COLLEGE of AMERICAN PATHOLOGISTS

October 23, 2017

Administrator Seema Verma
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Re: Preliminary private payor rate-based CLFS payment amounts

Dear Administrator Verma:

The College of American Pathologists (CAP) appreciates the opportunity to comment on the proposed Clinical Laboratory Fee Schedule (CLFS) rates published on September 22, 2017. 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. In 2016, the CAP accredited approximately 8,000 laboratories with 21 discipline-specific checklists, offering the quality practices that are essential to providing world-class patient care.

Given the integral roles pathologists play in directing clinical laboratories, overseeing the quality and appropriateness of laboratory testing in their medical communities, and developing laboratory tests, the CAP and its members have a significant stake in the implementation of the Protecting Access to Medicare Act (PAMA) of 2014. Like the Centers for Medicare and Medicaid Services (CMS), the CAP desires that the implementation of PAMA minimize disruption and ensure the ongoing provision of laboratory tests to Medicare beneficiaries. However, based on a review of the proposed rates, the CAP is concerned about several key elements of the released information. The CAP believes that there are flaws in the underlying data collection, the implementation of the PAMA methodology, and the data release that are causing major discrepancies in the proposed rates. Therefore, the CAP urges the CMS to delay the implementation of the proposed CLFS rates and engage with the laboratory stakeholder community until the discrepancies are reconciled.

1. Flaws in Data Collection
   As the CAP has stated many times, the CMS interpretation of the PAMA statute on applicable laboratories subject to data reporting does not accurately reflect the national laboratory landscape. The CMS' methodology excludes many laboratories including most hospital outreach laboratories and physician office laboratories, which provide necessary services for the welfare of patients. The exclusion of these laboratories causes the underlying data collected by the CMS to underrepresent many segments of the industry and skews the resulting PAMA rates. The CMS should engage laboratory stakeholders to ensure that all sectors of the laboratory market are a part of the data collection process and allow the laboratory community more time to validate the results of the data collections process. More representative data reporting might also address the codes for which the CMS did not collect any private payor data.

   Furthermore, the CAP rejects the CMS' assertion that "there would be no significant impact on projected CLFS spending when reporting is increased." The CMS takes an overall view on the concept of impact, which the CAP finds problematic for two reasons. First, the overall view obstructs the fact that the individually calculated rates are extremely sensitive to change based on the use of a measure of central tendency such as the weighted median. Any additional data could have a large impact on the calculated rates of an individual code, an impact that could be hidden by the overall view. Second, the CMS expresses the overall view in percentages and suggests that the difference

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between -21.9% and -19.9% impact on total spending is not a large difference. However, in a $7 billion dollar industry, a difference of 2% translates to a $140 million in a single year. Surely the CMS must recognize that this sum is not insignificant, and would correct the data collection process to address its shortcomings. The CAP believes that more complete data collection would increase the accuracy of the resulting rates and be fair to all providers involved.

2. Flaws in Methodology
   The CAP believes that the CMS did not correctly apply the PAMA methodology's 10% decrease limit to codes with a $0 National Limit Amount (NLA). For instance, code 80061 *Lipid panel* has a NLA of $0, but has locality payments ranging between $13.44 and $18.37. The new PAMA rate of $11.23 for this code would be a 38% decrease from $18.37 and 16% decrease from $13.44, both of which exceed the 10% limit. The CAP urges the CMS to reconsider the use of $0 NLA as the benchmark for any code where there are clearly positive payments to more reasonably represent the national Medicare payments for those codes.

3. Flaws in Transparent Data Release
   The CAP appreciates the CMS' efforts in releasing so much new information, but the CMS neglected to provide full, coherent, and transparent material with the PAMA rate release that would have helped stakeholders better understand the proposed changes. For example, the dataset published with the rate release seems to contain a number of errors and inconsistencies. The raw data should be able to be used by the public to corroborate the CMS' calculations. However, after analyzing the database, the CAP calculated different rates and therefore could not validate the median using the published data for almost 20% of codes included. As another example, the CMS mentioned that there were 247 HCPCS codes that were reported on by fewer than ten TINs, but did not specify which codes these were in the raw data, only in a separate spreadsheet. The CAP believes that the CMS could benefit from more time to fully explain the multitude of changes to the CLFS and the materials that were published.

For these three reasons, the CAP believes that the release of the proposed CLFS rates was premature. The incomplete, miscalculated, and nontransparent results could result in an impact on the provision of services by providers and therefore beneficiaries' access to services. **Therefore, the CAP recommends that the CMS delay the implementation of the proposed CLFS rates until the CMS can work directly with the laboratory community to solve the issues mentioned above.**

We are pleased to have the opportunity to respond to CMS on the proposed CLFS rates and appreciate your consideration of the CAP's comments. Should you have any questions regarding the CAP's comments, please do not hesitate to contact Mark Adelsberg at madelsb@cap.org or 202-354-7118.

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