



**ASSOCIATION FOR MOLECULAR PATHOLOGY**

*Education. Innovation & Improved Patient Care. Advocacy.*

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March 1, 2019

Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attention: CMS-3356-NC  
P.O. Box 8016  
Baltimore, MD 21244-8016

Regarding: Docket ID: CMS-2018-0166, Medicare Program; Clinical Laboratory Improvement Amendments of 1988 (CLIA) Fees

Comments submitted electronically at [www.regulations.gov](http://www.regulations.gov)

To Whom It May Concern:

On behalf of the Association for Molecular Pathology (AMP), thank you for the opportunity to submit these comments to Docket ID: CMS-3356-NC regarding the Clinical Laboratory Improvement Amendments of 1988 (CLIA) Fees. AMP is an international medical and professional association representing approximately 2,500 physicians, doctoral scientists, and medical technologists who perform or are involved in laboratory testing based on knowledge derived from molecular biology, genetics, and genomics. Membership includes professionals from academic medicine, hospital-based and private clinical laboratories, the government, and the in vitro diagnostics industry.

AMP writes to you in support of the one-time adjustment, i.e., 20% increase, to both the certificate fees used to cover the general costs of administering the CLIA program and the inspection fees for non-accredited laboratories as proposed in the Federal Register notice published on December 31, 2018. Recognizing that the fees have not been increased since 1992, while at the same time laboratories are using more complex testing platforms and laboratory developed testing procedures (LDPs), AMP appreciates the need for additional resources to meet the needs of the CLIA program so that it may continue to be solvent.

We believe the CLIA program plays an integral role in the oversight of LDPs and promoting patient access to high quality and reliable tests. In 2015, AMP shared a proposal with policymakers that would modernize the CLIA program to reflect advances in laboratory medicine and continue to advocate for its implementation.<sup>1</sup> As part of this effort, AMP supports expanding the use of proficiency testing and

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<sup>1</sup> <https://www.amp.org/advocacy/advocacy-resources/laboratory-developed-testing-procedures-ldps/>

standardized reference materials, as well as expanding on recent efforts by CMS to update the list of analytes. AMP recognizes that increasing responsibility for the agency also requires an increase in resources, which is why AMP is supportive of the proposed fee adjustment. We hope that the CLIA program will devote some of the revenue generated with this fee increase to modernize the program itself to meet the needs of a field of medicine that has evolved significantly in the more than three decades since the program's inception.

Thank you again for the opportunity to submit these comments on the one-time fee adjustment for the CLIA program. Recognizing its value and role in promoting public health, AMP remains a strong advocate for CLIA and offers its assistance with this and future efforts to modernize the program. If you have any questions, please contact Tara Burke, AMP Senior Director of Public Policy and Advocacy at [tburke@amp.org](mailto:tburke@amp.org).

Sincerely,

Victoria M. Pratt, PhD, FACMG  
President, Association for Molecular Pathology