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Laboratory Market Stakeholders Call for Suspension of Draft PAMA Rates; Urge CMS to Take Immediate Action to Address Flawed Data Collection and Methodology

ACLA, NILA, AdvaMedDx and POCTA Issue Joint Release Echoing Stakeholder Letter to Administrator Verma

WASHINGTON, D.C. – Leading laboratory stakeholders in a joint letter to Centers for Medicare and Medicaid Services (CMS) Administrator Seema Verma today called on the agency to take immediate action to address the significant deficiencies in its process to establish new clinical laboratory payment rates. CMS recently issued drastically low draft payment rates for lab tests under the Protecting Access to Medicare Act (PAMA). Stakeholders pointed to serious flaws in the data collection process, which resulted in unreliable and unsustainable draft payment rates that will threaten the viability of lab services and Medicare beneficiary access to important tests.

"ACLA is deeply concerned that CMS has issued draft rates determined by a process that clearly did not adhere to congressional intent," said Julie Khani, president of the American Clinical Laboratory Association (ACLA). "ACLA stands with other laboratory stakeholders in the call for suspension of PAMA draft payment rates until issues with data integrity and market exclusion are addressed."

The letter, signed by 22 stakeholders, states:

The payment data collected by CMS for tests on the Clinical Laboratory Fee Schedule (CLFS) does not result in an accurate weighted median of private payer rates for most tests on the CLFS, as required by the Protecting Access to Medicare Act (PAMA). We believe the data used to set the proposed rates would not stand up to statistical validity review. The data sources used to determine the preliminary rates do not appear to reflect the various market segments, which CMS has the authority to consider in order to validate the data submitted. It is also clear from our review that the overly burdensome regulatory requirements resulted in the submission of inaccurate and incomplete laboratory payment data that is not reliable for use in its current form. As a stakeholder community, we have repeatedly pointed out to CMS, HHS, and Congress in formal comments and in meetings our concerns with the final PAMA regulation, including the serious limitations and skewed process the regulation created."

Additionally, the groups stress that the CLFS rates will "now result in significant harm to the nation's surveillance network for emergent public health issues, job losses across the United States, and significantly reduced access to clinical laboratory testing for Medicare beneficiaries, particularly those in rural geographic and post-acute care settings."

"The HHS Office of the Inspector General previously stated in its evaluation of the regulation that it may lead to inaccurate Medicare payment rates for lab tests," says Mark S. Birenbaum, Ph.D., NILA Administrator. "We see with the release of flawed payment data that the OIG was correct. NILA urges Congress to work with HHS to suspend any implementation of revised Medicare payment rates until they can resolve the regulatory issues that have prohibited the government from accurately assessing data from all segments of the laboratory market. The consequences of getting this wrong are too grave, threatening access to clinical laboratory testing relied on by physicians and seniors for medical diagnoses, treatment, and monitoring of care."

The letter cites revisions to the PAMA regulation that must be addressed before stakeholders can support implementation. Specific concerns include data integrity, market representation of all segments of the laboratory market including national independent, community and rural independent, hospital outreach, and physician office laboratories, and the validation of data collection by CMS.

AdvaMedDx Executive Director Andrew Fish noted, “For many tests, the Medicare reimbursement cuts now projected to take place under the PAMA are dramatically deeper than Congress originally envisioned, which could imperil patient access to important diagnostic tests.” Fish continued, “It appears that this is due in significant measure to serious flaws in the lab-reported data CMS used to calculate the new payment rates, which do not accurately reflect the private market. CMS should suspend implementation of new rates under PAMA until stakeholders can be assured that they fairly reflect the full diagnostics marketplace and are consistent with Congressional expectations when PAMA was enacted.”

Signers to the letter to Administrator Verma include: AdvaMedDx, American Academy of Family Physicians, American Association of Bioanalysts, American Association for Clinical Chemistry, American Clinical Laboratory Association, American Hospital Association, American Medical Association, American Medical Technologists, American Society for Clinical Laboratory Science, American Society for Clinical Pathology, American Society for Microbiology, Association of American Medical Colleges, Association of Public Health Laboratories, Clinical Laboratory Management Association, COLA, College of American Pathologists, Medical Group Management Association, National Association for the Support of Long Term Care, National Independent Laboratory Association, New York State Clinical Laboratory Association, New York State Society of Pathologists and Point of Care Testing Association.

CMS’ period for comment on the proposed draft PAMA rates ends October 23rd.
To view the letter, click here.

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