AMA
AMERICAN MEDICAL ASSOCIATION

JAMES L. MADARA, MD
EXECUTIVE VICE PRESIDENT, CEO

ama-assn.org
t (312) 464-5000

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The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

Dear Administrator Verma:

On behalf of the physician and medical student members of the American Medical Association (AMA), I appreciate the opportunity to submit written comments on the Centers for Medicare & Medicaid Services' (CMS) Clinical Laboratory Fee Schedule (CLFS), including the 60 test codes for which CMS received no data and/or insufficient data to calculate a weighted median private payor rate. As noted during the AMA's public comments, we continue to have significant concern that, even where CMS has received data for codes on the CLFS, there are significant data integrity questions raised given the retrospective collection period. The concerns are reinforced by the late notice provided by CMS that no data was produced at all for 60 codes. For the reasons outlined below, we strongly oppose removing any of the 60 codes until CMS has implemented reasonable measures to ascertain the accuracy and reliability of the submitted data or lack of data.

CMS has requested comments on whether 60 codes should be included on the CLFS for which CMS receives no applicable information as part of the Protecting Access to Medicare Act (PAMA) reporting exercise. CMS asks further, should the codes remain on the CLFS, what method of payment should be used to price the test codes (crosswalking or gapfill). On the one hand the 60 codes may no longer be offered by applicable laboratories, on the other hand these tests may still be offered. Based on the information provided by CMS, it is not possible to ascertain. It is inconsistent with law and premature to remove any of these 60 codes from the CLFS for calendar year 2018 (CY 2018) because no and/or insufficient data was received during the reporting period. The PAMA final rule states that "for a CDLT for which CMS receives no applicable information, payment is made based on the crosswalking or gapfilling methods described in 414.508(b)(1) and (2)." The final rule makes no mention that if no applicable information is received from a CDLT that it should be removed from the CLFS. The AMA noted in our comments to the proposed rule implementing the PAMA CLFS data collection obligations, that prospective data collection was needed to ensure that applicable laboratories had time to implement system changes to collect data as specified by CMS. Instead CMS implemented a retrospective data collection period that even the largest clinical laboratories had difficulty culling from their systems despite, reportedly, expending substantial resources. We emphasize that the AMA is not asserting that applicable laboratories failed to utilize best efforts to submit accurate data. Instead, based on what we have learned it appears that for most, if not all, applicable laboratories the retrospective accurate data collection requirement constituted impossibility. We strongly urge that CMS issue an interim final rule

so that CMS is able to conduct a survey of private payer payments for clinical tests. We recommend further that CMS survey for variance among the market segments, including reference laboratories, physician office–based laboratories, and independent laboratories, for example. The purpose of the survey is to validate whether the data is accurate and, where needed, to adjust the final amount calculated. The foregoing will ensure congressional intent is achieved, namely that CMS payment rates reflect private market payments. Furthermore, before CMS removes the 60 codes from the CLFS, CMS should seek more reliable information than simply relying on the fact that no data was submitted by applicable laboratories given reporting has been riddled with problems.

The lack of adequate notice and insufficient time to implement substantial changes has been the hallmark of PAMA implementation. We are very concerned that patient access will be harmed in early 2018, which will undermine nascent and important efforts to implement payment and delivery reform under the Medicare Access and CHIP Reauthorization Act. Reasonable and measured policy adjustments are needed so that the most frail and vulnerable are not required to shoulder the consequences of poor implementation. This will also ripple across the healthcare infrastructure and impose additional pressure that is not necessary because there are reasonable and sensible alternatives that will provide CMS with essential facts to guide policy decision-making.

Thank you for the opportunity to comment. If you have questions, please contact Shannon Curtis, Assistant Director of Federal Affairs at shannon.curtis@ama-assn.org or (202)789-8510.

Sincerely,

James L. Madara, MD