December 6, 2021

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

Dear Secretaries Becerra, Walsh, and Yellen:

On behalf of the more than 80,000 members of the American College of Surgeons (ACS), we thank you for the opportunity to comment on the "Requirements Related to Surprise Billing; Part II" interim final rules with comment (IFR) implementing certain provisions of the No Surprises Act issued by the Office of Personnel Management; Internal Revenue Service, Department of the Treasury; Employee Benefits Security Administration, Department of Labor; and Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS) (collectively referred to as the "Departments" in this letter).

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 No Surprises Act. This letter focuses solely on the sections of the rule implementing the good faith estimate (GFE) and advance explanation of benefits (aEOB) provisions. Our comments on other portions of the IFR are included in a separate letter signed by several surgical organizations.

facs.org

CHICAGO HEADQUARTERS
633 N. Saint Clair Street
Chicago, IL 60611-3295
T 312-202-5000
F 312-202-5001
E-mail: postmaster@facs.org

WASHINGTON OFFICE
20 F Street, NW Suite 1000
Washington, DC 20001
T 202-337-2701
F 202-337-4271
E-mail: ahp@facs.org

In the IFR, CMS implements provisions related to GFEs for uninsured and self-pay individuals while deferring enforcement of certain other provisions related to aEOBs for patients with private coverage. The comments below therefore focus on the GFE for self-pay and uninsured individuals but are largely applicable to providing reasonable estimates to all patients—no matter their insurance type—and 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.

Protections for the Uninsured

Upon scheduling an item or service to be furnished, the No Surprises Act requires that providers and facilities provide a notification of the GFE of the expected charges for furnishing such item or service (including any item or service that is reasonably expected to be provided in conjunction with such scheduled or requested item or service or reasonably expected to be so provided by another provider or facility), with the expected billing and diagnostic codes for any such item or service. If an individual is not enrolled in a certain type of plan or coverage or is not seeking to file a claim, the No Surprises Act requires providers and facilities to furnish the GFE directly to the individual.

The Departments acknowledge that it could take time to establish processes to meet these requirements for GFEs provided to uninsured (or self-pay) individuals from January 1, 2022, through December 31, 2022. As such, HHS will exercise its enforcement discretion in situations where a GFE provided to an uninsured (or self-insured) individual does not include expected charges from co-providers or co-facilities.

The ACS recognizes the importance of helping patients avoid unanticipated medical bills but welcomes the Departments' acknowledgement of the challenges of developing the technical infrastructure necessary for providers and facilities to transmit good faith estimate data to plans. **Therefore, we support HHS' plan to exercise enforcement discretion and urge the Departments to err on the side of the providers who make a reasonable attempt to provide the necessary information to patients.** We would also point out that the development of standards for what items and services are actually included in such estimates is equally vital if we hope to provide accurate GFEs for any patient regardless of coverage status.

Good Faith Estimates for Uninsured and Self-Pay Individuals

As currently drafted, the GFE for uninsured and self-pay individuals would require 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. For a care encounter such as a wellness visit, diagnostic test, or a simple procedure in the office, this might be straightforward. However, treatment for many diagnoses and conditions, such as

facs.org

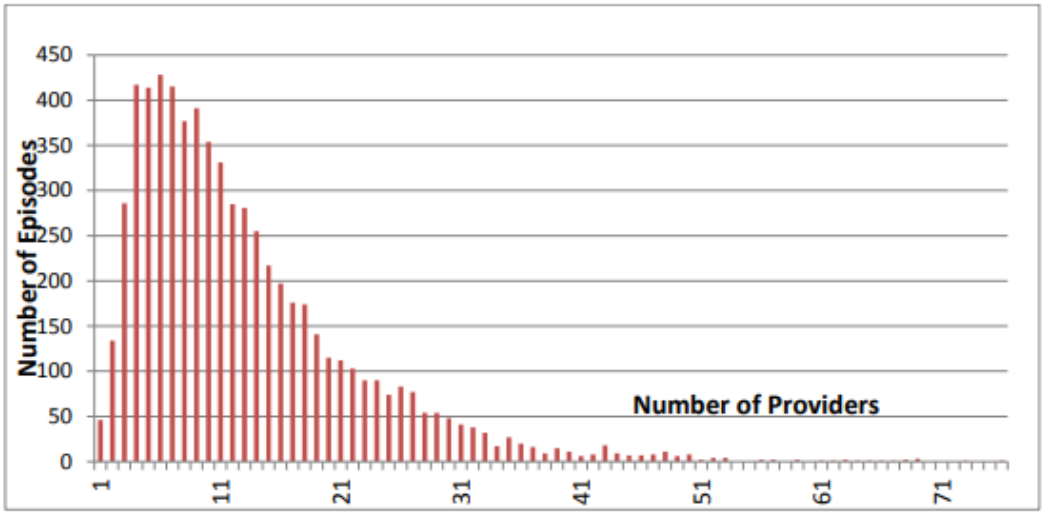
CHICAGO HEADQUARTERS
633 N. Saint Clair Street
Chicago, IL 60611-3295
T 312-202-5000
F 312-202-5001
E-mail: postmaster@facs.org

WASHINGTON OFFICE
20 F Street, NW Suite 1000
Washington, DC 20001
T 202-337-2701
F 202-337-4271
E-mail: ahp@facs.org

cancer or a major surgical procedure, might involve the skill and expertise of a large team and may occur across multiple sites of service.

Using the Episode Grouper for Medicare (EGM) grouping tool 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



The process of producing the GFE is further 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 to collect 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 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.

facs.org

CHICAGO HEADQUARTERS
633 N. Saint Clair Street
Chicago, IL 60611-3295
T 312-202-5000
F 312-202-5001
E-mail: postmaster@facs.org

WASHINGTON OFFICE
20 F Street, NW Suite 1000
Washington, DC 20001
T 202-337-2701
F 202-337-4271
E-mail: ahp@facs.org

The ACS recognizes the acknowledgement on the part of the Departments regarding the challenges related to the secure transmission of GFE information between providers and facilities and welcomes the one-year discretion of enforcement in cases where information from co-providers and facilities is not included in the GFE. However, as noted above, the difficulties with these requirements go beyond the lack of a secure process for the transmission of GFE information. As illustrated by Figure 2 below, 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.

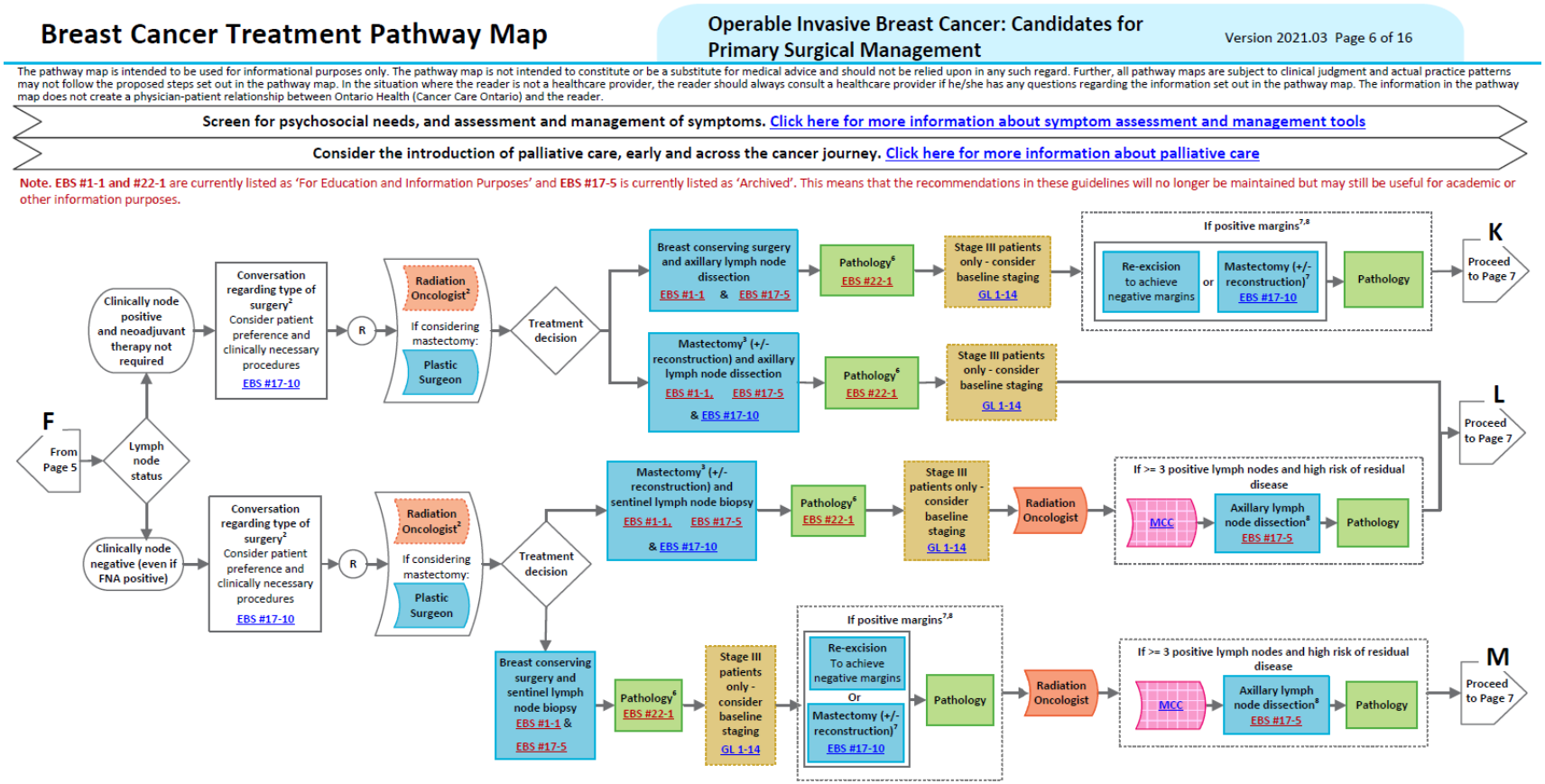
In the case of charges "substantially in excess" of the GFE, the law provides for a process of enforced patient-provider dispute resolution. The IFR defines substantially in excess as "an amount that is at least $400 more than the total amount of expected charges for the provider or facility listed on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

facs.org

CHICAGO HEADQUARTERS
633 N. Saint Clair Street
Chicago, IL 60611-3295
T 312-202-5000
F 312-202-5001
E-mail: postmaster@facs.org

WASHINGTON OFFICE
20 F Street, NW Suite 1000
Washington, DC 20001
T 202-337-2701
F 202-337-4271
E-mail: ahp@facs.org

Figure 2.



facs.org

CHICAGO HEADQUARTERS
633 N. Saint Clair Street
Chicago, IL 60611-3295
T 312-202-5000
F 312-202-5001
E-mail: postmaster@facs.org

The Departments seek comment on ways to leverage the Transparency in Coverage requirements that go into effect in 2023 in implementing the No Surprises Act plan obligations.

The ACS agrees that the similarity between the requirements of the Transparency in Coverage regulations and the requirements for aEOBs for insured patients under the No Surprises Act are 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[1], ACS agrees that price disclosure can inform and empower consumers whether they shop for items and services individually or as part of service packages (i.e., individual shoppable services, explicit or implicit items within bundles, or episodes of care), and we believe that out-of-pocket cost, in addition to total cost of care, are important types of price information for patients. However, ACS also noted in the letter that while a surgeon or other provider may have a reasonable idea of what services are likely to be provided in conjunction with a given surgical procedure, he or she may not know (or have any influence over) who will be furnishing those ancillary services or whether that provider will be in-network for an insured patient. This holds true for purposes of implementing the No Surprises Act and for that reason, we wish to reiterate that physicians, who are focused first and foremost on providing the best quality of care for their patients, are frequently not in a position to know the exact team who will be providing all services in the case of complex care. Therefore, it is unreasonable to require estimates at the level of precision currently required in this rule.

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.

The Departments seek comment on whether it would be feasible for providers and facilities to provide an estimate or range of estimated costs for insured consumers upon request for 2022.

ACS believes that it would be feasible to begin providing ranges of estimated costs for

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

facs.org

CHICAGO HEADQUARTERS
633 N. Saint Clair Street
Chicago, IL 60611-3295
T 312-202-5000
F 312-202-5001
E-mail: postmaster@facs.org

WASHINGTON OFFICE
20 F Street, NW Suite 1000
Washington, DC 20001
T 202-337-2701
F 202-337-4271
E-mail: ahp@facs.org

insured consumers in 2022 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 and could further facilitate ongoing price transparency efforts while reducing unnecessary burdens that add little value.

Developing an aEOB for an episode of care is a multi-step process that will involve a number of parties such as physicians and other care providers, facilities, insurers, and, to a certain degree, the patient, as their health status, care preferences and choices will have an influence on where their care takes place and who is involved in that care. This process is extremely burdensome and time consuming and given the unpredictability of health care outcomes, the extra cost and effort associated with trying to provide a patient-specific estimate of all services and charges likely to be delivered in conjunction with the scheduled care will not be a valuable undertaking for the patient.

Ratebooks as the basis for aEOBs

By starting with pre-populated, insurer-specific ratebooks detailing the average cost of the common services used by the majority of patients undergoing the same or similar care, a strong foundation is created on which to build an aEOB. This can then be made more precise by filling in detailed GFEs from as many providers as possible, and in fact, the exercise of creating the ratebook would inform providers and patients alike how many people are likely to be involved in that care.

Taking the example of a given surgical care episode, we can generate a base aEOB for a typical patient using a common core of typical services and items, including the surgical procedure and associated care. While there are multiple groupers available, ACS feels that the episode definitions and grouper logic maintained by the PACES Center for Value in Healthcare are the most functional and complete for this purpose.

The PACES grouper would be run on insurers' claims to establish the complete list of services and charges associated with each episode and subcategory. This grouper was designed to count each dollar only once and to assign charges to either the most relevant episode or divide them across all concurrent episodes assigned to a patient for which that service could be plausibly provided. For the purpose of the ratebook, it would be more logical to assign the full cost of the surgical procedure, the facility, anesthesia, pathology, and "any item or service reasonably expected to be provided in conjunction with the scheduled procedure" to the aEOB to provide the most realistic estimate. An added benefit of using the PACES grouper to derive this estimate is that the list of items and services

facs.org

CHICAGO HEADQUARTERS
633 N. Saint Clair Street
Chicago, IL 60611-3295
T 312-202-5000
F 312-202-5001
E-mail: postmaster@facs.org

WASHINGTON OFFICE
20 F Street, NW Suite 1000
Washington, DC 20001
T 202-337-2701
F 202-337-4271
E-mail: ahp@facs.org

generated would be based on objective evidence (past claims) and therefore likely more comprehensive than lists generated on the fly by overburdened Convening Providers or Convening Facilities.

For a patient presenting to a surgeon with colon cancer, the surgeon will recommend surgical removal (e.g., a colectomy as described by CPT code 44145). PACES defines a Gastrointestinal cluster of episodes which includes colectomy. The colectomy episodes include a subcategory of patients with a diagnosis of cancer.

PACES can use the relevant payor database to run the episode logic and its business logic to determine the overall price variability for a colectomy. The prices vary for multiple reasons, most likely because different services are deemed necessary based on the patient's co-morbidities and any complications that might occur as a result of the procedure. This information could also be provided as part of the range of estimated prices to better inform the patient of what they might expect. The surgeon can then provide the patient with a GFE for a core-based service set as well as a range of prices tied to patient risk categories.

In the future, the PACES grouper could be used for more precise estimates that account for variations and complications related to the episode of care. For example, patients' clinical histories and characteristics such as comorbidities could be used to place them into risk groups, each associated with a range of prices—including the mean and median—based on historical data from similar patients. The grouper could also be run on a given insurer's claims to generate the expected ranges of out-of-pocket costs based on the specific health professionals and facilities selected by the patient. The same information generated could also be invaluable in meeting requirements of price transparency regulations.

The ACS appreciates the opportunity to provide feedback on this interim final rule and looks forward to continuing dialogue with CMS on improving transparency and value for surgical patients. If you have any questions about our comments, please contact Matthew Coffron, ACS Manager of Policy Development, at mcoffron@facs.org.

Sincerely,

David B. Hoyt

David B. Hoyt, MD, FACS
Executive Director

facs.org

CHICAGO HEADQUARTERS
633 N. Saint Clair Street
Chicago, IL 60611-3295
T 312-202-5000
F 312-202-5001
E-mail: postmaster@facs.org

WASHINGTON OFFICE
20 F Street, NW Suite 1000
Washington, DC 20001
T 202-337-2701
F 202-337-4271
E-mail: ahp@facs.org