



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 493

[CMS-3355-N]

RIN 0938-AT55

Clinical Laboratory Improvement Amendments of 1988 (CLIA) Proficiency Testing Regulations Related to Analytes and Acceptable Performance; Extension of Comment Period

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS; Centers for Disease Control and Prevention (CDC), HHS.

ACTION: Proposed rule; extension of comment period.

SUMMARY: This document extends the comment period for the notice of proposed rulemaking with comment entitled “Clinical Laboratory Improvement Amendments of 1988 (CLIA) Proficiency Testing Regulations Related to Analytes and Acceptable Performance” that appeared in the February 4, 2019 **Federal Register**. The comment period for the proposed rule, which would end on April 5, 2019, is extended 60 days.

DATES: The comment period for the proposed rule published February 4, 2019, at 84 FR 1536, is extended to 5 p.m., eastern daylight time, on June 4, 2019.

ADDRESSES: You may submit comments as outlined in the February 4, 2019 proposed rule (84 FR 1536). Please choose only one method listed.

FOR FURTHER INFORMATION CONTACT: Sarah Bennett, CMS, (410) 786-3531; or Nancy Anderson, CDC, (404) 498-2741.

SUPPLEMENTARY INFORMATION:

In the “Clinical Laboratory Improvement Amendments of 1988 (CLIA) Proficiency Testing Regulations Related to Analytes and Acceptable Performance” proposed rule that appeared in the February 4, 2019 **Federal Register** (84 FR 1536), we solicited public comments on proposed changes to current proficiency testing (PT) analytes, including acceptance limits, in addition to technical changes to the PT referral regulations to more closely align them with the CLIA statute.

We received an inquiry from several PT programs regarding the 60-day comment period for the proposed rule. The commenters stated that providing all stakeholders additional time to review and comment would allow them to conduct a more comprehensive review in order to develop detailed responses to the technical aspects of this proposed rule given that it would represent the first comprehensive change to the PT regulations since the implementation of CLIA in 1992.

In order to maximize the opportunity for the public to provide meaningful input to CMS and CDC, we believe that it is important to allow additional time for the public to prepare comments on the proposed rule. In addition, we believe that granting an extension to the public comment period in this instance would further our overall objective to obtain public input on the potential changes related to PT that we are considering. Therefore, we are extending the comment period for the proposed rule for an additional 60 days.

Dated: March 29, 2019.

Seema Verma,

Administrator,

Centers for Medicare & Medicaid Services.

Dated: April 1, 2019.

Robert Redfield,

Director,

Centers for Disease Control and Prevention and

Administrator,

Agency for Toxic Substances and Disease Registry.

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