ACS AMERICAN COLLEGE OF SURGEONS

November 14, 2022

Xavier Becerra
Secretary
U.S. Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Martin J. Walsh
Secretary
U.S. Department of Labor
200 Constitution Avenue NW
Washington, DC 20210

Janet Yellen
Secretary
U.S. Department of the Treasury
1500 Pennsylvania Avenue NW
Washington, DC 20220

RE: Request for Information; Advanced Explanation of Benefits and Good Faith Estimate for Covered Individuals (CMS-9900-NC)

Dear Secretaries Becerra, Walsh, and Yellen:

On behalf of the more than 84,000 members of the American College of Surgeons (ACS), I thank you for the opportunity to comment on provisions of the No Surprises Act (NSA) related to good faith estimates (GFEs) and advanced explanations of benefits (AEOBs). I welcome this chance to provide comments on the potential benefits, burdens and challenges associated with implementation of the transparency focused provisions of the No Surprises Act.

The ACS is a scientific and educational association of surgeons founded in 1913 to improve the quality of care for the surgical patient by setting high standards for surgical education and practice. With our 100-year history in developing policy recommendations to optimize the delivery of surgical services, lower costs, improve program integrity, and increase the value of healthcare in the United Sates, we welcome this opportunity to provide our insights to the implementation of the NSA.

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The detailed questions in the RFI demonstrate the recognition of the complexity of implementation and the danger of placing undue burden on both plans and providers. The ACS appreciates the measured approach and sees an additional potential pitfall of implementation bringing greater confusion rather than clarity to patients if multiple methods result in different estimated prices.

ACS provided comments in December 2021 focused on the GFE for self-pay and uninsured individuals and many of those comments are pertinent to the implementation of AEOBs for insured patients as well. We reiterate and expand on those ideas as part of our response to this RFI as well as addressing several of the specific questions posed. Providing reasonable, comparable estimates to all patients—no matter their insurance type or status—should remain a priority and is key to price transparency efforts in general. A unified strategy with standardized definitions for price information has the potential to reduce some of the complexity and mystery often experienced by patients shopping for or undergoing care and is furthermore less burdensome to implement than having a different strategy and definitions for each application.

Standardized Methods for Developing GFEs and AEOBs

The NSA creates new requirements on facilities, physicians, and other health providers to produce GFEs upon request, upon scheduling delivery of an item or service, or when obtaining consent for the provision of out-of-network care. Depending on the insurance status of the patient, the scope of what must be included in the GFE and to whom it is delivered may differ. In the case of an uninsured or self-pay patient for example, the convening provider is required to collect estimates of not only their charges but also all expected charges for any item or service that is reasonably expected to be provided in conjunction by another provider or facility and that estimate is provided directly to the patient (although enforcement has been deferred for failing to provide information on co-providers and co-facilities through the end of 2022). On the other hand, in the case of an insured patient, a surgeon is required to produce a GFE of their own charges and transmit the estimate to the insurer for purposes of producing an AEOB reflecting the patient's coverage and out of pocket responsibilities. These GFEs must include key information such as the expected billing and diagnostic codes.

Currently, there is little assurance that price estimates provided to patients will be comparable from delivery system to delivery system or that estimates for the same delivery system will be comparable between insurers. This is because there is currently no standard definition of what items or services are "reasonably expected" to be included. The ACS strongly supports the development of standards for what items and services are included in such estimates, particularly in the case of complex care such as surgical procedures, and believes that this is most readily achieved through the adoption of standard episode definitions.

Consistency in Uninsured/Self-Pay GFEs

Without standard episode definitions, a surgeon acting as the convening provider would need to develop a list of all other services and items that would be delivered in relation to

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the surgical procedure in question. Once this list was developed, the surgeon would need to know in advance which specific providers would deliver these services in the facility where the procedure takes place (and potentially in the post-hospitalization period). This process would be excessively burdensome, and the information simply might not be available to the physician, especially not within the timeframe outlined for provision of the GFE.

For uninsured and self-pay patients, the lack of comparability in estimates is the logical consequence of putting the responsibility of collecting information on the convening provider or facility. The GFE for uninsured and self-pay individuals requires the convening health care facility or the convening health care provider to know in advance not only what services will be provided during the course of the patient's care, but also which specific physician or provider will be delivering each service. In many cases, especially for more complex care such as a surgical operation, the surgeon or facility scheduling the care will have no way of knowing in advance who will be providing services and therefore billing for their services. They also may not recognize all of the services involved and are therefore unlikely to fully recognize the potentially substantial number of different TINs billing for various services that could be considered "reasonably expected".

Consistency in GFEs and AEOBs for Insured Patients

The problem for insured patients is similar, in that various physicians, hospitals, or other providers might have differing definitions of what charges are reasonably related to the care being scheduled and should therefore be included in the GFE provided to the insurer. If a patient with multiple care options available were to then shop around and request AEOBs from their insurer for the same procedure at different hospitals, they could get estimates reflecting different sets of included and excluded items and services.

Another consideration in the case of AEOBs for insured patients is the question of who will be in charge of requesting and collecting all necessary GFEs from the potentially large list of clinicians and facilities involved in care. As noted, the process of producing the GFE for uninsured patients is complicated due to the need to first determine who the convening entity is, which specific other entities will be involved in the care of the patient for the service in question, and then tasking the convening entity with collecting detailed estimates from each individual provider or facility. For a surgical procedure, the surgeon will likely frequently receive the initial request for the GFE and will therefore be considered the Convening Health Care Provider for uninsured patients under the rule as written. In cases where the surgeon is employed by the hospital or is part of an integrated health system, this may not cause excessive burden. However, surgeons in private practice or employed outside of the hospital setting may not have access to the information necessary to determine who will be providing many of the services associated with the patient's inpatient and post-acute care, and will therefore find it time consuming, prohibitively expensive, or simply impossible to assemble the long list of estimates necessary for a complete GFE. **For that reason, we urge the departments not to adopt a similar convening entity approach to the collection of GFEs for AEOB development.** In addition to creating unnecessary burden on physicians, such an approach would lead to less

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reliable AEOBs, since physicians lack access to the claims data and other information needed.

A Phased Approach for GFE and AEOB Generation

Pricing in healthcare is currently extremely opaque for patients in most cases and often also for physicians, despite multiple state and federal efforts to increase price transparency. It is therefore important that the process to increase transparency begin without undue delay. To accomplish as much as possible in a meaningful manner, it would make sense to utilize a phased approach, beginning with single services or simple episodes with little variation that can be estimated quickly, reliably, and accurately such as a wellness visit, diagnostic test, or a simple procedure in the office. AEOBs in such cases could be a matter of collecting one or a small number billing codes and transmitting them to the insurer to prepare the AEOB. For many diagnoses and conditions, such as cancer or a major surgical procedure, it may not be as straightforward to produce an estimate that is meaningful to patients.

More complex care often comes with greater variation since it might involve the skill and expertise of a large team and may occur across multiple sites of service. AEOBs and GFEs developed for these more complex services should reflect this likelihood of variation. This can be accomplished using an episode grouper to produce the average price along with information on likely variation. Developing such estimates will take time and should be phased in, along with a continuation of the deferral of enforcement of GFEs and AEOBs that lack information on all ancillary services.

ACS believes that it would be feasible to begin providing ranges of estimated costs for insured consumers quickly if standardized episode definitions are used as the basis for such estimates. The use of standard definitions of what services are associated with a given diagnosis would create a groundwork for these comparisons which could then be used to create a ratebook-style range of what patients with similar circumstances have actually paid for similar care.

This estimate could be populated with as much information as feasible for the specific patient, care team, and insurance product, and over time AEOBs using this method would become increasingly precise. This strategy could be applied to both GFEs for uninsured and self-pay patents and AEOBs for insured patients. This could further facilitate ongoing price transparency efforts while reducing unnecessary burdens that add little value. The ACS outlined a potential process for the development of AEOB ratebooks in our December 6, 2021, comment letter in response to the "Requirements Related to Surprise Billing; Part II[1]" interim final rule and we would refer you to that letter for greater detail.

AEOB Development for Care with Significant Variation

The RFI includes questions on what factors should be considered when determining

[1] https://www.facs.org/media/kdzivnll/acs-nsa-part-ii-gfe-comment-letter.pdf

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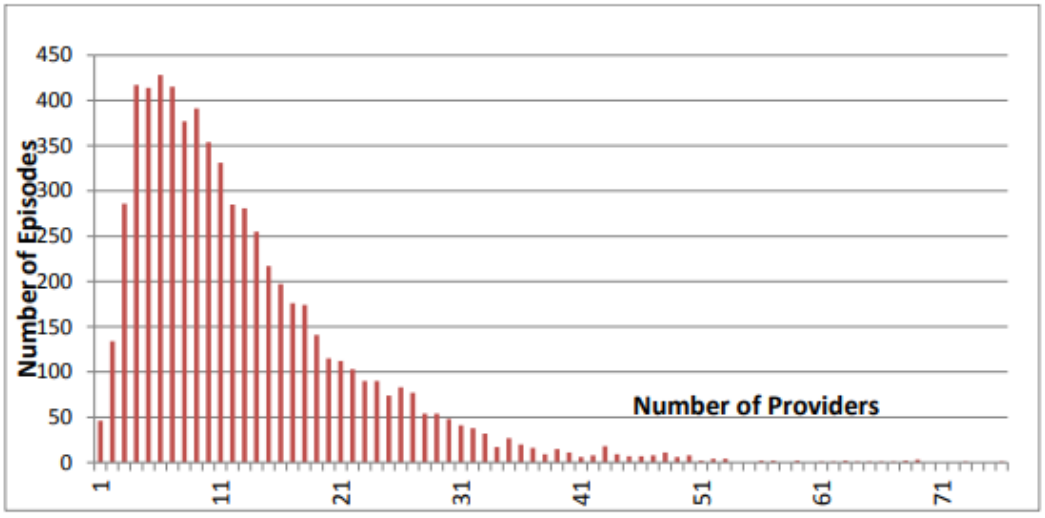
what items or services have low utilization or significant variation in costs, such as when furnished as part of a complex treatment, for the purposes of modifying AEOB timing requirements. What are some examples of items or services that have low utilization or significant variation in costs and how should AEOB timing requirements be modified with respect to the specified items or services?
Beyond modification of timing requirements, there is a strong argument for creating a separate process for GFE and AEOB development in the case of complex care with significant variation. Most major surgical procedures would likely fall into this category as there are numerous decision points in the care pathway.

Using the Episode Grouper for Medicare (EGM) grouping tool as maintained by the not-for-profit PACES Center for Value in Health to look retrospectively at colectomy surgery on Medicare patients shows that a surprising number of distinct parties are involved in the provision of care for a single beneficiary. A typical colectomy episode will include one or more surgeons, anesthesiologists, pathologists, radiologists, and other consultants along with multiple locations of care such as imaging centers, lab sites, hospitals, and operating suites. While the total number of billing taxpayer identification numbers (TINs)/national provider identifiers (NPIs) for the episodes included in this analysis was typically fewer than 15, a significant number of patients experienced episodes of care involving teams of 20, 30, 40 or more.

Figure 1. Distribution of Providers in Colectomy Episodes



Digging deeper into this example shows that even in Medicare in a single region, where payment amounts vary little, the total price of a colectomy for a cancer diagnosis can vary greatly based on the severity of the patient, especially in the pre- and post-facility phases of care where sicker patients with more complex needs require additional resources to prepare for and recover from surgery. An AEOB that fails to acknowledge that a sicker patient is more likely to require additional services before or after surgery would be incomplete and

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therefore more likely to lead to surprises when final bills are received. In the case of colectomy for cancer outlined in the table nearly 55 percent of the variation in price would be missed if the AEOB focused solely on the intra-facility phase of care.

Table 1. Mean Episode Allowed Amounts of Services by Phase of Surgery

	All	**Low Severity, HCC score, 0-1 (382 episodes)**	**Medium Severity, HCC score, 1-3 (584 episodes)**	**High Severity, HCC score 3+ (641 episodes)**
Number of Episodes	3,182	918	1,275	989
Mean Total Episode	$29,954	$26,605	$27,018	$36,850
Pre-facility	$780	$679	$650	$1,036
Intra-facility	$23,175	$21,865	$21,765	$26,209
Post-facility	$6,479	$4,891	$4,859	$9,741

Figure two below visualizes the same episode in a different way to further demonstrate the difficulty of including all relevant items and services accurately in advance of care. As you can see there are many items and services that may or may not be included and others that could be substituted. Capturing this exactly in advance is impossible but providing patients with a typical episode and letting them know in advance how the care pathway (and subsequently the price of care) might vary is important in avoiding unnecessary surprises.

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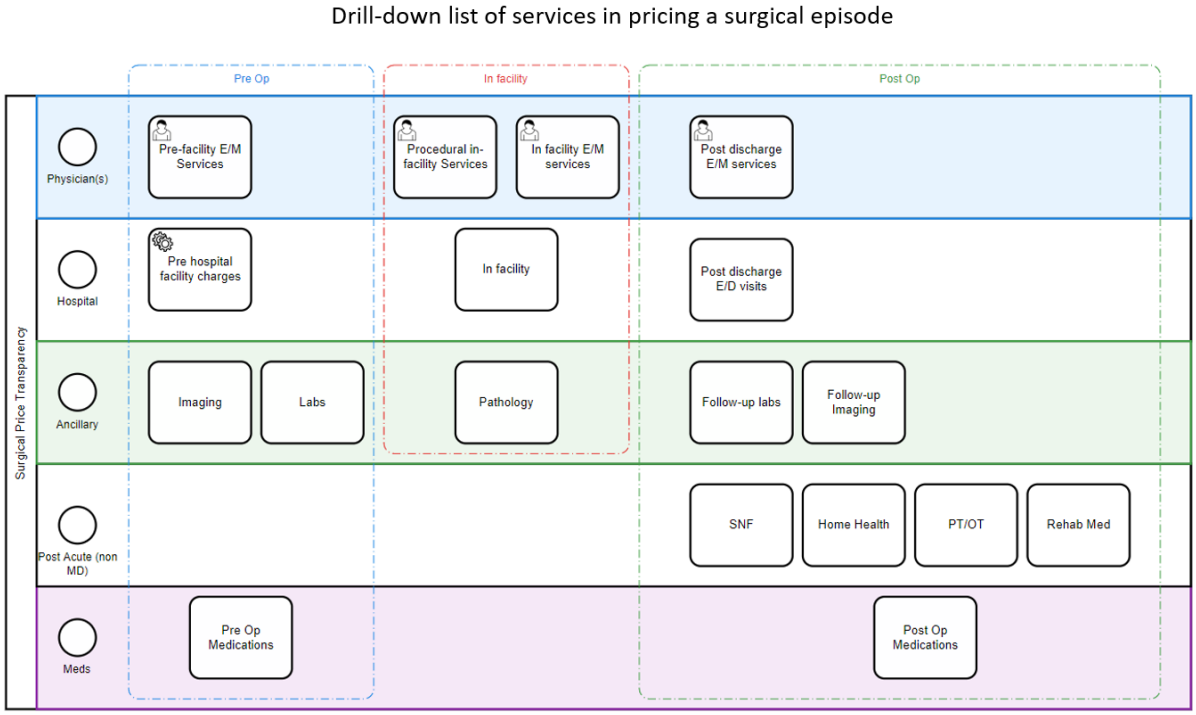
Figure 2. Services in Pricing a Surgical Episode by Phase of Care



The Departments previously acknowledged the challenges related to the secure transmission of GFE information between providers and facilities and announced a one-year discretion of enforcement in cases where information from co-providers and facilities is not included in the GFE for uninsured and self-pay patients. However, as noted previously, the difficulties with these requirements go beyond the lack of a secure process for the transmission of GFE information. As illustrated by Figure 3 below, which depicts a treatment pathway for a patient with breast cancer, the patient journey can be quite complex, and some aspects and decisions associated with a particular treatment may not—or cannot—occur in advance of the date of service.

If a patient recently diagnosed with breast cancer were to request a GFE from his or her physician, for example, it would be nearly impossible to provide one that encompasses the full course of treatment that meets the requirements of this regulation. There would be a great deal of uncertainty as the care pathway has multiple decision points which can lead to drastically different prognoses and care requirements. Even if the exact care pathway could be determined at the time of scheduling care, it is still unlikely that the full team of ancillary providers involved would be known. The uncertainty of this pathway furthermore might require different or additional team members with significantly higher or lower cost than originally foreseen.

In the case of charges "substantially in excess" of the GFE, the law provides for a process of enforced patient-provider dispute resolution. The IFR defines substantially in excess as "an amount that is at least $400 more than the total amount of expected charges for the

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provider or facility listed on the good faith estimate," setting a static target rather than a percent. While $400 may appear to be a reasonable amount, as demonstrated above, there is a large degree of uncertainty associated with the pathway, care team and costs of complex care episodes, which can cause the cost of an episode to easily vary by amounts substantially greater than this.

As an alternative, the process map outlined in Figures 4a, 4b, and 4c show an alternative pathway for developing the list of services and related codes used to populate a GFE and ultimately, in the case of the insured patient, an AEOB. In the case of a simple service or single encounter the process would be the straightforward development and transmittal of the GFE to the plan or patient directly. However, in the case of a more complex encounter or episode which could have significant variation across patients, the clinician could instead collect a subset of necessary information such as the diagnostic codes and triggering service codes along with pertinent information on the patient and first use an episode grouper. The episode grouper, such as the one maintained by the PACES Center, would then generate the actual list of service codes likely to be billed in conjunction with the care in question based on the characteristics of the patient, derived from historical data from the actual experiences of real patients. This list could then be used by the plan or insurer to develop an AEOB with a more accurate typical estimate.

The AEOB as currently envisioned in statute and proposed regulations would seem to reflect an estimate for the ideal patient. However, patients are individuals with unique needs, differing health and socioeconomic status, disease progression, and other factors that contribute to different treatment needs and outcomes. Use of the PACES grouper to show a typical price will already be more accurate than providers scrambling to predict what care will be needed in complex episodes, but it could also provide the additional information necessary to reflect this variation in utilization and subsequent price. By showing not only the mean price estimate, but also examples of how much this type of treatment would cost in the most efficient, straightforward instance as well as in a case with unforeseen complications or the need for additional post-acute care. PACES offers the ability to generate an observed to expected personalized patient report which could account for variation. Arming patients with such examples and information in advance would be an excellent way to reduce surprises when bills are received, which is a core goal of the NSA.

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Figure 3.

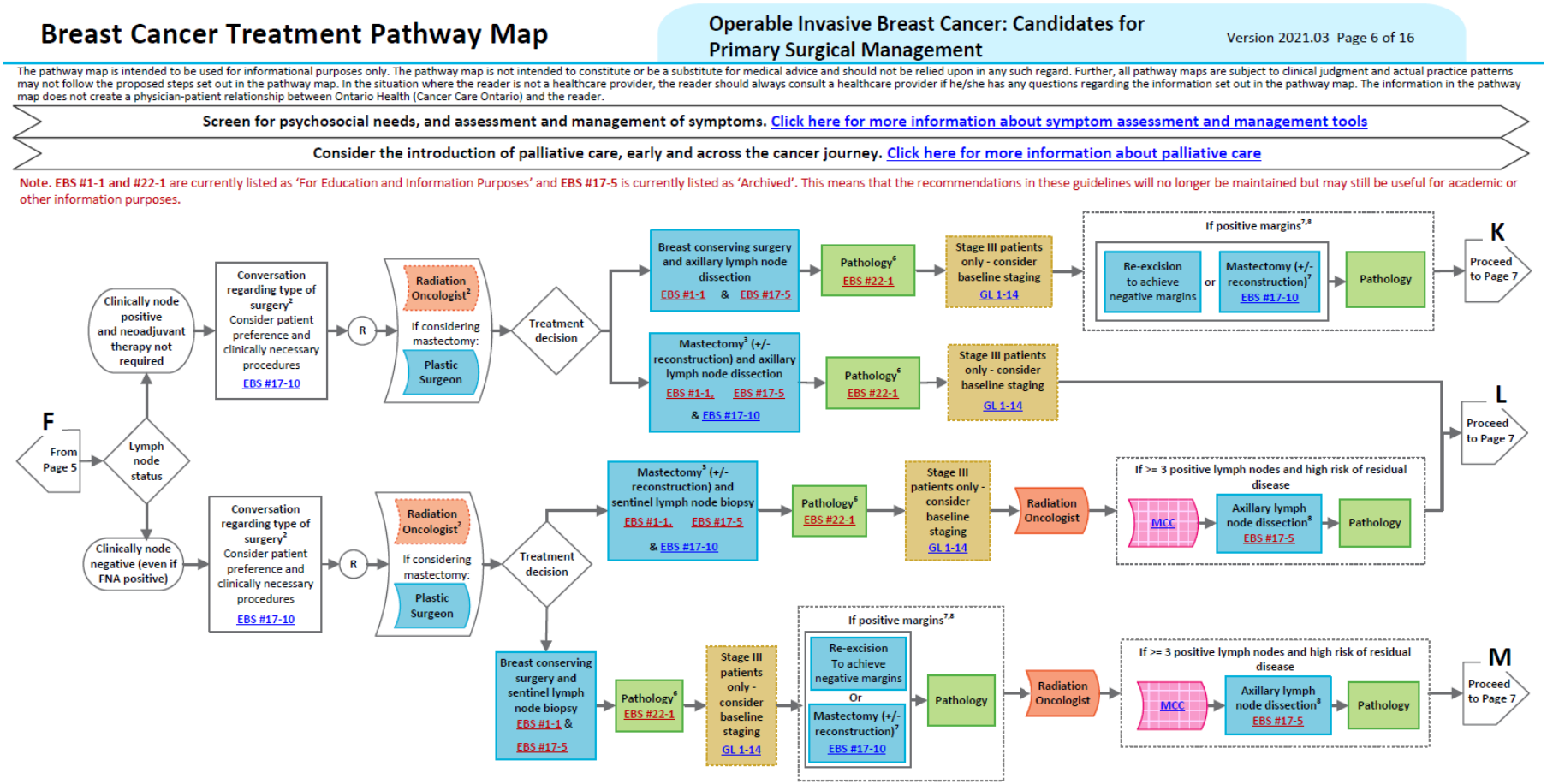

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Figure 4a.

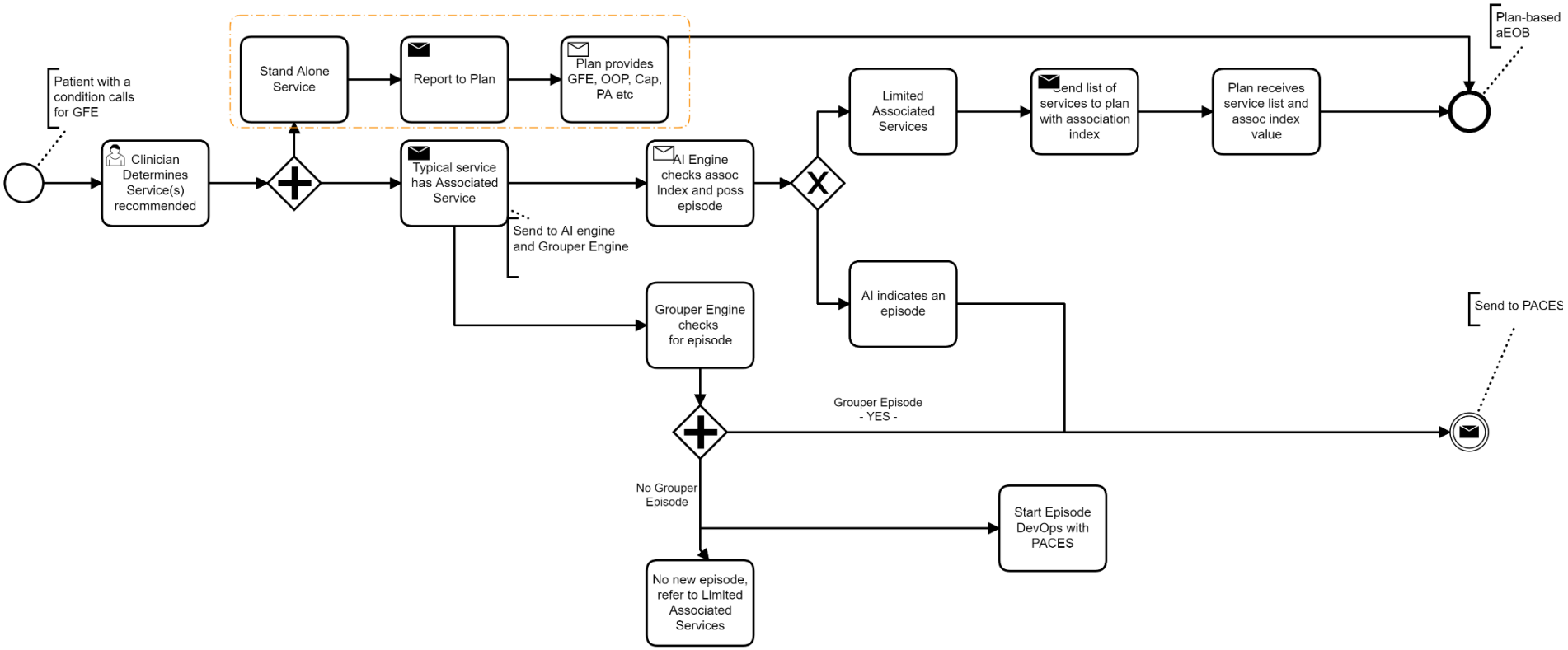

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Figure 4b.

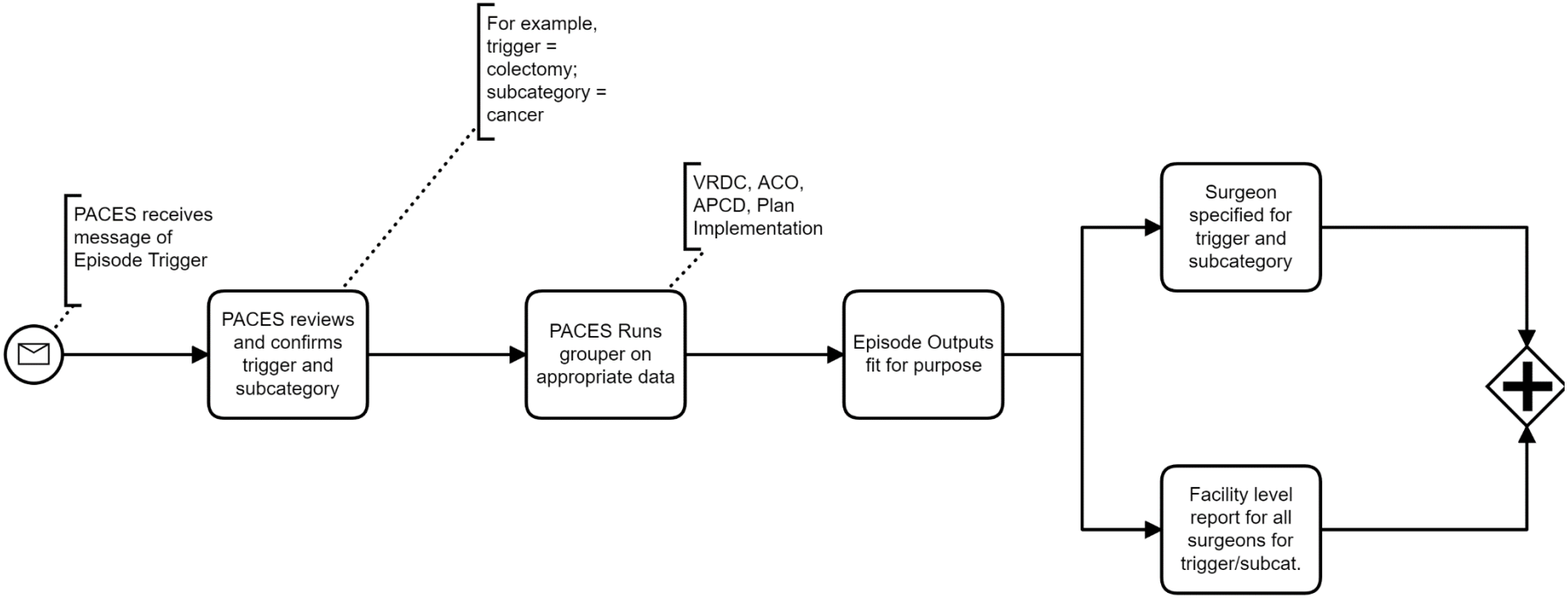

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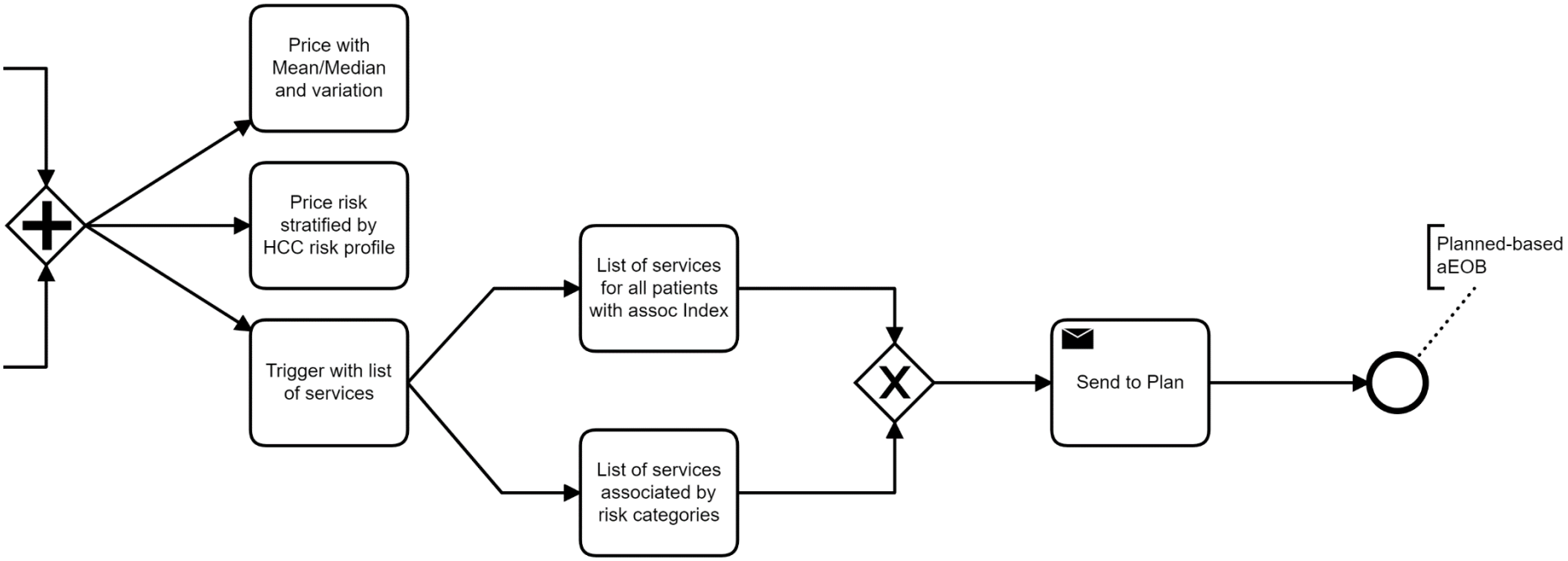
Figure 4c.



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Aligning AEOB Requirements with other Price and Cost Efforts

There are significant similarities between the requirements of the Transparency in Coverage regulations and the requirements for AEOBs for insured patients under the No Surprises Act. This is an obvious area for regulatory alignment. The goals of allowing patients to compare quality and cost of services between physicians, facilities and systems is closely related to the goal of providing up-front cost estimates to avoid unexpected medical bills. **Therefore, the logic used to create GFEs and AEOBs should be as close as possible to that which is used to create price transparency and ideally would be identical. Failing to align these provisions would not only be a missed opportunity in expanding transparency in price but would also potentially result in unnecessary burdens on all parties involved, including patients.** Without a single price transparency and estimation method, patients would need to first compare providers on price and quality more generally and then get estimates of their specific out-of-pocket responsibilities based on a different set of definitions that likely would vary greatly.

As noted in our previous comments on the Transparency in Coverage rule[2], ACS agrees that price disclosure can inform and empower consumers whether they shop for items and services individually or as part of service packages. ACS continues to assert that the episode of care is the appropriate unit of comparison for complex healthcare. Further, the definition of the episode and which services are included in the analysis should be the same for purposes of price transparency, for patient cost estimates such as the GFE and AEOB, and even for assessments in payment programs such as episode-based cost measures in order to avoid potential confusion.

It is also vital to ensure that the episode definitions are inclusive enough to paint the most accurate picture of the full price of care. Some episode groupers currently in use for payment or other purposes are either too exclusive (i.e., focused only on the perfect episode or on services utilized in all such episodes) or too inclusive, grouping all costs over a time window (perhaps with a few exclusions) whether or not the charges are plausibly associated with the treatment in question. For this reason, the ACS supports the episode grouper maintained by the PACES Center which we believe strikes the proper balance between inclusion of related costs and exclusion of extraneous ones.

Other RFI Questions

The Departments are seeking information on what issues to 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 Departments note that much information exchange between providers and plans issuers and carriers relies on older technologies such as fax or phone. They seek information on potential burdens or barriers that would be encountered by small, rural or other providers in complying with industry-wide standards-based API technology requirements for the exchange of AEOB and GFE data?

[2] https://www.facs.org/-/media/files/advocacy/regulatory/acs_comment_transparency_in_coverage.ashx

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The ACS is a strong proponent of API technology and agrees that FHIR-based API technology is an important tool for achieving more scalable and efficient interoperability and achieving real time exchange of price data for GFE and AEOB development. This promise could be achieved more quickly and efficiently if such APIs were standardized across vendors and therefore the ACS believes that any future digital tools or requirements that enhance transparency, quality programs or enable payor metrics should be engineered with an architecture that can be implemented and scaled on an open standards-based platform that deploys open source, standards-based infrastructure, such as FHIR. The current lack of standards results in vendors creating proprietary APIs.

In some cases, efforts to eliminate data blocking have instead resulted in private vendors charging large sums for proprietary, potentially non-compatible technology. It is not enough to reduce clinical burden of data aggregation if the fiscal burden of constrained, proprietary vendor actions consumes more and more precious resources that could otherwise be devoted to patient care. While ACS understands the importance of improved data flow through FHIR-based APIs, we note that self-employed surgeons, small surgical practices, and surgeons practicing in rural areas may still lack access to state-of-the-art technology due to geography or resources. These practices would likely find it more difficult to comply with requirements to submit GFE data using standards-based API technology. A phased rollout that provides additional time or flexibility would be beneficial for such entities, as would hardship exemptions or alternative data transfer methods. For example, standardized episode definitions as described above, that can be used to provide a good estimate of the likely range of services used by real patients could be provided as a service through a secure web-portal that meets AEOB data exchange requirements.

The Departments are interested in how the interplay between State laws and the No Surprises Act can be taken into account to ensure that information provided to patients in AEOB's accurately reflects their financial responsibility. Specifically, in the case of nonparticipating providers the agencies are interested in comments on if, how, and when the provider should transmit information to plans, issuers, or carriers of the individual's consent as part of the notice and consent process.

To generate the most accurate AEOB, the GFE transmitted to the insurer should include affirmative consent when this has been obtained by the provider, or when the provider expects to obtain such consent and the GFE being transmitted already reflects the amount to be charged upon obtaining such consent. It should not be necessary to disclose on every GFE every time a service is scheduled that no consent was obtained. This should simply be the default.

The Agencies ask if there are reasons why they should or should not propose a requirement that plans, issuers and carriers provide a copy of the AEOB to the provider or facilities, rather than just allowing for such a transfer but not requiring it.

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Price transparency is important not just for patients but also for physicians, facilities and other health professionals. ACS believes that any AEOBs prepared by insurers for patients should also be transmitted to surgeons and others involved in providing this care. Surgeons need to have the same information as the patients they are treating to be able to provide the highest quality of care and to be able to answer questions from patients as they arise. Since insurers will be aggregating GFEs and plan information to develop the AEOB, surgeons may have an incomplete picture of care or possibly a different course of care envisioned for the patient than the insurer, particularly in the post-facility phase of surgical care for example. If this information is not available when patient questions arise, it could cause delays in care or additional action on the part of the patient such as submitting the estimate to the physician's practice.

The Departments are interested in the perspective of plans, issuers and carriers on whether a diagnosis code would be required for the calculation of an AEOB.

While this question was directed specifically at insurers, ACS would like to weigh in on the importance of including diagnostic codes to the accuracy of an AEOB. This is because the expected course of care for a surgical procedure can vary greatly depending on why that procedure is being done. for example, a colectomy for cancer as described in Table 1 will have a different team, service profile and expected price than colectomy performed for another diagnosis such as inflammatory bowel disease. Therefore at least in the case of complex care with significant variation, the inclusion of a diagnosis code will be indispensable for providing the most accurate AEOB possible.

The RFI seeks comments on the additional burden that 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? The agencies further ask if providers and facilities are commonly performing these types of verifications in the regular course of business, such that minimal additional burden would be imposed and should providers by permitted to rely on an individual's representation of whether they are enrolled in a health plan or coverage.

Physicians typically collect insurance information from patients at the time of scheduling a consultation or service but are not in the practice of verifying coverage for each individual item or service delivered in the course of an encounter or procedure. Requiring verification of coverage for each individual item would be equivalent to implementing universal prior authorization and would therefore be incredibly burdensome and costly with little benefit to the patient. ACS would strongly discourage the departments from requiring verification of insurance status or verification of coverage for each item and service. Physicians and other clinicians should be allowed to rely on an individual's representation of coverage status when transmitting

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information for the purpose of AEOBs.

The ACS appreciates the opportunity to provide information on this complex issue and looks forward to continuing dialogue with the departments on improving transparency and value for surgical patients. If you have any questions about our comments or would be interested in further information please contact Matthew Coffron, ACS Chief of Health Policy Development, at mcoffron@facs.org.

Sincerely,

Patricia L. Turner, MD, MBA, FACS
Executive Director & CEO

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