DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 493

[CMS–3355–F2]

RIN 0938–AT55

Clinical Laboratory Improvement Amendments (CLIA) Proficiency Testing Related to Analytes and Acceptable Performance; Correction

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Final rule; correction.

SUMMARY: In the July 11, 2022 issue of the **Federal Register**, we published a final rule that updated proficiency testing (PT) regulations under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) to address current analytes (that is, substances or constituents for which the laboratory conducts testing) and newer technologies. The effective date was August 10, 2022, except for the amendments in amendatory instructions 2 and 5 through 21, which are effective July 11, 2024. This document corrects one technical error identified in the July 11, 2022 final rule.

DATES: This document is effective July 11, 2024, and is applicable beginning August 10, 2022.

FOR FURTHER INFORMATION CONTACT: Sarah Bennett, CMS, (410) 786–3531; or Heather Stang, CDC, (404) 498–2769.

SUPPLEMENTARY INFORMATION:

I. Background

In FR Doc. 2022–41513 (87 FR 41240), the final rule entitled ''Clinical Laboratory Improvement Amendments of 1988 (CLIA) Proficiency Testing Regulations Related to Analytes and Acceptable Performance'' (hereinafter referred to as the July 11, 2022 final rule), there was a technical error that is identified and corrected in the regulation text of this correction. The provision of this correction revises a regulation that become effective on July 11, 2024.

II. Summary of Errors

On page 41240 of the July 11, 2022 final rule, we made a technical error in ''Table 2 to Paragraph (c)(2)'' of § 493.933. In this table, we inadvertently noted the units for ''Carcinoembryonic antigen (CEA)'' as ''ng/dL'' when the correct units are ''ng/mL.'' Accordingly, we are revising ''Table 2 to Paragraph (c)(2)'' of § 493.933.

III. Waiver of Proposed Rulemaking and Delay in Effective Date

We ordinarily publish a notice of proposed rulemaking in the **Federal Register** to provide a period for public comment before the provisions of a rule take effect in accordance with section 553(b) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). However, we can waive this notice and comment procedure if the Secretary finds, for good cause, that the notice and comment process is impracticable, unnecessary, or contrary to the public interest, and incorporates a statement of the finding and the reasons therefore in the rulemaking.

Section 553(d) of the APA ordinarily requires a 30-day delay in effective date of final rules after the date of their publication in the **Federal Register**. This 30-day delay in effective date can be waived, however, if an agency finds for good cause that the delay is impracticable, unnecessary, or contrary to the public interest, and the agency incorporates a statement of the findings and its reasons in the rule issued.

This correction merely corrects an error in one analyte unit of measurement in the regulation text of the July 11, 2022 final rule. We are correcting this technical error to ensure that the table accurately reflects the policy adopted in the final rule. Therefore, we find that undertaking further notice and comment procedures to incorporate this minor technical correction into the final rule is unnecessary and contrary to the public interest.

For the same reasons, we are also waiving the 30-day delay in effective date for this correction. We believe that it is in the public interest to ensure that the July 11, 2022 final rule accurately states the correct units. Thus delaying the effective date of this correction would be contrary to the public interest. Therefore, we also find good cause to waive the 30-day delay in effective date.

Correction

■ Effective July 11, 2024, in FR Doc. 2022–41513, appearing at 87 FR 41194 in the **Federal Register** of July 22, 2022, on page 41240, in amendatory instruction 18 for § 493.933, in table 2 to paragraph (c)(2), the entry for ''Carcinoembryonic antigen (CEA)'' is corrected to read as follows:

§ 493.933 [Corrected]

* * * * *

(c) * * *

(2) * * *

TABLE 2 TO PARAGRAPH (c)(2)—CRITERIA FOR ACCEPTABLE PERFORMANCE

The criteria for acceptable performance are—Analyte or test	Criteria for acceptable performance
* * * * * * *	
Carcinoembryonic antigen (CEA)	Target value ±15% or ±1 ng/mL (greater).
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Elizabeth J. Gramling,

Executive Secretary to the Department, Department of Health and Human Services.

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