



Better health through  
laboratory medicine.

February 15, 2019

Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
P.O. Box 8016  
Baltimore, Maryland 21244-8016

Attention CMS-3356-NC

Dear Sir/Madam:

The American Association for Clinical Chemistry (AACCC) welcomes the opportunity to provide input to the Centers for Medicare and Medicaid Services (CMS) regarding its December 31, 2018 *Federal Register* notice that outlines the agency's plan for increasing the fees paid by laboratories under the Clinical Laboratory Improvement Amendments (CLIA) program. The agency proposes to increase CLIA fees by 20 percent to address a pending budgetary shortfall in program funding. AACCC supports the payment increase.

AACCC is a global scientific and medical professional organization dedicated to clinical laboratory science and its application to healthcare. AACCC brings together more than 50,000 clinical laboratory professionals, physicians, research scientists, and business leaders from around the world focused on clinical chemistry, molecular diagnostics, mass spectrometry, translational medicine, lab management, and other areas of clinical laboratory science to advance healthcare through collaboration, knowledge, expertise, and innovation.

As CMS seeks additional fees to pay for the CLIA program, AACCC suggests that the agency outline how it plans to allocate these funds—not only for existing activities, but also for any future initiatives. AACCC has recently recommended improvements to the program, one of which is to restart CMS' Certificate of Waiver (CoW) project. Under this previously implemented project, the agency inspected two percent of waived laboratories annually, uncovering serious quality problems in some of these facilities that could then be addressed. CMS discontinued the program in 2016 to focus on physician-performed microscopy laboratories.

The data from CoW inspections was invaluable not only to the laboratories that were inspected, but also in helping CDC and CMS develop best practice documents and modules to improve the performance of all CoW laboratories. As testing performed by waived facilities continues to grow and expand, it becomes more important to ensure these entities provide the highest quality testing possible. Inspections should include a wide variety of CoW testing sites, such as physician office laboratories, home health agencies, pharmacies, retail stores, and nursing homes.

CMS

February 15, 2019

Page Two

Other aspects of CLIA that need examination are the standards pertaining to laboratory developed tests (LDTs). In recent years, there has been much discussion among policymakers and healthcare stakeholders about the need for expanded regulation of these tests, which are distinct from *in vitro* diagnostic testing platforms. AACC asserts that the CLIA oversight structure for LDTs is appropriate and would support reasonable evidence-based improvements within the confines of CLIA to address LDT concerns. CMS should play a central role in facilitating this process.

On behalf of AACC, I would like to thank you for the opportunity to provide comments on this proposal. If you have any questions, please email Vince Stine, PhD, AACC's Senior Director of Government and Global Affairs, at [vstine@aacc.org](mailto:vstine@aacc.org).

Sincerely,

A handwritten signature in black ink, appearing to read 'Carmen Wiley', with a stylized flourish at the end.

Carmen L. Wiley, PhD, DABCC, FAACC  
President, AACC