

April 4 2019

Seema Verma  
Administrator  
Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
7500 Security Boulevard  
Baltimore, MD 21244-1850

Submitted via Regulations.gov

Re: CMS-3355-P Clinical Laboratory Improvement Amendments of 1988 (CLIA) Proficiency Testing Regulations Related to Analytes and Acceptable Performance

Administrator Verma,

The Association for Public Health Laboratories (APHL) appreciates the opportunity to comment on the proposed rule regarding proficiency testing.

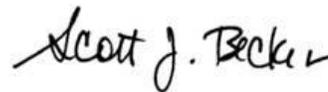
APHL supports the proposed change in the criteria defining acceptable performance for blood lead in CMS-approved proficiency testing (PT) programs. Despite success in reducing mean blood lead levels among young children to less than 2µg/dL, childhood lead poisoning remains a significant environmental health issue. In 2012, CDC changed from using a 10 or more µg/dL “level of concern”, to the current 5µg/dL “reference value” used to identify children with lead exposure who require case management. Changing the PT criteria for an acceptable response for blood lead from +/- 4µg/dL to the proposed values in § 493.937 of  $\pm 10\%$  or  $\pm 2\mu\text{g/dL}$  (whichever is greater) around the target value is more appropriate at a reference value of 5µg/dL.

APHL’s state and local governmental health laboratory members detect infectious disease outbreaks, chemical contaminants in people and the environment, foodborne illness clusters, screen newborns for genetic and metabolic conditions, respond to natural disasters, industrial accidents and suspected biological, chemical or radiological terrorism and support enforcement of water, food, dairy and environmental safety laws through testing. We appreciate your attention to this issue and if we can be of any assistance, please contact Kuki Hansen, APHL’s Manager of Regulatory and Public Policy at [kuki.hansen@aphl.org](mailto:kuki.hansen@aphl.org) or 240 485 2746.

Sincerely,



Paul Moyer, MS  
Chair, Environmental Health Committee  
Association of Public Health Laboratories



Scott J. Becker, MS  
Executive Director  
Association of Public Health Laboratories

*APHL works to strengthen laboratory systems serving the public’s health in the US and globally. APHL’s member laboratories protect the public’s health by monitoring and detecting infectious and foodborne diseases, environmental contaminants, terrorist agents, genetic disorders in newborns and other diverse health threats.*