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**ACLA Warns CMS’ Proposed Coding and Payment Proposals that Pose Draconian Cuts to Innovative Life-Saving Diagnostics**

**Will Jeopardize the Advancement of Personalized Medicine**

*Leading National Clinical Lab Association Cautions Payment Proposals Threaten*

*Patient Access to Critical Diagnostic Tests by Failing to Acknowledge Clinically Validated Data*

(WASHINGTON, DC) – The nation’s largest organization representing the public policy interests of clinical laboratories across the U.S., the [American Clinical Laboratory Association (ACLA)](http://www.acla.com/), said today coding and payment proposals for highly advanced molecular diagnostic tests recently released by the Centers for Medicare and Medicaid (CMS) will seriously hamstring physicians’ ability to determine the best course of treatment and impact patient care for those depending on accurate diagnoses and effective medications.

“Clinical laboratories and the scientists and laboratorians ushering in the new frontier of personalized medicine are changing the lives of patients and enhancing their quality of care every day,” said Alan Mertz, President of ACLA. “President Obama has highlighted the clear potential for precision medicine to improve healthcare for patients and continue the country’s progress as a world leader in medical innovation. Slashing payment of these tests – some up to ninety percent – will have a profound impact on the success we’ve achieved thus far, thanks to life-saving diagnostic discoveries.”

CMS’ proposed payment determinations for new codes paid under the Clinical Laboratory Fee Schedule (CLFS) in CY2016, include severe cuts to the set of nine codes for advanced diagnostic laboratory tests (ADLTs) that are currently covered and paid for by Medicare through their respective local contractors. These proposed cuts of 33% to as much as 91%, if finalized, are in direct conflict with the agency’s precedent for establishing rates for these type tests through the local contractors. This proposed rate-setting methodology is inconsistent with the vast majority of stakeholder input and the recommendations of CMS’ own Advisory Panel on Clinical Diagnostic Laboratory Tests.

“These highly advanced diagnostics tests are on the cutting edge of science and guiding physicians in the area of treatment for several conditions afflicting hundreds of thousands of Americans, including heart disease, cancer, and rheumatoid arthritis,” said Mertz. “These proposals represent an enormous step back from the huge leaps and bounds we have seen in diagnostic science and the direct impact on saving lives.”

CMS allows for a 30-day comment period on these proposed rates. Mertz noted ACLA will work with CMS to change the payment determinations to gapfill to ensure continued patient access and consistency with current law and past precedents.

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*The ACLA is a not-for-profit association representing the nation’s leading national, regional and esoteric clinical laboratories on key issues of common concern, including federal and state government reimbursement and regulatory policies.*