COLLEGE of AMERICAN PATHOLOGISTS

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."[1]

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 (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

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

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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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