Progress Toward Advanced Explanation of Benefits (AEOB) Rulemaking and Implementation (December 2024 Update)

December 13, 2024

The No Surprises Act (NSA), which was enacted as part of the Consolidated Appropriations Act, 2021,[1] establishes critical consumer protections from surprise medical bills and new price transparency policies that empower patients. These new transparency policies include requirements that ensure consumers who schedule care in advance receive information about expected out-of-pocket costs for health care items and services before care is provided, rather than having to wait until after care is provided, and can also request pricing information before scheduling care. Providers and facilities generally must provide uninsured (or self-pay) individuals a personalized good faith estimate (GFE) of their expected charges upon scheduling care or at the individual's request. The NSA requires GFEs to include expected costs for each item or service, including those expected to be furnished by other providers (referred to as co-providers). For individuals with most commercial health insurance, upon scheduling care or at the individual's request, the NSA generally requires providers and facilities to send a GFE to the individual's health plan or issuer (payer). The payer must then use the GFE to create a personalized advanced explanation of benefits (AEOB) that includes the provider's or facility's expected charges, the portion the payer expects to cover, and the amount the individual is expected to pay. This information is intended to help consumers understand their expected costs before care is provided and allow them to budget and make cost-conscious decisions about their care. Consumers can also use GFEs or AEOBs to compare prices among providers.

Background

In April 2024, the Departments of Labor, Health and Human Services, and the Treasury (the Departments) and the Office of Personnel Management (OPM) published an update on progress toward rulemaking to implement the insured GFE and AEOB provisions of the NSA (April 2024 update).[2] In that update, the Departments and OPM outlined comments that were received in response to the *Advanced Explanation of Benefits and Good Faith Estimate for Covered Individuals Request for Information* (RFI) published on September 16, 2022,[3] and discussed how the Departments and OPM are considering that feedback as we work toward AEOB rulemaking. The April update also discussed a user research project that CMS conducted with the Digital Service at CMS (DSAC).[4] As part of that research, DSAC spoke with providers and payers of various sizes and other impacted stakeholders such as electronic health records vendors, clearinghouses, and standards development organizations to help the Departments and OPM gain a better understanding of their business processes and technical resources. Lastly, the Departments

[1] Pub. L. 116-260 (Dec. 27, 2020).
[2] The April 2024 update can be found at https://www.cms.gov/files/document/progress-aeob-rulemaking-implementation.pdf.
[3] Request for Information; Advanced Explanation of Benefits and Good Faith Estimate for Covered Individuals, 87 FR 56905 (September 16, 2022), available at https://www.federalregister.gov/documents/2022/09/16/2022-19798/request-for-information-advanced-explanation-of-benefits-and-good-faith-estimate-for-covered.
[4] More information can be found at https://www.cms.gov/digital-service.

and OPM expressed in the April 2024 update that a real-world demonstration of possible data transfer standards may provide helpful insight for future rulemaking.

Consumer research

As part of the Departments' and OPM's continued work toward AEOB rulemaking, following the April 2024 update, CMS conducted a second user research project with the DSAC to better understand how consumers plan and budget for medical expenses. This research will inform proposed requirements related to the content and format of the AEOB so that it is an understandable, actionable, and timely resource for patients and their families.

As part of this research, DSAC conducted user interviews with consumers of different ages, genders, races, and ethnicities from states across the U.S. Research participants, who were all enrolled in commercial insurance, responded to questions about their own experiences navigating their health insurance coverage and budgeting for medical expenses for themselves and their families. Participants discussed what type of information they need to plan for medical expenses and how far in advance they need the information. Participants were also presented with prototype AEOBs developed for the purpose of consumer testing and answered questions about how well they understood the prototypes and how they might use specific pieces of information they contained.

Participants expressed a general uneasiness about navigating their insurance coverage and understanding their health care costs. They overwhelmingly supported having cost estimates in advance of receiving medical care and expressed a desire to have as much upfront information as possible. Most participants understood that an estimate can change during the course of care. However, all participants mentioned that the most important factor in an estimate is an accurate representation of how much a service would cost them out of pocket. Some participants also emphasized the importance of including a breakdown of their costs based on the provider's billed amount, how much their insurance will pay, progress toward their deductible, and relevant medical billing codes in the event of a subsequent billing issue. This research underscored the importance of standardized, understandable, and accurate cost information in advance of care.

Industry progress on developing electronic standards for exchanging GFE and AEOB data

As noted in the April update, research conducted by DSAC showed an overwhelming preference among the payers and providers responsible for producing an AEOB that the Departments and OPM propose an industry-wide data exchange standard for the receipt of GFEs by payers. Most commenters weighing in on this issue in response to the RFI agreed. However, a number of commenters also raised important considerations related to naming a single industry-wide standard. Several commenters cautioned against relying on a single standard or technology if it is not fully functional by the compliance date and others suggested adoption of a specific data exchange standard may be overly burdensome for some stakeholders. On the other hand, without unifying standards, there is a risk that the insured GFE and AEOB provisions will be harder to implement and may ultimately be less successful, as providers and payers may adopt solutions that are not interoperable. Issues with interoperability could ultimately yield AEOBs for patients that are not timely, accurate, useful, or consistent across different payers or settings of care. The Departments and OPM agree these are important issues and are taking them into consideration.

The Departments are closely monitoring industry's progress toward the development and testing of standards for the exchange of GFE data from providers to payers. The Departments and OPM are aware of three options, discussed below, that have potential for providers to transmit GFE information to payers. As the Departments and OPM advance towards the rulemaking phase of implementation, we expect industry stakeholders to make additional information available about the viability of each of the options, including via public comments in response to a notice of proposed rulemaking. In evaluating each option, the Departments and OPM are weighing considerations such as the relative cost and burden to providers and payers to implement and use each of these standards; whether each standard has been tested in real-world settings, promotes interoperability and minimizes manual interventions, and efficiently and accurately transmits information; and whether there is evidence and consensus that the standard is viable when the Departments and OPM propose regulations. Below, we discuss each option, highlight some of the standards development work that remains to be done, and indicate the information the Departments and OPM expect industry to make available.

X12 837 Modified to Include a "Faux Claim" Indicator

One option is to leverage the existing electronic data standard for sending medical claims to transmit GFEs from providers to payers. Specifically, this approach would use the X12 837 version 5010 health care claim transaction with a "faux claim" indicator to alert the payer that the transaction is for a prospective estimate, as opposed to a post-service claim. The American Hospital Association (AHA) and AHIP convened a workgroup to consider this approach. The workgroup meets regularly to identify the operational changes necessary for the 837 transaction to support GFE transmission, given that this standard is intended for electronic claims. Representatives from the Departments and OPM attend these workgroup discussions to better understand provider and payer perspectives as well as in-depth technical and operational considerations associated with this approach.

The Departments and OPM understand from industry stakeholders that modifying the existing X12 837 version 5010 transaction to include a "faux claim" indicator may be the least costly option for many stakeholders and may require the fewest changes to administrative workflows. This is largely because the current version of the X12 837 claims transaction, version 5010, has been the data standard required under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) administrative simplification requirements for electronic claims transactions since 2012.[5] According to the Council for Affordable Quality Healthcare (CAQH) 2023 Index Report, 98% of medical claims in the U.S. are submitted electronically using the HIPAA-mandated X12 837 claims transaction.[6] Due to the mass adoption of the 837 transaction across industry, using a modified 837 to transmit GFE information from providers to payers would leverage existing workflows, standards, and technologies and minimize the costs associated with implementing a new standard. Additionally, many RFI commenters suggested that the GFE can essentially be thought of as a pre-claim that payers will use to create an AEOB the way a post-care claim is used to create an Explanation of Benefits.

However, the Departments and OPM need more information about how the existing 837 claims transaction would be modified to support this new functionality. For example, the Departments and

[5] More information can be found at https://www.cms.gov/priorities/key-initiatives/burden-reduction/administrative-simplification/hipaa/adopted-standards-operating-rules.
[6] CAQH 2023 Index Report, available at https://www.caqh.org/hubfs/43908627/drupal/2024-01/2023_CAQH_Index_Report.pdf.

OPM need to resolve questions about its functionality and the implications for providers' workflows and systems, and to understand the level of effort and time required for providers, payers, and other stakeholders to implement it. The Departments and OPM also need further insight into whether there are plans to test the modified 837 and how industry stakeholders would transition from the modified 837 transaction to the X370 transaction (discussed below) without causing disruptions.

X12 X370

Another X12 option is the X370 transaction currently under development for transmitting GFEs from providers to payers. The X370 transaction would be based on the existing 837I (Institutional) and 837P (Professional) health care claims standards combined into a single standard.[7] CMS reviewed an early proposal for the X370 and provided comments to X12 in February 2024. As with the modified 837, the X370 would leverage existing technology and workflows already being used by providers and payers. As such, adopting this option may help minimize administrative and financial burden on providers by limiting the extent to which they would need to update back-end business processes and technology. On the other hand, the X370 is a new transaction. As such, many details about this transaction are not yet known, including its relative implementation cost.

Currently, the Departments and OPM, as well as other industry stakeholders, including many provider organizations, have limited visibility into how the X370 will function or the level of effort required for implementation because it is not yet available for public review. For example, it is unclear to the Departments and OPM whether the X370 GFE use case would support providers' ability to send GFEs to payers individually without requiring a convening provider[8] to package multiple GFEs from co-providers first, or for a convening provider to collect GFEs from co-providers and submit them to a payer as a bundle, or both workflows. More insight into the development of the X370 GFE use case, as well as more information about the timeline for its release and adoption as an implementable standard, would help the Departments and OPM evaluate the X370 as a viable standard for transmitting GFE data from providers to payers.

Finally, it is the Departments' and OPM's understanding that neither of the X12 options (i.e., the modified 837 and the X370) support communication between providers. Even if co-providers submit GFEs directly to payers without going through a convening provider, providers would need to communicate with each other about the need to create a GFE, patient information, the expected service, and an identifier that allows payers to link multiple GFEs from different providers together, among other things. Given that, if the Departments and OPM were to require the use of either of these standards, providers may need to adopt other nonstandard or manual approaches to coordinate among convening and co-providers as they prepare to submit GFEs using the selected standard. The Departments and OPM heard significant concerns from RFI commenters about the challenges providers would face in communicating a high volume of information with other providers without a standardized way of doing

[7] X12, Rationale Behind X12's Health Care Good Faith Estimate (X370) (Feb 2, 2024), available at https://x12.org/sites/default/files/documents/2024-02-15_x370_vs_predetermination.pdf.

[8] For purposes of the regulations implementing the good faith estimate for uninsured (or self-pay) individuals, a convening provider or facility is "the provider or facility who receives the initial request for a good faith estimate from an uninsured (or self-pay) individual and who is or, in the case of a request, would be responsible for scheduling the primary item or service." 45 CFR 149.610(a)(2)(ii).

so. The Departments and OPM need more information about how these transactions can be automated and efficient under both the modified 837 and X370 options.

HL7 Da Vinci PCT IG (FHIR)

The third option, which we discussed in the April update, is the Health Level 7 (HL7) Da Vinci Patient Cost Transparency (PCT) Implementation Guide (IG), which uses a Fast Healthcare Interoperability Resources (FHIR)-based Application Programming Interface (API) to support the exchange of GFE and AEOB information. On March 30, 2023, the HL7 Da Vinci Workgroup published the PCT IG Release 1, which includes detailed guidance for providers to transmit GFEs to payers, for payers to transmit AEOBs to patients, and optionally, for payers to return AEOBs to the initiating provider using HL7 FHIR-based standards.[9] The PCT Workgroup has been working toward publishing a second release of the IG and testing it in clinical settings. The Departments and OPM continue to attend workgroup meetings and monitor the IG's progress.

Adoption of an HL7 FHIR-based standard would align with HHS and CMS strategic priorities to improve patient access to their health information to better manage their own health care, and for payers and providers to exchange information to better manage patient care, particularly with respect to patient outcomes and quality of care. For example, HHS has finalized requirements for certain payers to implement and maintain HL7 FHIR-based APIs to improve the electronic exchange of health care data, as well as to streamline prior authorization processes.[10] Under the ONC Health IT Certification Program,[11] HHS also engages in certification of health IT modules for compliance with FHIR standards for exchange of electronic health information,[12] and has proposed additional certification criteria for the exchange of certain administrative data using FHIR-based implementation specifications in recent rulemaking activities.[13] HL7 FHIR-based standards are open-source standards that anyone can access, freely implement, and recommend changes to through a consensus-based process.[14] These standards support the transmission of health data in a standard, structured, but flexible format. The flexibility and transparency of HL7 FHIR is a major strength and would help move industry toward a more interoperable health care system with input from across industry stakeholders.[15]

However, even as the health care industry has rapidly embraced FHIR, it was developed more recently and has not been as widely adopted as X12 for exchanging information from providers to payers. For this reason, implementing a FHIR-based standard for this GFE transaction could require more significant investment by providers and payers, including purchasing and implementing new technology systems and modifying existing workflows. To weigh the benefits of a FHIR-based solution against other

[9] Patient Cost Transparency Implementation Guide (March 30, 2023), available at https://build.fhir.org/ig/HL7/davinci-pct/.
[10] CMS Interoperability and Prior Authorization Final Rule CMS-0057-F (Jan 17, 2024), available at https://www.cms.gov/newsroom/fact-sheets/cms-interoperability-and-prior-authorization-final-rule-cms-0057-f.
[11] See https://www.healthit.gov/topic/certification-ehrs/about-onc-health-it-certification-program.
[12] See the "Standardized API for patient and population services" at 45 CFR 170.315(g)(10), available at: https://www.healthit.gov/test-method/standardized-api-patient-and-population-services.
[13] See the ASTP/ONC HTI-2 Notice of Proposed Rulemaking (89 FR 63498), available at: https://www.federalregister.gov/documents/2024/08/05/2024-14975/health-data-technology-and-interoperability-patient-engagement-information-sharing-and-public-health.
[14] What Is FHIR®?, available at https://www.healthit.gov/sites/default/files/2019-08/ONCFHIRFSWhatIsFHIR.pdf.
[15] For more information about FHIR, see https://www.healthit.gov/topic/standards-technology/standards/fhir.

potentially less costly options, more information about the expected costs relative to the interoperability benefits is needed. The Departments and OPM are hopeful that HL7 Da Vinci's efforts to test these standards in real-world settings will yield useful information about implementation cost and level of effort for the Departments' and OPM's analysis, but that testing has not yet begun.

Additionally, more information about the PCT IG's functionality is needed. For example, unlike both of the X12 options, the PCT IG includes a solution for coordinating and streamlining the exchange of GFE information between convening and co-providers. It supports the ability for a "coordination platform" to facilitate this communication and to gather multiple GFEs for a given period of care and submit them as a bundle to a payer. However, these coordination platforms do not yet exist. According to HL7, entities that could operate as coordination platforms include clearinghouses, vendors, hospital systems, or even payers. The Departments and OPM need more information about what the scope of these platforms would be and how they would be developed in order to support this communication between convening and co-providers.

Finally, the Departments and OPM expect payers will leverage and modify their existing adjudication systems to process GFEs into AEOBs. Although many adjudication systems are proprietary, they are built to accommodate existing X12 837 claims data transactions. As such, a GFE sent using a FHIR-based API would likely need to be mapped to some extent to the existing X12 837 standard for processing. Progress toward such mapping has been slow, and it is not clear what the implications would be for the PCT IG if there were no standardized data mapping between these standards.

Looking Ahead

The Departments and OPM look forward to utilizing information gathered from the user research project with consumers and DSAC to develop proposed requirements that maximize the meaningfulness and usability of AEOBs for consumers. The Departments and OPM are optimistic about the progress industry has made toward developing options for establishing an industry-wide data standard for transmitting GFEs. The exchange of information using consensus-based standards is an important part of ensuring that AEOBs provide meaningful information to patients. These standards may be most effective if they are developed and tested by the payers and providers who will ultimately use them. Continued progress on these options and industry participation are necessary for the Departments and OPM to determine the viability of each of these options and to assess the relative costs and burdens associated with adopting each. In addition, the Departments and OPM recognize that any policy approach should consider how to allow for innovation in this area over time. Therefore, we are also considering whether there are hybrid approaches to use or allow for different standards that would maximize innovation pathways for industry. The Departments and OPM look forward to continuing to engage with industry partners and other stakeholders as we work toward rulemaking to implement requirements for accurate and timely advanced cost estimates for consumers.