Issue Brief

FEDERAL ISSUE BRIEF • July 11, 2022

CMS Releases Final Rule Regarding Clinical Laboratory Improvement (CLIA) Proficiency Testing Related to Analytes and Acceptable Performance

The Centers for Medicare and Medicaid Services have issued a final rule regarding Clinical Laboratory Improvement (CLIA) Proficiency Testing (PT) Related to Analytes and Acceptable Performance. The rule is scheduled for publication in the ***Federal Register*** on July 11. A copy is already available at: https://www.govinfo.gov/content/pkg/FR-2022-07-11/pdf/2022-14513.pdf.

The rule will update proficiency testing (PT) regulations to address current analytes (that is, substances or constituents for which the laboratory conducts testing) and newer technologies. The rule also makes technical changes to PT referral regulations to "better align them with the CLIA statute."

Participation in PT is required under the CLIA statute for laboratories that perform moderate or high complexity testing. PT evaluates a laboratory's performance by testing unknown samples just as it would test patient samples.

The rule's requirements affects approximately 35,967 clinical laboratories subject to participation in PT, resulting in some cost implications. In addition, as a result of this final rule, the eight existing CLIA-approved PT programs will incur some costs as they modify their programs to meet the specified requirements. It will also have an effect on CLIA-exempt States regarding State PT requirements.

The rule's is effective August 10, 2022, except for the amendments to §§ 493.2 and 493.801 through 493.959 (amendatory instructions 2 and 5 through 21), which are effective July 11, 2024.

Final Actions

A. Effective Date and Ongoing Process for Updating PT Regulations (§§ 493.2 and 493.801 through 493.959).

- CMS is delaying the effective date of the revisions to §§ 493.2 and 493.801 through 493.959 until 2 years after the publication of this rule in the ***Federal Register***.

continued

4712 Country Club Drive
Jefferson City, Mo. 65109

P.O. Box 60
Jefferson City, Mo. 65102

573/893-3700
www.mhanet.com

MHA
MISSOURI HOSPITAL ASSOCIATION

B. Definitions (§ 493.2) – The rule amends the definitions and PT requirements and Participation in Proficiency Testing for Laboratories Performing Nonwaived Testing; and Proficiency Testing Programs for Nonwaived Testing in the CLIA regulations.

- CMS says it did not receive any comments on the proposed definition of "acceptance limit" and is finalizing the definition with a clarifying technical edit.
- Based on the public comments received, CMS says it is finalizing the proposed definition of "peer group" with a clarifying technical edit.
- CMS is revising and finalizing the proposed definition for "target value."
- CMS is not finalizing the proposed definition of "unacceptable score."

C. Enrollment and Testing of Samples (§§ 493.20(c) and 493.25(d))

- CMS is finalizing its proposed revisions at §§ 493.20(c) and 493.25(d).
- CMS is finalizing the proposed revisions at §§ 493.801 and 493.861. Section 493.801 will require laboratories to report PT results for microbiology organism identification to the highest level that they report results on patient specimens. Section 493.861 will amend the satisfactory performance criteria for failure to attain an overall testing event score for unexpected antibody detection from "at least 80 percent" to "100 percent."
- CMS says it received no comments on the proposed revisions at §§ 493.801 and 493.861.

D. PT Program Approval and Administration (§§ 493.901, 493.903, 493.905)

- CMS is finalizing its proposed changes to §§ 493.901(a), (c)(8), (e), (f), 493.903(a)(3), and 493.905.
- Based on comments received, CMS is not finalizing the proposed addition at § 493.901(c)(6).

E. Proposed Changes to Microbiology PT (§§ 493.911 through 493.919)

- CMS is finalizing the proposed revisions at §§ 493.911 through 493.919 by removing the types of services listed for each microbiology subspecialty and inserting a more general list of organisms.
- CMS is finalizing the proposed revisions at §§ 493. 911(a), 493.913(a), and 493.915(a) that are related to growth or no growth and mixed culture requirements (50 percent to 25 percent).
- CMS is finalizing the proposed performance criteria revisions at §§ 493.911(b),493.913(b), 493.915(b), 493.917(b), and 493.919(b).
- CMS is finalizing the proposed addition of "without identification" to the end of the phrase currently in the subspecialty

continued

of parasitology at § 493.917(a)(1)(ii)(A) to be consistent with the other subspecialties.

- CMS is finalizing the proposed revised requirement at §§ 493.911(b)(2), 493.913(b)(2), 493.915(b)(2), 493.917(b)(2), and 493.919(b)(2) to clarify and emphasize that laboratories should detect and identify organisms to the highest level that they report results on patient specimens.
- CMS will amend §§ 493.911(b)(1), 493.913(b)(1), 493.915(b)(1), 493.917(b)(1), 493.919(b)(1) to clarify that for the purpose of achieving consensus, PT programs must attempt to grade using both participant and referee laboratories before determining that the sample is ungradable.
- CMS is finalizing the proposed revisions to § 493.911(a) through (b) related to Gram stains, direct antigen detection, bacterial toxin detection, and performance and scoring related to direct antigen and bacterial toxin detection for the subspecialty of bacteriology.
- CMS is finalizing the proposed addition to § 493.915(a) related to requiring direct antigen testing for the subspecialty of mycology.
- CMS is finalizing the proposed addition to § 493.917(a) related to requiring direct antigen testing for the subspecialty of parasitology.
- CMS is finalizing the proposed revision to § 493.919(a) related to requiring direct antigen testing for the subspecialty of virology.
- CMS is removing the reference to resistance testing in the subspecialty of bacteriology and have removed references to "resistance testing" in the requirement for antimicrobial susceptibility testing of select bacteria at § 493.911.
- CMS is not finalizing the proposed requirements for PT of antimicrobial susceptibility and resistance testing in the subspecialties of mycobacteriology, mycology, and virology and have removed the requirement at §§ 493.913, 493.915, and 493.919.

F. Proposed Changes to PT for Non-microbiology Specialties and Subspecialties (§§ 493.921 through 493.959)

- CMS is finalizing the proposed revision at §§ 493.923(a), 493.927(a), 493.931(a), 493.933(a), 493.937(a) and 493.941(a) to remove the option that PT samples "at HHS option, may be provided to HHS or its designee for on-site testing."
- CMS is finalizing the proposed addition of 29 analytes and the deletion of five analytes.

continued

Analytes for Addition

CLIA Regulation	Analytes
General Immunology § 493.927	Anti-HBs Anti-HCV C-reactive protein (high sensitivity)
Routine Chemistry § 493.931	B-natriuretic peptide (BNP) ProBNP Cancer antigen (CA) 125 Carbon dioxide Carcinoembryonic antigen Cholesterol, low density lipoprotein, direct measurement Ferritin Gamma glutamyl transferase Hemoglobin A1c Phosphorus Prostate specific antigen, total Total iron binding capacity (TIBC), direct measurement Troponin I Troponin T
Endocrinology § 493.933	Estradiol Folate, serum Follicle stimulating hormone Luteinizing hormone Progesterone Prolactin Parathyroid hormone Testosterone Vitamin B12
Toxicology § 493.937	Acetaminophen, serum Salicylate Vancomycin

The following analytes will be deleted:
§493.931 LDH isoenzymes, §493.937 ethosuximide, quinidine, primidone, and procainamide (and its metabolite, N-acetylprocainamide).

- CMS is amending §§ 493.923(b)(1), 493.927(c)(1), 493.931(c)(1), 493.933(c)(1), 493.937(c)(1), 493.941(c)(1), and 493.959(d)(1) to clarify that for the purpose of achieving consensus, PT programs must attempt to grade using both participant and referee laboratories before determining that the sample is ungradable.

- Section 493.927 (General Immunology)
  ++ CMS is correcting typographical or editorial errors in the proposed criteria for acceptable performance for alpha-1-antitrypsin, alpha-fetoprotein (tumor marker), complement C3, complement C4, antinuclear antibody, antistreptolysin O.
  ++ CMS is modifying the proposed acceptance limits (AL) for immunoglobulin A (IgA) of ±15 percent and finalizing the AL for IgA as ±20 percent based on public comments
  ++ CMS is finalizing the proposed criteria for acceptable performance for antinuclear antibody, antistreptolysin O, rheumatoid factor, and rubella.

- Section 493.931 (Routine chemistry)
  ++ CMS is finalizing the proposed ALs in the criteria for acceptable performance.
  ++ CMS is correcting the units for prostate specific antigen (total).

continued

Analysis provided for MHA by Larry Goldberg, Goldberg Consulting

++ CMS is making a technical change to CK-MB isoenzymes to address measurement by electrophoresis or direct mass determination.
++ CMS is also modifying the proposed criteria for acceptable performance for hemoglobin A1c of +/- 10 percent and finalizing the AL for hemoglobin A1c to +/- 8 percent based on public comments.

- Section 493.933 (Endocrinology)
  ++ CMS is finalizing the proposed percentage based ALs in the criteria for acceptable performance.

- Section 493.937 (Toxicology)
  ++ CMS is finalizing the proposed concentration limits and percentage based ALs in the criteria for acceptable performance.
  ++ CMS is finalizing the proposed requirement that PT programs must provide samples that cover the full range of samples that could occur in patient specimens.
  ++ CMS is correcting the units for phenytoin and vancomycin.

- Section 493.941 (Hematology)
  ++ CMS is finalizing the proposed AL for leukocyte count.
  ++ CMS is finalizing the proposed revision to units of reporting for prothrombin time to include seconds and INR (international normalized ratio) and that laboratories must report prothrombin time in the same was as they report patient results.
  ++ CMS is finalizing the proposed requirement that laboratories performing both cell counts and differentials must enroll and participate in PT for both.
  ++ CMS is finalizing the proposed change to the criteria for acceptable performance for "cell identification" from 90 percent to 80 percent.

- Section 493.959 (Immunohematology)
  ++ CMS is finalizing the proposed change to the criteria for acceptable performance for unexpected antibody detection from 80 percent to 100 percent.

COMMENT

This is an unusually organized rule in that it has made much reiteration to the proposed version followed by final actions such that the reader needs to compare the final with the proposed changes.

The rule is reg text intensive consuming some 36 pages, but it may be easier to decipher the reg information than the preamble.