

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C2-21-16
Baltimore, Maryland 21244-1850



Center for Clinical Standards and Quality/Quality Safety & Oversight Group

March 15, 2023

Dear PT Program Providers,

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. It will also affect any laboratory that participates in PT referral involving waived testing.

This final rule includes:

- the addition and deletion of analytes or tests that require proficiency testing (PT), as well as updates the criteria for acceptable performance and administrative processes for CLIA PT programs.
- an update to align the CLIA regulations with the statute (42 U.S.C. 263a (i)(4)), which does not exclude waived tests from the ban on improper PT referral.

The revisions to PT requirements related to the addition and deletion of analytes or microbiology tests and updates to the criteria for acceptable performance and administrative processes for PT programs (§§ 493.2 and 493.801 through 493.959) are effective on July 11, 2024, two years after the publication date of the final rule in the Federal Register. **The implementation date for the laboratories and PT program providers for these revisions will be January 01, 2025 which is in alignment with our current process for PT program providers and PT enrollment.**

Learn more about the final rule in the [Federal Register](#).

If you have any questions, please contact Sarah Bennett and Penny Keller at the following email address:

Sarah.Bennett1@cms.hhs.gov and Penny.Keller@cms.hhs.gov.

Sincerely,

A handwritten signature in black ink, appearing to read "G. Brandush".

Gregg S. Brandush, RN, JD
Director, Division of Clinical Laboratory Improvement
and Quality
Quality Safety and Oversight Group
Center for Clinical Standards and Quality