COLLEGE of AMERICAN PATHOLOGISTS

November 14, 2022

Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-9900-NC
7500 Security Boulevard
Baltimore, MD 21244-1850

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

Dear Administrator Brooks-LaSure:

The College of American Pathologists (CAP) appreciates the opportunity to comment on the Advanced Explanation of Benefits and Good Faith Estimate for Covered Individuals request for information (RFI). As the world's largest organization of board-certified pathologists and leading provider of laboratory accreditation and proficiency testing programs, the CAP serves patients, pathologists, and the public by fostering and advocating excellence in the practice of pathology and laboratory medicine worldwide.

The CAP has been continually engaged in the implementation of the good faith estimate (GFE) requirements for uninsured or self-pay patients, including a March 22, 2022 meeting, an April 2022 follow-up letter (attached), and an October 12, 2022 listening session in which we provided additional details from the co-provider perspective. We sincerely appreciate the time that Centers for Medicare & Medicaid Services (CMS) staff have provided to discuss with us these details around the GFE requirements. However, despite additional guidance and education, our members continue to express concerns and confusion about how to comply with these requirements. And while many of these same concerns are similarly applicable in the context of covered or insured individuals, the impending requirements add yet another layer of difficulty and burden on our already concerned members. We appreciate the Department of Labor, the Department of Health and Human Services, and the Department of the Treasury (collectively, the Departments) seeking additional information to better inform future rulemaking in this area; yet, we wish to stress that the requirements for GFEs for covered individuals (1) add further administrative burden and increased complexity, (2) present potential for misuse by insurers, and (3) are a threat to patient access to, and quality of, care.

Background

As you know, under the *No Surprises Act*, all health care providers and facilities must generally inquire if an individual has health insurance coverage (and is seeking to submit a claim), or if the individual is uninsured (or self-pay). If an individual is uninsured (or self-pay,) the provider/facility must provide a GFE of the expected charges to the individual. However, for covered individuals, providers/facilities are required to provide a GFE to the individual's insurer. The insurer then provides an Advanced Explanation of Benefits (AEOB) to the covered individual. This AEOB includes information such as the network status of the provider or facility, the contracted rate for the item or service, the GFE received from the provider or facility, and the amount of any cost sharing which the

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covered individual would be responsible for paying with respect to the GFE received from the provider or facility.

While the Departments have already issued regulations implementing the requirements related to GFEs for uninsured (or self-pay) individuals – and the CAP has engaged in this implementation, as explained above – the agency deferred enforcement of the requirements related to covered individuals, noting that compliance with these requirements was likely not possible by January 1, 2022. Indeed, compliance with these additional requirements will be extremely difficult, beyond data transfer and infrastructure concerns. In addition to consideration of our specific comments below, we urge the Departments to work with us, engage other provider stakeholders, and gradually and carefully implement the additional requirements with maximum flexibility.

Administrative Burden and Increased Complexity

As we have explained before, there is significant difficulty in determining the cost of pathology services in advance of services conducted by the pathologist. For instance, a surgical or invasive diagnostic procedure performed by a surgeon, gastroenterologist, urologist, or other clinician may result in no specimens obtained or it may result in multiple specimens requiring histopathologic evaluation. Additionally, anatomic pathology services typically involve a pathologist performing a gross and microscopic analysis of tissue or body fluids to determine whether a cancer or other disease is present and, if so, further characterize it. The complexity of work up required is typically not known in advance of the microscopic examination conducted by the pathologist, making it impossible to provide a reliable estimate of costs.

This difficulty is also particular to pathology, and it is the norm, not the exception, for the extent of medically necessary pathology services not to be known in advance – in fact, uncertainty as to diagnosis is the typical reason for physicians or other providers to utilize the services of their pathology colleagues. Unlike other physicians, pathologists are frequently required to perform ancillary testing after review of the initial hematoxylin and eosin-stained slides. This reality is reflected by CMS in Medicare's Benefit Policy Manual with a surgical/cytopathology exception that notes a pathologist may need to perform additional tests after an examination or interpretation, "even though they have not been specifically requested by the treating physician/practitioner."[1] We continue to urge CMS to recognize this pathology-specific difficulty more explicitly in regulations or sub-regulatory guidance, for both the existing uninsured/self-pay individual requirements and in any future rulemaking related to covered individuals.

Importantly, the CAP agrees that patients should be able to make informed decisions about their health care, and we understand how access to accurate price information prior to services would be useful for patients, especially those that are uninsured or self-pay. Yet beyond the difficulty in providing an accurate GFE, we are skeptical of how helpful pathology GFE information can be to covered individuals, knowing that the estimates will frequently differ from actual costs and that the changes in estimate/cost will likely not have the same impact for covered individuals as they would for the uninsured or self-pay patients. Indeed, for covered individuals, issues with increased out-of-pocket costs[2] would be more appropriately addressed in evaluating the quality of

[1] https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf

[2] https://revcycleintelligence.com/news/out-of-pocket-healthcare-spending-increased-leading-up-to-pandemic

coverage provided by insurers, network adequacy, and other tactics used by insurers to shift medically necessary health care costs onto enrollees.[3]

Further, providing this information in advance and then again after completion of the services is extremely burdensome, especially given the limited benefit for covered individuals. Pathologists and laboratories across the country are currently facing tremendous administrative and reporting burdens while continuing to work in a strained environment as a result of the COVID-19 public health emergency, increasing respiratory illnesses, and staffing shortages. Imposing additional regulatory requirements without appropriate flexibility risks interfering with pathologists' ability to provide important care and services to patients. At the same time, we would note that insurers are making record profits[4] and increasing market power, which in turn causes "competitive harm to consumers and providers of care."[5] Finally, the only meaningful information on covered individuals' specific cost calculations is held by the enrollee's health plan. We urge CMS to consider how to streamline the process and lessen the burden on providers, while maximizing utilization of the information already held by insurers and which they can therefore more readily provide (i.e., refrain from placing requirements on physicians and other providers to submit duplicative information).

Potential for Misuse

As noted above, insurer market power is increasing, and a recent American Medical Association (AMA) study found that the majority of health insurance markets in the United States are highly concentrated.[6] We are concerned that the provision of GFE information to insurers and the aggregate data collection will exacerbate an already uneven playing field that will be harmful for physicians and a threat to independent/small practices (potentially impacting physician networks, contract arrangements, vertical hospital consolidation, private equity, etc.). As the agency works to propose regulations, we urge CMS to consider protections and limits on the use of the data divulged to insurance companies, beyond addressing any patient privacy issues. This should include measures to explicitly prevent insurers from using AEOB and GFE data for anything other than the provision of advanced estimates.

Threat to Patient Care

Ultimately, the most important concern is patients' access to, and quality of, care. Pathologists are physicians whose timely and accurate diagnoses drive care decisions made by patients, primary care physicians, specialists, and surgeons. Pathologists are acutely aware that the right test at the right time can make all the difference in a patient's diagnosis, treatment, and outcome. As such, the CAP is especially alarmed about any delay or hurdle that may lead to care abandonment, as well as insurers inappropriately steering patients to other providers or altering the patient's course of treatment.

To start, we are concerned that fewer independent/small practices and/or increased consolidation as described above – or simply, insurer steerage of patients to lower cost care outside of their community – would limit access in underserved and marginalized

[3] https://documents.cap.org/documents/CAP-Letter-re-UHC-DDP.pdf
[4] https://www.healthcaredive.com/news/health-insurers-profits-rise-q1-hospital-cost-increases/623371/
[5] https://www.ama-assn.org/system/files/competition-health-insurance-us-markets.pdf
[6] https://www.ama-assn.org/system/files/competition-health-insurance-us-markets.pdf

communities areas and worsen health disparities. For example, lack of transportation is an increased concern for rural communities on top of higher poverty rates and a higher proportion of elderly individuals.[7] These factors pose challenges for patients looking to access care outside of their community, whether due to need or because of insurer direction. Relatedly, especially for underserved and marginalized communities, confusion around a GFE, the certainty of cost, and/or the need for additional items/services beyond the original GFE could result in care abandonment. Our members have seen firsthand how these patients – including even covered individuals – may reject care that appears beyond what was promised, regardless of the level of need.

But, even if the care is close to home and certain, we have previously expressed concerns about insurers encouraging patients to shop for lower-cost health care, where it could jeopardize coordination and quality of patient care. Providing insurers with GFE information in advance of medical services received (or perhaps even contemplated) by a patient increases the risk that insurers will inappropriately steer patients to other providers or alter the patient's course of treatment. In fact, we have already seen instances of insurers attempting to steer patients to "designated" providers by subjecting patients to the full payment for services received at in-network, but non-designated providers.[8] The CAP agrees that patients should be empowered to make cost-effective health care choices, but selecting a lower-cost service may present coordination/quality of care issues, and possible additional utilization and/or costs downstream due to lack of coordination/communication among providers. Further, an insurer-driven focus on cost over quality undervalues important aspects of care that pathologist members of the medical community provide (tumor boards, hospital committees, serving as medical director of the hospital laboratory, providing consultations to clinical colleagues, etc.), which would not be available from alternative providers of laboratory services.

Unless patients have a full understanding of all pricing information and potential consequences of delay and discoordination in shopping for care, there is a risk of patients making care decisions that disrupt coordination, add burdens, or lead to lower quality. This is a particular concern for the most vulnerable patient populations, including those with low income and/or chronic conditions. The CAP strongly urges CMS to ensure appropriate safeguards are in place to limit gratuitous interference in the patient-physician relationship and thereby ensure timely access to medically necessarily care.

Finally, the CAP is also concerned about GFE requirements and unintended consequences to residency training if providers/facilities which provide such medical education are disadvantaged by the impact of the CMS-acknowledged additional costs associated with their commitment to education on, the provision of a GFE amount. We urge CMS to explore additional options and flexibility in its regulations that would ensure residents continue to get the fullest education and experience so they can provide the highest quality of care to patients.

Summary

Again, the CAP appreciates our continued dialogue with CMS on the GFE requirements, as well as the opportunity to provide comments on this RFI, while continuing efforts to help our members comply with current and future regulations. Now more than ever,

[7] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7043306/
[8] https://documents.cap.org/documents/CAP-Letter-re-UHC-DDP.pdf

patients and their treating physicians need to rely on the expertise of pathologists and the availability of appropriate testing. The significant – and particular – difficulty in determining the cost of pathology services in advance presents many challenges, but the impending requirements for covered individuals add yet another layer of difficulty and burden, present potential for misuse, and are a threat to patient access to and quality of care. We urge CMS to continue to work with us to determine how to best include pathologists in the *No Surprises Act* GFE requirements.

Please contact Elizabeth Fassbender, CAP Assistant Director, Economic and Regulatory Affairs at efassbe@cap.org if you have any questions on these comments.

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COLLEGE of AMERICAN PATHOLOGISTS

April 13, 2022

Dear Ms. Robbins:

We sincerely appreciate the time you and other CMS staff provided to discuss with us the details around the good faith estimate requirements included in the *No Surprises Act*. As requested, we are following up with written examples explaining the significant – and particular – difficulty in determining the cost of pathology services in advance of services conducted by the pathologist.

As we explained during our March 22nd meeting, we are requesting guidance from CMS so that we can educate our pathologist members and advise them on how they may provide appropriate good faith estimates to patients. As we currently understand the requirements, we see no clear way to proceed in providing prospectively reliable estimates for pathology services, as pathologists are not the initiator of the tissue or fluids submitted for diagnosis, and will know neither what will be submitted nor what will need to be done until the pathologist has reviewed the original specimen(s) from each individual patient. For instance, an endoscopic procedure performed by a gastroenterologist may result in no specimens or it may result in multiple specimens. When specimens are received pathologists perform "routine" microscopic examination to determine if disease is present (e.g., inflammatory conditions, pre-cancerous neoplasms, or cancer). In some instances, based on this evaluation, additional special studies may be required (e.g., special histologic stains, immunohistochemistry, in situ hybridization, or molecular testing). The need for ancillary testing will typically not be known in advance of this initial microscopic analysis, making it impossible to provide a reliable estimate of costs. It should be noted that benign diagnoses can be challenging as well, sometimes requiring multiple special studies to exclude more ominous look-alikes. This reality is reflected by CMS in Medicare's Benefit Policy Manual with a surgical/cytopathology exception that notes a pathologist may need to perform additional tests after an examination or interpretation, "even though they have not been specifically requested by the treating physician/practitioner."[9]

We also need to explain to our members when they can – and when they cannot – rely on the fact that the regulations "do not require the good faith estimate to include charges for unanticipated items or services that are not reasonably expected and that could occur due to unforeseen events." As we expressed during our call, it is the norm, not the exception, for the extent of medically necessary pathology services to be unanticipated – in fact, if physicians or non-physician providers were *certain* of a diagnosis, they would not need to utilize the services of their pathology colleagues. Thus, while it may be possible for a pathologist to provide an estimate for a single particular service, it would be quite unpredictable whether the final result would be a "higher billed amounts after receipt of care" when other or additional services are required, which an SDR entity may not understand.

Below are some additional examples to demonstrate the difficulty expressed above:

- A patient undergoes a lung biopsy because a mass or other localized finding is seen on radiographic exam. The purpose of the biopsy in this common scenario is to determine what the lesion is (cancer, fungal or bacterial infection, etc.), typically requires a workup with various specific stains, determined based on the microscopic appearance of the biopsy. If it is infectious, one set of (microbial) stains may be required; if it is neoplastic

[9] https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf

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(a tumor), a whole set of other stains (immunohistochemical stains) would be required. And additional molecular testing is usually needed after it is determined to be neoplastic – for instance, when the lung carcinoma is identified as an adenocarcinoma, a pathologist would then order molecular testing such as ALK, PD-L1, and EGFR. It is also possible no stains would be required if the biopsy showed only benign lung tissue. But none of this is known in advance.

- Often – but not always – resections of a breast mass and skin cancers to ensure total removal of the cancer require a pathologist to evaluate margins, which means multiple frozen sections or intraoperative gross examinations, the exact number of which can only be determined in intraoperative real time. There would be no reliable way to provide an accurate prospective estimate of the charges in these cases.

- Likewise ENT cases with direct visualization of the upper respiratory tract may result in no or one or many frozen section specimens to guide the operative procedure, but again this will not be clear until the procedure is underway.

- Cancer staging in gynecologic oncology cases could require multiple biopsies, based in part on the surgeon's intraoperative findings. Additionally, intraoperative assessments ("frozen sections") may be requested by the surgeon. Such studies may not be requested, or the pathologist might be called to the operating room five times or more.

- Another issue is fine needle aspiration (FNA) procedure for enlarged lymph nodes. This may be done to assess for malignancy or infection. In addition to the potential for multiple intraprocedural assessments for specimen adequacy by the pathologist, until the specimen is examined microscopically, pathologists will not know whether the specimen will require special studies. This could range from none to a few immunohistochemical stains definitively to characterize the most common head and neck cancers to an extensive work up for lymphoma with immunohistochemical stains and/or flow cytometry studies and molecular studies. The range of reasonably required additional studies in this scenario could thus be from $0 to over $5,000 if the patient has lymphoma – and not knowing in advance which it will be is in fact the reason for the pathology assessment.

To sum up, the role of the pathologist is to receive a patient specimen(s) and make a diagnosis. This involves determining the presence or absence of disease, and when disease is present, its nature and extent. It is the pathologist's responsibility to undertake this step-wise process as expeditiously as is consistent with the ultimate rendering of a definitive diagnosis to guide treatment. What specimen or specimens will be submitted to the pathologist is determined not by the pathologist but by the treating provider and as in the examples above, the treating provider will often not know prior to the procedure whether or how many specimens will be obtained. It is in the setting of these multiple levels of complexity that pathologists are potentially being asked to provide a good faith estimate of costs, and in which we in turn are seeking your guidance in how to advise them.

Thank you again for your time and assistance. Please contact Elizabeth Fassbender, CAP Assistant Director, Economic and Regulatory Affairs at efassbe@cap.org if you have any questions on these comments.

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