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**Center for Clinical Standards and Quality**

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**Ref: Admin Info-23-07-CLIA**

**DATE:** May 03, 2023

**TO:** State Survey Agency Directors

**FROM:** Directors, Quality, Safety & Oversight Group (QSOG)

**SUBJECT:** Implementation Notification for Final Rule CMS-3355-F, Clinical Laboratory Improvement Amendments of 1988 (CLIA) Proficiency Testing - Analytes and Acceptable Performance Final Rule

**Memorandum Summary**

- This Admin Info memo clarifies that the Proficiency Testing Final Rule (CMS-3355-F) requirements effective July 11, 2024 will be implemented on January 1, 2025.
- The implementation date applies to regulations at §§ 493.2 and 493.801 through 493.959.

**Background:**

Participation in Proficiency Testing (PT) is required under the CLIA statute for laboratories that perform moderate or high complexity testing. PT evaluates a laboratory's performance by testing of unknown samples just as it would test patient samples. An HHS-approved PT program sends unknown samples to a laboratory for analysis. After testing, the laboratory reports its results to the PT program, which grades the results using the CLIA grading criteria and provides the laboratory with its scores. PT is crucial to maintaining the quality of laboratory testing because it independently verifies the accuracy and reliability of laboratory testing, including the competency of testing personnel. As an example, glucose (blood sugar) and white blood cell count measurements are analyte test procedures required as part of PT programs.

CMS published a final rule related to proficiency testing - analytes and acceptable performance on July 11, 2022 with an effective date of July 11, 2024 for §§ 493.2 and 493.801 through 493.959. On July 11, 2022, CMS published a memorandum, [QSO-22-21-CLIA](#), that included the effective dates of the final rule and summarized the new requirements. The final rule CMS-3355-F, Clinical Laboratory Improvement Amendments of 1988 (CLIA) Proficiency Testing Regulations Related to Analytes and Acceptable Performance, was published in the Federal Register on July 11, 2022. This final rule will affect laboratories that perform testing for any of the analytes or microbiology subspecialties listed in the CLIA regulations under subpart I.

The final rule may be viewed at <https://www.federalregister.gov/>.

**Discussion:**

The Proficiency Testing Final Rule (CMS-3355-F) requirements related to PT program providers and laboratories, including PT enrollment, while effective July 11, 2024, will be implemented on January 1, 2025.

**Contact:**

For questions or concerns relating to this memorandum, please contact [LabExcellence@cms.hhs.gov](mailto:LabExcellence@cms.hhs.gov).

**Effective Date:**

Immediately. Please communicate to all appropriate staff within 30 days.

/s/

David R. Wright  
Director, Quality, Safety & Oversight Group