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ACLA Supports CMS Response on Genetic Specialty

Washington, DC - The American Clinical Laboratory Association (ACLA) commends the Centers for Medicare and Medicare Services (CMS) for its measured response to a citizens' petition to create a "genetic testing specialty" under the Clinical Laboratory Improvement Amendments of 1988 (CLIA). In its August 15, 2007 response, CMS concluded that they can more effectively oversee genetic testing under existing regulations and infrastructure and that the arguments and evidence do not justify rulemaking to establish a new genetics specialty under CLIA.

The letter reiterates that "(u)nder existing regulations, all laboratories performing genetic testing of moderate or high complexity must maintain the accuracy of their testing procedures, and at least twice annually verify the accuracy of any genetic test or procedure they perform...The CMS intends to continue to ensure that laboratories fulfill their regulatory obligations to meet [these requirements]." The agency stated it will continue to apply existing quality control and other CLIA requirements to genetic testing and monitor further developments in the field of genetics.

Alan Mertz, President of ACLA, applauded CMS' decision. "Laboratories that perform genetic testing are already subject to stringent CLIA requirements for quality, personnel qualifications and proficiency testing," Mr. Mertz said. "ACLA has long advocated strict enforcement of CLIA standards to ensure the accuracy and reliability of all testing performed by CLIA certified laboratories. We support CMS' ongoing efforts to enhance the oversight of genetic testing as the most appropriate approach to maximizing the benefits to our patients of this promising new technology."

ACLA represents the leading national, regional and local laboratories.

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