COLLEGE of AMERICAN PATHOLOGISTS

December 3, 2020

Medicare Payment Advisory Commission (MedPAC)
425 I St, NW
Suite 701
Washington, DC 20001

Re: Mandated report: The Protecting Access to Medicare Act of 2014's changes to the Medicare clinical laboratory fee schedule

To Whom It May Concern:

Given the integral roles pathologists play in ensuring availability of clinical laboratory services, overseeing the quality and appropriateness of laboratory testing in their medical communities, and developing laboratory tests, the College of American Pathologists (CAP) and its members have a significant stake in the continued implementation of the Protecting Access to Medicare Act (PAMA). Thus, we have consistently called for changes to CMS's data reporting requirements that ensure a broad representation of the laboratory market and more accurate payment rates. We appreciate the Commission's thoughtfulness in addressing this issue and responding to the report mandated by Congress. However, we have some concerns and hope to provide necessary clarification following MedPAC's public meeting in September. As expressed when we met with MedPAC staff in May, the CAP is available as a resource on this issue and looks forward to this opportunity to provide input prior to MedPAC's publication of its completed report.

As you know, PAMA required significant changes to how Medicare pays for clinical diagnostic laboratory tests under the Clinical Laboratory Fee Schedule (CLFS). Currently, the Commission is investigating these changes, including the methodology that CMS used to set private payer-based rates for laboratory tests and the least burdensome data collection process that would result in a representative and statistically valid data sample of private payer rates from all laboratory market segments. This is because, as was noted during the September public meeting, initial data reporting included an overrepresentation of independent laboratories while hospital and physician office laboratories were underrepresented. In fact, although hospital laboratories account for the more than a quarter of all Medicare payments under the CLFS, fewer than two dozen hospital laboratories — out of more than 9,000 — reported pricing data under CMS's initial final rule. It was also mentioned during the meeting, but it deserves emphasis, that hospital laboratories typically receive higher rates from private payors than do independent laboratories, and therefore the exclusion of these data undermined the accuracy of CMS's calculations and future reimbursements for laboratories providing clinical laboratory services. The CAP is committed to improving patient care and addressing escalating health care costs, but we have been significantly concerned about the impact any failure in collecting accurate data will have on quality patient care and access to medically necessary laboratory testing.

First, it was noted during the September meeting that if substantial access issues occurred, those changes would be reflected in utilization data. Yet, in addition to the fact that reductions are being phased in slowly, it must also be considered that overall utilization trends do not accurately reflect access for varying communities across the country. Obviously, utilization could go up for a specific segment of the country while going down for others – and that could mean, for example, rural areas and smaller communities face access issues while other communities do not. In fact, the Commission highlighted that volume increased by 2.4 percent

College of American Pathologists
1001 G Street, NW, Suite 425W
Washington, DC 20001
202-354-7100

for independent labs and decreased by about 1 percent for both hospital and physician office labs, which demonstrates the varying impact the inadequate rates have in different settings. Yet, the Commission attributes this change to a "longer-term trend of large, independent laboratories growing their market shares," not acknowledging the negative impact on smaller laboratories. Further, the idea that labs can simply "readjust their revenue mix" to maintain their operation and maintain access does not reflect the current laboratory environment/market. Private payers are, as was noted during the discussion, being aggressive in terms of negotiating rates for laboratory tests, while pathology practices and laboratories across the country continue to face increasing regulatory burden and ongoing public health crises including the COVID-19 public health emergency.

Additionally, as the Commission explained, spending increases were largely due to technical changes under PAMA and increased use of new, high-cost tests – and this spending increase was concentrated primarily at independent laboratories while spending declined for both hospital and physician office laboratories. Again, this demonstrates the extent to which inaccurate payment rates disproportionately harm the smaller, hospital, and rural laboratories across the country. Further, the idea mentioned during the meeting that rural hospital data and/or small practice data does not matter because "Medicare should pay similar rates for similar care" fails to take into consideration the different nature of the cost inputs across various settings and fails to comport with the plain meaning of the statute, which requires a national market-based reimbursement scheme based on data from all independent and hospital-based laboratories that receive most of their Medicare revenues from serving beneficiaries who are not hospital in-patients or out-patients. Smaller and rural laboratories and pathology practices provide valuable services to their communities. To not meaningfully take into consideration the range of activities within pathology services and the variation of associated costs and resources across different settings will limit the ability for patients to continue to receive these important diagnostic services.

We understand that because of the weighted median component, greater hospital and physician office laboratory reporting may only increase payment rates modestly. However, the CAP has long maintained that including the full spectrum of laboratories (and especially hospital outreach laboratories) is especially important in ensuring an accurate, market-based payment system for laboratories paid through the CLFS. Similarly, while the CAP supports efforts to understand how private payer laboratory rates could be collected through a survey, if – as was suggested during the meeting – only larger laboratories are sampled, the issue Congress intended to address through this report will only be exacerbated.

Regarding comments about utilization, we want to remind the Commission that pathologists and clinical laboratories do not control test ordering and any concerns about increased utilization should not result in penalizing the laboratories who provide the test in response to the requests by the patient's physicians. Further, the CAP has concerns with utilization management efforts that inappropriately dictate or limit health care provider decision-making or patient care, as these policies impinge on the practice of medicine and improperly encumber medically necessary laboratory and pathology services. Pathologists know that the right test at the right time can make all the difference in a patient's diagnosis, treatment, and outcome. We remain committed to improving patient care and addressing escalating health care costs, but policies that interfere with a patient's ability to receive timely and appropriate services risk negatively affecting patients, providers, and the entire health care system.

Finally, regarding the concerns expressed around molecular testing and cost escalation, we have previously provided recommendations to CMS for ways to improve coding and

documentation requirements for Medicare or Medicaid payment, including discontinuing "unlisted" coding practices. To help with transparency in this area, the CAP believes Medicare Administrative Contractors (MACs) should discontinue directing physicians/providers to report "unlisted" codes when a specific AMA's Current Procedural Terminology (CPT) code exists. Additionally, "unlisted" codes should not be required by the MACs, as established HCPCS/CPT codes should be considered proper for coverage and payment. Federal contractors should not be allowed to require physicians/providers to use "non-HIPAA" codes to report their services.

Please direct questions to Elizabeth Fassbender, JD, Assistant Director, Economic and Regulatory Affairs. She can be reached at efassbe@cap.org or 608-469-8975. Thank you for your consideration of these comments.

Sincerely,

Jonathan L. Myles, MD, FCAP
Chair, Council on Government and Professional Affairs
College of American Pathologists

College of American Pathologists
1001 G Street, NW, Suite 425W
Washington, DC 20001
202-354-7100