comments received before the close of the comment period on the following website as soon as possible after they have been received:

www.regulations.gov. Follow the search instructions on that website to view public comments. The Departments and OPM will not post on *Regulations.gov* public comments that make threats to individuals or institutions or suggest that an individual will take actions to harm another individual. The Departments and OPM continue to encourage individuals not to submit duplicative comments. We will post acceptable comments from multiple unique commenters even if the content is identical or nearly identical to other comments.

I. Background

On December 27, 2020, the Consolidated Appropriations Act, 2021 (CAA), which includes the No Surprises Act, was enacted.¹ The No Surprises Act provides Federal protections against surprise billing and limits out-of-network cost sharing under many of the circumstances in which surprise bills arise most frequently. Surprise billing occurs when an individual receives an unexpected medical bill from a health care provider or facility, including providers of air ambulance services, after receiving medical services from a provider or facility that, usually unknown to the covered individual, is a nonparticipating provider or facility in the individual's health plan or health insurance coverage.

Public Health Service (PHS) Act section 2799B-6, as added by section

¹ Public Law 116-260 (December 27, 2020).

112 of title I of Division BB of the CAA, requires providers and facilities,² upon an individual's scheduling of an item or service, or upon an individual's request, to inquire if the individual is enrolled in a group health plan or group or individual health insurance coverage. If the individual is enrolled in a plan or coverage and is seeking to have a claim for such item or service submitted to such plan or coverage, providers and facilities must provide to the plan, issuer, or carrier, a good faith estimate (GFE) of the expected charges for furnishing the scheduled item or service (and any items or services reasonably expected to be provided in conjunction with those items or services, including those provided by another provider or facility), along with the expected billing and diagnostic codes for these items or services. If the individual is not enrolled or is not seeking to have a claim for such item or service submitted to such plan or coverage (that is, an uninsured or self-pay individual), providers and facilities must provide the GFE directly to the individual, as described in PHS Act section 2799B–6 and implementing regulations at 45 CFR 149.610. The Department of Health and Human Services (HHS) interprets the requirements described in PHS Act section 2799B–6 to apply to providers and facilities furnishing items or services to individuals covered by the Federal Employees Health Benefits (FEHB) Program in the same manner as for individuals enrolled in a group health plan or group or individual health insurance coverage.³

If the uninsured (or self-pay) individual schedules an item or service to be furnished by the provider or facility at least 3 business days in advance of the date the item or service is expected to be furnished, the GFE must be provided within 1 business day after the date of scheduling the item or service. However, if the item or service is scheduled at least 10 business days in

advance of the date the item or service is expected to be furnished, or if the uninsured (or self-pay) individual requests the information, the GFE must be provided no later than 3 business days after the date of the request.⁴ These provisions apply beginning on January 1, 2022.

Internal Revenue Code (Code) section 9816(f), Employee Retirement Income Security Act of 1974 (ERISA) section 716(f), and PHS Act section 2799A–1(f), as added by section 111 of title I of Division BB of the CAA, require group health plans and health insurance issuers offering group or individual health insurance coverage, upon receiving a GFE regarding an item or service as described in PHS Act section 2799B–6, to send a covered individual, through mail or electronic means, as requested by the covered individual, an advanced explanation of benefits (AEOB) in clear and understandable language. Pursuant to 5 U.S.C. 8902(p), FEHB carriers must comply with AEOB requirements in the same manner as those provisions apply to a group health plan or health insurance issuer offering group or individual health insurance coverage. The plan, issuer, or carrier must provide an AEOB to the covered individual no later than 1 business day after the plan, issuer, or carrier receives the GFE. However, if such item or service was scheduled at least 10 business days before such item or service is to be furnished (or if the covered individual requested the information) the plan, issuer, or carrier must provide an AEOB to the covered individual within 3 business days after the date on which the plan, issuer, or carrier receives the GFE or request. The AEOB must include the following information: (1) the network status of the provider or facility; (2) the contracted rate for the item or service, or if the provider or facility is not a participating provider or facility, a description of how the covered individual can obtain information on providers and facilities that are participating; (3) the GFE received from the provider or facility; (4) a GFE of the amount the plan or coverage is responsible for paying; (5) the amount of any cost sharing which the covered individual would be responsible for paying with respect to the GFE received from the provider or facility; (6) a GFE of the amount that the covered individual has incurred towards meeting the limit of the financial responsibility (including with respect to deductibles and out-of-pocket maximums) under the plan or coverage

as of the date of the AEOB; and (7) disclaimers indicating whether coverage is subject to any medical management techniques (including concurrent review, prior authorization, and step-therapy or fail-first protocols). The AEOB must also indicate that the information provided is only an estimate based on the items and services reasonably expected to be furnished, at the time of scheduling (or requesting) the item or service, and is subject to change; and any other information or disclaimer the plan, issuer, or carrier determines is appropriate and that is consistent with information and disclaimers required under this section of the statute. These provisions apply with respect to plan years (in the individual market, policy years) beginning on or after January 1, 2022.

HHS issued regulations implementing PHS Act section 2799B–6 related to GFEs for uninsured (or self-pay) individuals in interim final rulemaking that was published in the **Federal Register** on October 7, 2021, but deferred enforcement of the portion of PHS Act section 2799B–6 related to GFEs for covered individuals who are seeking to have a claim submitted to their plan or issuer for scheduled items or services.⁵ In the preamble to that rule (and as stated in guidance issued by the Departments), the Departments also deferred enforcement of Code section 9816(f), ERISA section 716(f), and PHS Act section 2799A–1(f) related to the requirement that plans and issuers provide an AEOB.⁶ The decision to defer enforcement was made in response to stakeholder requests that the Departments first establish standards for the data transfer from providers and facilities to plans and issuers, and give plans, issuers, providers, and facilities enough time to build the infrastructure necessary to support the transfers. The Departments agreed that compliance with these sections was likely not possible by January 1, 2022, and indicated an intent to undertake notice and comment rulemaking in the future to implement these provisions, including establishing appropriate data transfer standards. Until that time, HHS is deferring enforcement of the

² Under 45 CFR 149.610(a)(2)(vii) through (viii), “[h]ealth care provider (provider)” is defined for purposes of the GFE requirements as “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)” is defined for purposes of the GFE requirements 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.”

³ See 86 FR 55980, 55983 at FN 12.

⁴ PHS Act section 2799B–6.

⁵ Requirements Related to Surprise Billing; Part II, 86 FR 55980, 55983 (October 7, 2021), available at <https://www.federalregister.gov/documents/2021/10/07/2021-21441/requirements-related-to-surprise-billing-part-ii>.

⁶ *Id.*; FAQs about Affordable Care Act and Consolidated Appropriations Act, 2021 Implementation Part 49 (August 20, 2021), Q6, available at <https://www.dol.gov/sites/dolgov/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-49.pdf> and <https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/FAQs-Part-49.pdf>.

requirement that providers and facilities must provide a GFE to plans and issuers for covered individuals enrolled in a health plan or coverage and seeking to have a claim submitted for scheduled (or requested) items or services to their plan or coverage, and the Departments are deferring enforcement of the requirement that plans and issuers must provide these covered individuals with an AEOB. FEHB carriers' compliance will be concurrent and consistent with implementing regulations issued by the Departments, subject to OPM regulation and FEHB contract terms.

II. Solicitation of Public Comments

Recognizing the complex issues involved in developing regulations to implement Code section 9816(f), ERISA section 716(f), and PHS Act sections 2799A–1(f) and 2799B–6, the Departments and OPM are requesting information from the public on a range of issues to better inform future rulemaking. The Departments and OPM welcome comments from all interested members of the public, including individuals potentially eligible to receive an AEOB, organizations serving or representing the interests of such individuals, health care providers and facilities, group health plans and health insurance issuers, carriers, third-party vendors, states, standards development organizations, and other health programs.

A. Transferring Data From Providers and Facilities to Plans, Issuers, and Carriers

As noted previously, the Departments and OPM have not yet established regulatory standards for the transfer of GFE data from providers and facilities to plans, issuers, and carriers. However, as CMS indicated in a blog post on December 8, 2021,⁷ the Health Level 7 (HL7®) Fast Healthcare Interoperability Resources (FHIR®) standard holds potential for supporting interoperability and enabling new entrants and competition throughout the health care industry. FHIR is a standard that was developed specifically to support interoperability and securely facilitate the exchange of health care information between systems. In the time since the FHIR standard was first created, the health care industry has rapidly embraced the standard through substantial investments in industry pilots, specification development, and the deployment of FHIR-based

Application Programming Interfaces (APIs) supporting a variety of business needs.⁸ Some industry-led FHIR Accelerator™ programs, such as Da Vinci and CARIN,⁹ have created implementation guides (IGs) that CMS has recommended for use in meeting the requirements of the CMS *Interoperability and Patient Access* final rule for Patient Access and Provider Directory APIs.¹⁰ In 2021, the Da Vinci FHIR Accelerator™ program launched a Patient Cost Transparency project dedicated to developing an IG that could be used to exchange AEOB and GFE information. This IG uses a FHIR-based API for exchange of AEOB and GFE data from providers to payers and is currently published as a Standard for Trial Use (STU). The current version of the STU is useable by industry today, and the Patient Cost Transparency workgroup continues to revise and update draft standard versions based on public comments received through the ballot process. The ballot process supports industry consensus on the IG and ensures its usability by all stakeholders—including payers, providers, and vendors—to ultimately serve patients and ensure they have access to the information they need.

The Departments and OPM invite the public to use their expertise and the information in this section to respond to the questions in this RFI in their comments. The input may help inform development of future regulations.

- What issues should the Departments and OPM consider as they weigh policies to encourage the use of a FHIR-based API for the real-time exchange of AEOB and GFE data?

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) requires the Secretary of HHS to adopt standards and operating rules for certain transactions that apply to covered entities (health plans, health care clearinghouses, and certain health care providers). The types of transactions to which these requirements apply are specified in section 1173(a)(2) of the

⁸ Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Interoperability and Patient Access for Medicare Advantage Organization and Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans on the Federally-Facilitated Exchanges, and Health Care Providers (CMS Interoperability and Patient Access final rule), 85 FR 25510 (May 1, 2020), available at <https://www.govinfo.gov/content/pkg/FR-2020-05-01/pdf/2020-05050.pdf>.

⁹ CMS supports Da Vinci and CARIN by funding contracts to build implementation guides (IGs). CARIN is an accelerator project responsible for the IG used for the Patient Access API. Other accelerators include Gravity (social risk data), Codex (Cancer), and Helios (Public Health).

¹⁰ 85 FR 25510.

Social Security Act. However, transactions related to advance cost estimates, such as exchanges of AEOB and GFE data, are not contemplated in section 1173(a)(2) of the Social Security Act and are therefore not among the financial and administrative transactions for which the Secretary of HHS must adopt HIPAA standards. As such, no law or regulation currently requires plans, issuers, carriers, providers, or facilities to use a specific transaction standard to exchange AEOB or GFE data. Instead, the Secretaries of the Treasury, Labor, and HHS (the Secretaries) have general rulemaking authority to establish standards necessary to implement the provisions of Code section 9816(f), ERISA section 716(f), and PHS Act section 2799A–1(f).

Although HIPAA Administrative Simplification provisions do not apply to the exchange of AEOB and GFE data, HIPAA Privacy and Security requirements do. Plans, issuers, carriers, providers, and facilities that conduct certain health care transactions electronically are generally considered covered entities under the HIPAA Privacy and Security Rules and must comply with HIPAA Privacy and Security requirements in exchanging AEOB and GFE data.¹¹

The Departments and OPM solicit feedback on the following:

- What privacy concerns does the transfer of AEOB and GFE data raise, considering these transfers would list the individual's scheduled (or requested) item or service, including the expected billing and diagnostic codes for that item or service? Does the exchange of AEOB and GFE data create new or unique privacy concerns for individuals enrolled in a plan or coverage? Are there any special considerations that Departments should take into account regarding individuals who are enrolled in a plan or coverage along with other members of their household? How should the Departments and OPM address these concerns?

Additionally, the Office of the National Coordinator for Health Information Technology (ONC) Health IT Certification Program¹² consists of specified standards, implementation specifications, and certification criteria that health IT modules, including electronic health records systems, can meet.

¹¹ 45 CFR part 160 and subparts A and E of 45 CFR part 164.

¹² See ONC Health IT Certification Program, available at <https://www.healthit.gov/topic/certification-ehrs/certification-health-it>.

⁷ Interoperability and the Connected Health Care System (December 8, 2021), available at <https://www.cms.gov/blog/interoperability-and-connected-health-care-system>.

- How could updates to this program support the ability of providers and facilities to exchange GFE information with plans, issuers, and carriers or support alignment between the exchange of GFE information and the other processes providers and facilities may engage in involving the exchange of clinical and administrative data, such as electronic prior authorization?

- Would the availability of certification criteria under the ONC Health IT Certification Program for use by plans, issuers, and carriers, or health IT developers serving plans, issuers, and carriers, help to enable interoperability of API technology adopted by these entities?

Many providers and facilities exchange information with plans, issuers, and carriers using manual or paper-based technologies, such as portals, fax machines, or call centers. Up to 46 percent of prior authorization requests are still submitted by fax, and 60 percent require a telephone call during the prior authorization process.¹³ The Departments and OPM are also interested in understanding if there are plans, issuers, and carriers that are small, rural, or have other characteristics (such as being new or financially vulnerable, or operating only in the individual or small group market), such that deploying standards-based API technology might pose a significant barrier to the plan's, issuer's, or carrier's ability to provide coverage to consumers.

- What, if any, burdens or barriers would be encountered by small, rural, or other providers, facilities, plans, issuers, and carriers in complying with industry-wide standards-based API technology requirements for the exchange of AEOB and GFE data? How many small, rural, or other providers, facilities, plans, issuers, and carriers would encounter these burdens or barriers in complying with such technology requirements?

- Are there any approaches that the Departments and OPM should consider, or flexibility that should be provided (such as an exception or a phased-in approach to requiring providers and payers to adopt a standards-based API to exchange AEOB and GFE data), to account for small, rural, or other providers, facilities, plans, issuers, and carriers?

- If the Departments and OPM were to provide such flexibility, what factors

should they consider in defining eligible providers, facilities, plans, issuers, and carriers?

B. Other Policy Considerations

In addition to issues related to how providers and facilities would transfer GFEs to plans, issuers, and carriers, there are also issues related to ensuring that providers and facilities transfer the necessary data for plans, issuers, and carriers to prepare accurate AEOBs that take into account how the No Surprises Act's or a State's surprise billing laws may affect an individual's benefits related to the items or services specified in the AEOB, and the individual's financial responsibility for these items or services.¹⁴ Under the No Surprises Act and its implementing regulations, nonparticipating providers of nonemergency items or services performed with respect to a visit to certain participating facilities are generally prohibited from charging individuals cost-sharing amounts greater than those that would apply in-network, and are prohibited from balance billing the individual; and, for these services, plans and issuers must count this cost sharing toward any in-network deductibles and out-of-pocket maximums. The same general standards also apply with respect to emergency services (including post-stabilization services, under certain circumstances) performed by nonparticipating providers and facilities, and to air ambulance services furnished by nonparticipating air ambulance service providers.

Additionally, with respect to post-stabilization services furnished by nonparticipating providers or facilities, and nonemergency services performed by nonparticipating providers with respect to patient visits to certain participating facilities, the nonparticipating provider or facility under certain circumstances may seek the individual's consent to waive those protections.¹⁵ The Departments and OPM request comment on the following questions in order to understand how to ensure that plans, issuers, and carriers have the requisite information to prepare an AEOB that takes into account an individual's consent, or lack of consent, to waiving balance billing and cost-sharing protections.¹⁶

¹⁴ Code section 9816(f), ERISA section 716(f), and PHS Act section 2799A-1(f).

¹⁵ For more detailed information on these requirements, see 86 FR 36872.

¹⁶ References to the GFE in these questions refer to the GFE that providers and facilities must provide to plans, issuers, and carriers with respect to individuals enrolled in a plan or coverage (and seeking to have a claim for the item or service

- Should a nonparticipating provider of nonemergency services be required to inform a plan, issuer, or carrier, as part of or concurrently with the GFE, whether the requested or scheduled items or services would be furnished with respect to the individual's visit to a participating facility? Should this requirement depend on whether the GFE was requested, as opposed to whether the furnishing of the items or services has been scheduled?

- In instances in which it is permissible for a nonparticipating provider or facility to request consent from an individual to waive the No Surprises Act's balance billing and cost-sharing protections, should the provider or facility be required to inform a plan, issuer, or carrier of the individual's consent, as part of or concurrently with providing the GFE, if it has already obtained the individual's consent? Should the nonparticipating provider or facility also be required to inform a plan, issuer, or carrier if the provider or facility intends to seek consent, or if the individual has already declined to give consent?

- If a nonparticipating provider is required to inform a plan, issuer, or carrier about the facility in which services are scheduled to be furnished, or if a nonparticipating provider or facility is required to inform a plan, issuer, or carrier about the status of a consent to waive the No Surprises Act's balance billing and cost-sharing protections, how should the nonparticipating provider or facility communicate the information? For example, should it be communicated as part of the GFE or in a separate document?

- In some cases in which an appointment for a nonparticipating provider or facility to furnish items or services at a facility is scheduled at least 72 hours prior to the date on which the individual is to be furnished the items or services, the provider (or the participating facility on behalf of the provider) or facility may provide notice and seek the patient's consent to waive the No Surprises Act's balance billing and cost-sharing protections not later than 72 hours prior to the date on which the individual is to be furnished the items or services. In cases in which the appointment is scheduled within 72 hours prior to the date on which the items or services are to be furnished,

submitted to such plan or coverage) upon scheduling an item or service or requesting a GFE, as specified in section 2799B-6 of the PHS Act, as opposed to the GFE required to be included in the notice and consent to be treated by a nonparticipating provider under section 2799B-2(d)(2)(B) of the PHS Act and 45 CFR 149.420(d)(2).

¹³ America's Health Insurance Plans (AHIP), New Fast PATH Initiative Aims to Improve Prior Authorization for Patients and Doctors (January 6, 2020), available at <https://www.ahip.org/new-fast-path-initiative-aims-to-improve-prior-authorization-for-patients-and-doctors/>.

providers and facilities are required to provide the notice on the date the appointment to furnish the items or services is scheduled. When an individual is provided the notice on the same date that the items or services are to be furnished, providers and facilities are required to provide the notice no later than 3 hours prior to furnishing items or services to which the notice and consent requirements apply. If a nonparticipating provider or facility is required to inform a plan, issuer, or carrier, as part of or concurrently with the GFE, about the status of a consent to waive the No Surprises Act's balance billing and cost-sharing protections, how should the notice and consent timing requirement be coordinated with AEOB and GFE timing requirements?

Additionally, provisions of the No Surprises Act's or a State's surprise billing laws may affect an individual's benefits related to the items and services specified in an AEOB, as well as the individual's financial responsibility for those items or services. Therefore, the Departments and OPM seek information on the following:

- Generally, how should the AEOB reflect the way in which the No Surprises Act's or a State's surprise billing and cost-sharing protections may affect an individual's benefits related to the items or services specified in an AEOB, and the individual's financial responsibility for these items or services?

- In instances in which a plan, issuer, or carrier has been notified by a provider or facility that consent has been obtained from an individual to waive the No Surprises Act's or a State's surprise billing and cost-sharing protections, should the cost and benefit data in the AEOB explicitly reflect that those protections do not apply? Should the AEOB specifically state that the data is premised on the relevant provisions not applying as a result of the individual's consent? Should the AEOB reflect two different sets of cost and benefit data instead, one set reflecting that the No Surprises Act's or a State's surprise billing and cost-sharing protections do not apply, and one set reflecting the application of these protections (to account for the possibility that the individual might later revoke consent¹⁷)?

- In instances in which the plan, issuer, or carrier, at the time it is preparing the AEOB, has knowledge that the No Surprises Act's or a State's surprise billing and cost-sharing

protections would apply unless individual consent has been given, but the plan, issuer, or carrier does not know whether consent has been given by the individual to waive those protections, should the AEOB include two sets of cost and benefit data, one set that would apply if consent is given, and one set that would apply if consent is not given?

The AEOB content requirements are similar to the Transparency in Coverage internet-based self-service tool requirements.¹⁸ Under those Transparency in Coverage requirements, plans, issuers, and carriers¹⁹ must make available to covered individuals (or an authorized representative) personalized enrollee cost-sharing information, including, when applicable, in-network rates for all covered health care items and services through an internet-based self-service tool and in paper form upon request. This information must be available for plan years (in the individual market, policy years) beginning on or after January 1, 2023, with respect to the 500 items and services identified by the Departments in Table 1 in the preamble to the *Transparency in Coverage* final rule;²⁰ and with respect to all covered items and services, for plan or policy years beginning on or after January 1, 2024.²¹ The Departments and OPM request input on how these requirements interact, or could interact, with AEOB requirements.

- To what extent could the Departments' and OPM's coordination of the internet-based self-service tool requirements with AEOB requirements help minimize the burden on plans, issuers, and carriers in implementing both requirements?

- Can plans, issuers, and carriers leverage technical work done to comply with the internet-based self-service tool requirements to help streamline the process for complying with AEOB requirements?

- What, if any, obstacles would be encountered if plans, issuers, and carriers were required to provide AEOBs to covered individuals for all covered items or services (rather than a specified

subset, similar to the rule for the first year of the internet-based self-service tool requirement) beginning with the first year of implementation of the AEOB provisions?

Some stakeholders have commented that a plan, issuer, or carrier providing a covered individual with an AEOB should also be required to provide a copy of the AEOB to the provider or facility that furnished the plan, issuer, or carrier with the GFE.

- Are there reasons why the Departments and OPM should or should not propose a requirement that plans, issuers, and carriers provide a copy of the AEOB to the provider or facility, as opposed to allowing such a transfer but not requiring it?

Code section 9816(f), ERISA section 716(f), and PHS Act section 2799A–1(f) allow covered individuals to make a request for an AEOB directly to their plan, issuer, or carrier. The plan, issuer, or carrier must provide an AEOB upon request to the covered individual no later than 3 business days after the date on which the plan, issuer, or carrier receives the request.²² The Departments and OPM are interested in recommendations for implementing this provision without placing unnecessary burden on plans, issuers, carriers, providers, and facilities.

- What, if any, burdens or barriers should be considered if the Departments and OPM propose to require plans, issuers, and carriers to communicate a covered individual's request for an AEOB to a particular provider or facility in order to receive GFE information from the provider or facility for use in formulating the requested AEOB?

Many individuals have multiple forms of health insurance coverage, including those to which AEOB requirements do not apply (such as Federal health care programs like Medicare, Medicaid, and TRICARE);²³

²² The plan, issuer, or carrier must provide the AEOB no later than 1 business day after the plan, issuer, or carrier receives the GFE, or if such item or service was scheduled at least 10 business days before such item or service is to be furnished (or if the covered individual requested the information), the plan, issuer, or carrier must provide an AEOB to the covered individual within 3 business days after the date on which the plan, issuer, or carrier receives the GFE or request. Code section 9816(f), ERISA section 716(f), and PHS Act section 2799A–1(f).

²³ A Federal health care program (as defined in section 1128B(f) of the Social Security Act) is not considered to be a "group health plan," "health insurance coverage," "individual health insurance coverage," "group health insurance coverage," or a "health insurance issuer," as referenced in Code section 9832, ERISA section 733, and PHS Act section 2791.

¹⁷ See 86 FR 36909 (discussing individuals' right to revoke consent regarding items and services not yet furnished).

¹⁸ Transparency in Coverage, 85 FR 72158 (November 12, 2020), available at <https://www.govinfo.gov/content/pkg/FR-2020-11-12/pdf/2020-24591.pdf>; 26 CFR 54.9815–2715A2(b); 29 CFR 2590.715–2715A2(b); and 45 CFR 147.211(b).

¹⁹ OPM instructed FEHB carriers to comply with the Transparency in Coverage Final Rule in Carrier Letter 2021–03 (February 17, 2021), available at <https://www.opm.gov/healthcare-insurance/healthcare/carriers/2021/2021-03.pdf>.

²⁰ 85 FR 72182 through 72190.

²¹ 26 CFR 54.9815–2715A2(c)(1); 29 CFR 2590.715–2715A2(c)(1); and 45 CFR 147.211(c)(1).

and excepted benefits such as limited-scope dental and vision benefits).²⁴

- What approaches should be considered when proposing requirements related to the AEOB and GFE that account for, or do not account for, secondary and tertiary payers?

- What approaches should be considered to address application of the requirements related to the AEOB and GFE that account for, or do not account for, unique benefit designs, such as account-based plans?

Code section 9816(f)(2), ERISA section 716(f)(2), and PHS Act section 2799A–1(f)(2) provide that in the case of a covered individual scheduled to receive an item or service that is a specified item or service, the Secretaries may modify any timing requirements relating to the provision of the AEOB to such covered individual with respect to such specified item or service. Under the statute, the term “specified item or service” means an item or service that has low utilization or significant variation in costs (such as when furnished as part of a complex treatment), as specified by the Secretaries.²⁵ The statute also provides that any modification made by the Secretaries may not result in the provision of the notification after the covered individual has been furnished the specified item or service.²⁶ The Director of OPM (Director) may modify any timing requirements relating to the provision of the AEOB to a FEHB covered individual in the same manner as any modification is authorized to be made by the Secretaries, subject to OPM regulation and FEHB contract terms.

- What factors should the Departments and OPM consider when determining what items or services have low utilization or significant variation in costs (such as when furnished as part of a complex treatment) for the purposes of modifying AEOB timing requirements, and why?

- What are some examples of items or services that have low utilization or significant variation in costs (such as when furnished as part of a complex treatment) that the Departments and OPM should consider designating as specified items or services? Would designation of items or services as specified items or services vary by

provider or facility type, or other variables, and why?

- How should AEOB timing requirements be modified with respect to the specified items or services, and why?

PHS Act section 2799B–6 requires GFEs, among other things, to include the expected billing and diagnostic codes for such items or services. Code section 9816(f)(1), ERISA section 716(f)(1), and PHS Act section 2799A–1(f)(1) require AEOBs to include the contracted rate under a plan or coverage for items or services (based on the billing and diagnostic codes provided by the provider or facility) expected to be provided by participating providers or participating facilities. Following issuance of interim final rules for GFEs for uninsured (or self-pay) individuals, HHS received feedback from providers and facilities that it is not always possible to provide a diagnosis code without first seeing and evaluating an individual, particularly with respect to 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. In response to this feedback, HHS indicated in guidance that a provider or facility is required to provide a diagnosis code only where one is required for the calculation of the GFE for an uninsured (or self-pay) individual.²⁷

- The Departments and OPM are interested in plans’, issuers’, and carriers’ perspectives on whether a diagnosis code would be required for the calculation of the AEOB. Are there items or services for which a plan, issuer, or carrier would not be able to determine points of information such as: (1) the contracted rate; (2) the coverage level (that is, if the plan or issuer covers an item or service associated with one diagnosis at a higher rate than an item or service associated with another); or (3) whether an item or service is covered (that is, if the item or service is covered for one diagnosis but not another) for an item or service based on the service code and other information in the GFE in the absence of a diagnosis code?

In developing processes for the AEOB and GFE for covered individuals, some industry groups have suggested that the provider or facility should verify the individual’s enrollment status in a

health plan or coverage for the scheduled (or requested) items or services with the plan, issuer, or carrier. Based on the results of this verification, the provider or facility would either provide the individual with a GFE that meets the requirements for GFEs for uninsured (or self-pay) individuals under 45 CFR 149.610, or provide a GFE for covered individuals to the individual’s plan, issuer, or carrier.²⁸ The Departments and OPM are interested in feedback on the potential impacts on providers, facilities, plans, issuers, or carriers if this verification were to be required.

- What, if any, additional burden would be created by requiring providers, facilities, plans, issuers, and carriers to conduct (1) verification to determine whether an individual is uninsured, self-pay, or enrolled in a health plan or coverage for AEOB and GFE purposes; (2) verification of coverage for each item or service expected to be included in an AEOB or GFE; or (3) verification of coverage from multiple payers? Do providers and facilities already perform these types of verifications in the regular course of business, such that minimal additional burden would be imposed?

- Would it alleviate burden to allow providers and facilities, for purposes of verifying coverage, to rely on an individual’s representation regarding whether the individual is enrolled in a health plan or coverage and seeking to have a claim for the items or services submitted to the plan or coverage? What might be the implications of taking this approach?

On January 20, 2021, President Biden issued Executive Order 13985, “Advancing Racial Equity and Support for Underserved Communities Through the Federal Government,”²⁹ directing that as a policy matter, “the Federal government should pursue a comprehensive approach to advancing equity for all, including people of color and others who have been historically

²⁴ Code section 9832(c)(2), ERISA section 733(c)(2), PHS Act section 2791(c)(2) exclude limited-scope dental or vision benefits, if offered separately, from the Code, ERISA, and PHS Act requirements, respectively.

²⁵ Code section 9816(f)(2)(B), ERISA section 716(f)(2)(B), and PHS Act section 2799A–1(f)(2)(B).

²⁶ Code section 9816(f)(2)(A), ERISA section 716(f)(2)(A), and PHS Act section 2799A–1(f)(2)(A).

²⁷ FAQs About Consolidated Appropriations Act, 2021 Implementation—Good Faith Estimates (GFE) for Uninsured (or Self-Pay) Individuals—Part 2 (April 5, 2022), available at <https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Guidance-Good-Faith-Estimates-FAQ-Part-2.pdf>.

²⁸ See Council for Affordable Quality Healthcare, Inc. (CAQH) Committee on Operating Rules for Information Exchange (CORE), Establishing the Building Blocks for Price Transparency: Industry Guidance on Provider to Payer Approaches for Good Faith Estimate Exchanges (2021), available at https://www.caqh.org/sites/default/files/CORE%20-%20Price%20Transparency%20Whitepaper_v4.pdf.

²⁹ 86 FR 7009 (January 20, 2021), available at <https://www.govinfo.gov/content/pkg/FR-2021-01-25/pdf/2021-01753.pdf>.

underserved, marginalized, and adversely affected by persistent poverty and inequality.” Executive Order 13985 also directs each agency to assess whether, and to what extent, its programs and policies perpetuate systemic barriers to opportunities and benefits for people of color and other underserved communities.

Consistent with Executive Order 13985, the Departments and OPM are exploring how best to ensure that plans’, issuers’, and carriers’ communication to covered individuals is accessible, linguistically tailored, and at an appropriate literacy level. The Departments and OPM also remind plans, issuers, and carriers of any existing obligations to comply with requirements to provide effective communication (including materials disseminated by way of electronic and information technology for individuals with disabilities) under the Americans with Disabilities Act of 1990 and section 504 of the Rehabilitation Act of 1973, to provide meaningful access for individuals with limited English proficiency under title VI of the Civil Rights Act of 1964, and to comply with nondiscrimination requirements under section 1557 of the Affordable Care Act.

The Departments and OPM request public comment and feedback on the following questions:

- What unique barriers and challenges do underserved and marginalized communities face in understanding and accessing health care that the Departments and OPM should account for in implementing the AEOB and GFE requirements for covered individuals?

- What steps should the Departments and OPM consider to help ensure that all covered individuals, particularly those from underserved and marginalized communities, are aware of the opportunity to request AEOBs and GFEs and are able to utilize the information they receive in order to facilitate meaningful decision-making regarding their health care?

- Code section 9816(f), ERISA section 716(f), and PHS Act sections 2799A–1(f) and 2799B–6 require the AEOB and GFE to be provided in clear and understandable language. What additional approaches should be considered that would facilitate the provision of AEOBs and GFEs that are accessible, linguistically tailored, and at an appropriate literacy level for covered individuals, particularly those from underserved and marginalized communities and those with disabilities or limited English proficiency? Is there

any specific language or phrasing that should be used to help mitigate any potential consumer confusion?

- Should the Departments and OPM consider adopting AEOB language access requirements that are similar to the Departments’ existing requirements for group health plans and health insurance issuers, such as the internal claims and appeals and external review and Summary of Benefits and Coverage (SBC) requirements to provide oral language services, notices in non-English languages, and non-English language statements in English versions of notices indicating how to access language services?³⁰ If so, what is the best way to ensure that information about language access services is communicated far enough in advance to facilitate the provision of the AEOB in the language that is most accessible to the individual?

C. Economic Impacts

The Departments and OPM are interested in understanding the potential economic impacts of implementing requirements related to the AEOB and GFE for covered individuals.

- Specifically, the Departments and OPM are interested in estimates of the time and cost burdens on providers and facilities, and separately on plans, issuers, and carriers, for building and maintaining a standards-based API for the real-time exchange of AEOB and GFE data.

- The Departments and OPM also seek comment on the extent to which

³⁰ For example, the rules governing internal claims and appeals and external review processes under 26 CFR 54.9815–2719(e), 29 CFR 2590.715–2719(e), and 45 CFR 147.136(e) require plans and issuers to provide oral language services, notices in non-English languages, and non-English language statements in English versions of notices indicating how to access language services, with respect to notices sent to an address in a United States county where ten percent or more of the population residing in the county is literate only in the same non-English language. Additionally, the SBC and Uniform Glossary regulations at 26 CFR 54.9815–2715(a)(5), 29 CFR 2590.715–2715(a)(5), and 45 CFR 147.200(a)(5) require group health plans and health insurance issuers to provide the SBC in a culturally and linguistically appropriate manner, in accordance with the thresholds and standards of 26 CFR 54.9815–2719(e), 29 CFR 2590.715–2719(e), and 45 CFR 147.136(e). The regulations governing the style and format of summary plan descriptions (SPD) under ERISA at 29 CFR 2520.102–2 require the SPD to be provided in non-English languages if, for a plan that covers fewer than 100 participants, 25 percent or more of all plan participants are literate only in the same non-English language; or, for a plan that covers 100 or more participants, if the lesser of: (1) 500 or more participants; or (2) 10 percent or more of all plan participants are literate only in the same non-English language.

providers, facilities, plans, issuers, and carriers are building and maintaining standards-based APIs for multiple purposes, or already have standards-based APIs in place that they can leverage to implement AEOB and GFE requirements. The Departments and OPM are also interested in how establishing standards-based APIs for these purposes may align with other HHS program requirements to implement standards-based APIs, such as requirements for certain payers covered under the CMS *Interoperability and Patient Access* final rule³¹ to use specific standards to implement the Patient and Provider Access APIs, as well as requirements applicable to health IT developers with health IT modules certified to certain criteria under the ONC Health IT Certification Program that provide standards-based API technology to providers and facilities as part of certified health IT products. In circumstances in which providers, facilities, plans, issuers, and carriers use or plan to use standards-based API technology for multiple purposes, the Departments and OPM are interested in estimates of the time and cost burden specifically related to AEOB and GFE implementation, separated out from the total cost of implementing and using this technology for multiple purposes, to accurately reflect the burden of implementing AEOB and GFE requirements.

- What would be the costs for purchasing and implementing a standards-based API for the real-time exchange of AEOB and GFE data from a third-party vendor, compared to building standards-based API functionality in-house? What percent of providers, facilities, plans, issuers, and carriers are likely to either purchase and implement the API via a third-party vendor compared to building and implementing the API in-house? How do these costs compare to alternative methods of exchanging AEOB and GFE data, such as through an internet portal or by fax?

³¹ Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Interoperability and Patient Access for Medicare Advantage Organization and Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans on the Federally-Facilitated Exchanges, and Health Care Providers Final Rule, 85 FR 25510 (May 1, 2020), available at <https://www.govinfo.gov/content/pkg/FR-2020-05-01/pdf/2020-05050.pdf>.

In the *Requirements Related to Surprise Billing; Part II* interim final rule, HHS estimated that a total of 511,748 providers associated with health care facilities, individual physician practitioners, and wholly physician-owned private practices would incur the burden and costs associated with generating a GFE for uninsured (or self-pay) individuals.³²

- Are there factors that should be considered that might alter the number of providers and facilities that would incur the burden and cost of providing a GFE to plans, issuers, and carriers for covered individuals?

Some states have adopted laws requiring providers and facilities; or plans and issuers; or both providers and facilities and payers, to provide cost estimates to consumers before health care items or services are furnished. These laws vary with respect to the entities covered, the items or services to which requirements apply, how individualized the estimates must be, the format and timing of the estimates, the contents of the estimates, other accompanying requirements, and enforcement of these requirements. The Departments and OPM request feedback on the potential impacts of these policies.

- The Departments and OPM are interested in studies or other evidence related to the implementation and any effects of State laws that require entities to provide expected charges for health care items or services to consumers in advance of receiving these items or services. The Departments and OPM are particularly interested in publicly available studies or evidence.

- Is there other information that the Departments and OPM could find useful for quantifying the benefits of implementing requirements related to AEOB and GFE for covered individuals?

III. Collection of Information Requirements

Please note, this is a request for information (RFI) only. In accordance with the implementing regulations of the Paperwork Reduction Act of 1995 (PRA), specifically 5 CFR 1320.3(h)(4), this general solicitation is exempt from the PRA. Facts or opinions submitted in response to general solicitations of comments from the public, published in the **Federal Register** or other publications, regardless of the form or format thereof, provided that no person is required to supply specific information pertaining to the commenter, other than that necessary for self-identification, as a condition of

the agency's full consideration, are not generally considered information collections and therefore not subject to the PRA.

This RFI is issued solely for information and planning purposes; it does not constitute a Request for Proposal (RFP), applications, proposal abstracts, or quotations. This RFI does not commit the U.S. Government to contract for any supplies or services or make a grant award. Further, the Departments and OPM are not seeking proposals through this RFI and will not accept unsolicited proposals. Responders are advised that the U.S. Government will not pay for any information or administrative costs incurred in response to this RFI; all costs associated with responding to this RFI will be solely at the interested party's expense. The Departments and OPM note that not responding to this RFI does not preclude participation in any future procurement, if conducted. It is the responsibility of the potential responders to monitor this RFI announcement for additional information pertaining to this request. In addition, the Departments and OPM will not respond to questions about the policy issues raised in this RFI.

The Departments and OPM will actively consider all input as the Departments and OPM develop future regulatory proposals or future subregulatory policy guidance. The Departments and OPM may or may not choose to contact individual responders. These communications would be for the sole purpose of clarifying statements in the responders' written responses. Contractor support personnel may be used to review responses to this RFI. Responses to this notice are not offers and cannot be accepted by the U.S. Government to form a binding contract or issue a grant. Information obtained as a result of this RFI may be used by the U.S. Government for program planning on a non-attribution basis. Responders should not include any information that might be considered proprietary or confidential. This RFI should not be construed as a commitment or authorization to incur cost for which reimbursement would be required or sought. All submissions become U.S. Government property and will not be returned. In addition, the Departments and OPM may publicly post the public comments received, or a summary of those public comments.

Signed at Washington DC.

Laurie Bodenheimer,
Associate Director, Healthcare and Insurance, Office of Personnel Management.

Signed at Washington DC.

Rachel D. Levy,
Associate Chief Counsel (Employee Benefits, Exempt Organizations, and Employment Taxes) Internal Revenue Service, Department of the Treasury.

Signed at Washington DC.

Carol A. Weiser,
Benefits Tax Counsel, Department of the Treasury.

Signed at Washington DC.

Ali Khawar,
Acting Assistant Secretary, Employee Benefits Security Administration, U.S. Department of Labor.

Xavier Becerra,
Secretary, Department of Health and Human Services.

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DEPARTMENT OF LABOR

Employee Benefits Security Administration

29 CFR Part 2550

[Application No. D-12022]

Z-RIN 1210 ZA07

Initial Regulatory Flexibility Analysis for Proposed Amendment to Prohibited Transaction Class Exemption 84-14 (the QPAM Exemption)

AGENCY: Employee Benefits Security Administration, U.S. Department of Labor.

ACTION: Notice of Initial Regulatory Flexibility Analysis for the proposed amendment to the QPAM Exemption.

SUMMARY: This document gives notice of the Department's Initial Regulatory Flexibility Analysis for a proposed amendment to prohibited transaction class exemption 84-14 (the QPAM Exemption).

DATES: Written comments must be submitted to the Department by October 11, 2022.

ADDRESSES: All written comments concerning the Initial Regulatory Flexibility Analysis should be sent to the Office of Exemption Determinations through the Federal eRulemaking Portal and identified by Application No. D-12022:

Federal eRulemaking Portal: <https://www.regulations.gov> at Docket ID

³² 86 FR 56080 (October 7, 2021).