

FACT SHEET

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

CMS is issuing a final rule regarding proficiency testing (PT) in laboratories. PT is a tool the laboratory can use to verify the accuracy and reliability of its testing, and can also be used to validate the entire testing process, including competency of your testing personnel. This final rule includes the addition and deletion of analytes (substances) which require PT and updates both the criteria for acceptable performance and PT program administrative processes. We are also finalizing proposed changes related to PT referral (the sending of PT from one lab to another).

PT programs were established to evaluate a laboratory's performance by testing unknown samples just as it would test patient samples. An HHS-approved PT program sends unknown samples to the laboratory for analysis and provides the laboratory with its scores. Participation in PT is required under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) statute for laboratories that perform moderate or high complexity testing.

Initial regulations were established in 1992, and testing has advanced significantly. Some tests that were not required in 1992 are now done on a routine basis, requiring an update to the regulations.

This fact sheet discusses the changes that CMS and CDC are finalizing:

For non-microbiology specialties and subspecialties such as chemistry, toxicology, etc, we are finalizing the addition of 29 analytes to Subpart I of the CLIA regulations, based upon the following criteria:

1. Current availability of proficiency testing materials
2. The number of proficiency testing programs that can provide the analytes
3. Volume of patient testing performed nationwide
4. Impact on patient health and/or public health
5. Cost and feasibility of implementation

For microbiology specialties and subspecialties such as bacteriology, virology, etc., we are finalizing the requirements to specify broad categories of tests for which proficiency testing is required in order to allow flexibility for new technologies currently in use and those that may be developed in the future.

We are also finalizing the regulations to reflect that laboratories that perform moderate and high complexity testing and also voluntarily participate in PT for waived tests (simple tests such as

urine pregnancy test), are subject to compliance. This will align the regulations with the CLIA statute, which does not exclude waived tests from the ban on improper PT referral.

Summary of Changes Proposed to Final Rule:

Delayed Effective Date and Ongoing Process for Updating PT Regulation

CMS is delaying the effective date of the revisions to proficiency testing requirements until 2 years after the publication of this final rule in the Federal Register based on public comment. However, the regulations related to laboratories performing tests of moderate complexity and high complexity testing that also perform waived testing and proficiency testing enrollment, will be effective 30 days after the publication date of this final rule.

Definitions

CMS is finalizing new definitions to clarify terms used in proficiency testing to align with current practices and stakeholder comment. The definition for “acceptance limit” was accepted, the definition of “peer group” was clarified with a technical edit, the definition of “target value” was revised, and the proposed definition of “unacceptable score” was removed.

Enrollment and Testing of Samples

The final rule includes an update to align the CLIA regulations with the statute which includes proficiency testing (PT) referral for waived tests.

PT Program Approval and Administration

The final rule requires that the PT program have at least 10 laboratory participants for each specialty, subspecialty, and analyte or test for which the proficiency testing program is seeking reapproval. CMS is clarifying certain contractors must be a private nonprofit organization or a Federal or State agency, or an entity acting as a designated agent for the Federal or State agency. The final rule allows for changes in the PT program reapproval process.

CMS will not be including the proposed addition of a mechanism to track changes submitted electronically based on public comment.

Changes to Microbiology PT

Microbiology regulations have been modified to remove the types of services listed for each microbiology subspecialty and to add categories of testing (that is, replace the list with broader categories of organisms) for each microbiology subspecialty.

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In the final rule, CMS will not include antigen and toxin detection in the mycobacteriology subspecialty and stains and antiparasitic susceptibility or resistance testing in the subspecialty of parasitology because no PT program offers applicable PT modules.

Changes to PT for Non-microbiology Specialties and Subspecialties

CMS and CDC determined which analytes should be added to, or deleted from, Subpart I. In addition, criteria for acceptable performance, which include the target values and acceptance limits (ALs) have been updated or established by CMS and CDC. All new and currently required analytes' criteria for acceptable performance were evaluated and amended to include percentages with or without fixed ALs.

A percentage-based criterion can be unnecessarily stringent at low concentrations – either because of technical feasibility or because medical needs at the low concentration do not require such tight precision. As a result, analytes have percentage based ALs with or without additional fixed ALs.

The final rule can be downloaded from the *Federal Register* at: <https://www.federalregister.gov/>.

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