Washington State Department of Health
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CMS Proposes New Rules for PT Regulations

Summary: The federal Centers for Medicare & Medicaid Services (CMS) has proposed modifications to current rules for proficiency testing, which include adding and deleting regulated analytes requiring proficiency testing, proposed modifications to current microbiology and non-microbiology specialty rules, proposed modifications for waived testing, and additional Proposed changes.

Please click here to see full article.

Source: Federal Register: Clinical Laboratory Improvement Amendments of 1988 (CLIA) Proficiency Testing Regulations Related to Analytes and Acceptable Performance: A Proposed Rule by the Centers for Medicare & Medicaid Services on Feb. 4, 2019.

Proposed changes addressed in this summary:
1) 29 analyte additions to CLIA subpart I
2) 6 analyte deletions to CLIA subpart I
3) Modifications to 42 CFR §493.911-919
4) Modifications for waived testing rules

1) **Specific Analytes Proposed for Addition to CLIA Subpart I (Table 1, Proposed Rule)**

General Immunology:
Anti-HBs,Anti-HCV, C-reactive protein (high sensitivity).

Routine Chemistry:
B-natriuretic peptide (BNP), ProBNP, cancer antigen (CA) 125, carbon dioxide, carcinoembryonic antigen, cholesterol, low density lipoprotein, ferritin, gamma glutamyl transferase, hemoglobin A1c, phosphorus, prostate specific antigen (total), total iron binding capacity, troponin I, troponin T.

Endocrinology:
Estradiol, folate (serum), follicle stimulating hormone, luteinizing hormone, progesterone, prolactin, parathyroid hormone, testosterone, vitamin B12

Toxicology:
Acetaminophen (serum), salicylate, vancomycin.

2) Specific Analytes Proposed for Deletion to CLIA Subpart I
LDH isoenzymes, ethosuximide, quinidine, primidone, and procainamide (and its metabolite, N-acetyl procainamide).

3) **Modifications to 42 CFR §493.911-919**

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Practice Guidelines

The following practice guidelines have been developed by the Clinical Laboratory Advisory Council. They can be accessed at the LQA website.

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Bleeding Disorders
Chlamydia
Diabetes
Group A Strep Pharyngitis
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Bacteriology

§ 493.911(a): For bacteriology, CMS proposes that PT is required for the following, and includes the performance and scoring criteria, as applicable:

- Gram stain, including the graded requirement for bacterial morphology;
- Direct bacterial antigen detection (this requirement has not changed);
- Bacterial toxin detection; and
- Identification of bacteria that includes one of the following:
  1. Detection of growth or no growth in culture media or identification of bacteria to the highest level that the laboratory reports results on patient specimens; and
  2. antimicrobial susceptibility or resistance testing on select bacteria.

§ 493.911(a)(2): For bacteriology, CMS proposes to decrease the required mixed cultures from 50 percent to 25 percent for culture challenges that require laboratories to report only the principal pathogen and those that require laboratories to report all organisms present.

§ 493.911(a)(3): For bacteriology, CMS proposes that the annual PT program contains representatives of the following major groups of medically important aerobic and anaerobic bacteria if appropriate for the sample sources:

- Gram-negative bacilli;
- Gram-positive bacilli;
- Gram-negative cocci; and
- Gram-positive cocci.

The general list of types of organisms will continue to cover the six major groups of bacteria currently listed in the regulations.

§ 493.911(b): The evaluation of a laboratory's performance would be modified to include bacterial morphology as one part of the performance criterion for scoring the Gram stain.

§ 493.911(a)(4): For bacteriology susceptibility, CMS proposes to require at least two PT samples per event for susceptibility or resistance testing, including one gram-positive and one gram-negative organism with a predetermined pattern of susceptibility or resistance to common antimicrobial agents.

Mycobacteriology

§ 493.913(a): For mycobacteriology, CMS proposes that PT is required for the following, as applicable:

- Acid-fast stain, and
- Detection and identification of mycobacteria that includes the following:
  1. Detection of growth or no growth in culture media or identification of mycobacteria; and
  2. Anti-mycobacterial susceptibility or resistance testing.

§ 493.913(a)(3): For mycobacteriology, CMS proposes that the annual program content must include the following:

- Mycobacterium tuberculosis complex and
- Mycobacterium other than tuberculosis (MOTT), if appropriate for the sample sources.

§ 493.913(a)(5): For mycobacteriology, CMS proposes a requirement of at least two PT samples per event for susceptibility or resistance testing, including mycobacteria that have a predetermined pattern of susceptibility or resistance to common anti-mycobacterial agents.

Mycology

§ 493.915(a): For mycology, CMS proposes that PT is required for the following, and includes the performance and scoring criteria, as applicable:

- Direct fungal antigen detection;
- Detection and identification of fungi and aerobic acti-

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nomycetes for the following:
1. detection of growth or no growth in culture media or identification of fungi and aerobic actinomycetes; and
2. antifungal susceptibility or resistance testing

§ 493.915(a)(3): For mycology, CMS proposes that the annual program content must include the following:
- Yeast or yeast-like organisms;
- Molds that include dematiaceous fungi, dermatophytes, dimorphic fungi, hyaline hyphomycetes, and mucormycetes; and
- Aerobic actinomycetes

§ 493.915(a)(4): For mycology, CMS proposes a requirement of at least two PT samples per event for susceptibility or resistance testing, including fungi that have a predetermined pattern of susceptibility or resistance to common antifungal agents.

Parasitology

§ 493.917(a): For parasitology, CMS proposes that PT is required for the following, and includes the performance and scoring criteria, as applicable:
- Direct parasite antigen detection; and
- Detection and identification of parasites including:
  1. detection of the presence or absence of parasites or
  2. identification of parasites.

§ 493.917(a)(3): For parasitology, CMS proposes that the annual program content must include the following:
- intestinal parasites and
- blood and tissue parasites, if appropriate for the sample sources.

Virology

§ 493.919(a): For virology, CMS proposes that PT is required for the following, and includes the performance and scoring criteria, as applicable:
- Viral antigen detection (this requirement has not changed);
- detection and identification of viruses; and
- antiviral susceptibility or resistance testing.

§ 493.919(a)(3): For virology, CMS proposes that the annual program content must include the following if appropriate for the sample sources:
- respiratory viruses;
- herpes viruses;
- enterovirus; and
- intestinal viruses, if appropriate for the sample sources.

§ 493.919(a)(4): For virology, CMS proposes a requirement of at least two PT samples per event for susceptibility or resistance testing, including viruses that have a predetermined pattern of susceptibility or resistance to common antiviral agents

Modifications to Waived Testing rules:

§ 493.801(b)(1) through (6): CMS proposes the following changes for CLIA-certified laboratories that perform waived testing, including
- Moderate and high complexity laboratories who perform waived testing,
- Certificate of Waiver laboratories, and
- Provider performed microscopy PPMP laboratories.

CMS proposes to amend the regulations to reflect that if moderate and high complexity laboratories also perform waived tests, compliance with **§ 493.801(a) and (b)(7)** are not applicable. However, we propose to continue to require compliance

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with **§ 493.801(b)(1) through (6)** to align the regulations with the CLIA statute (42 U.S.C. 263a(i)(4)), which does not exclude waived tests from the ban on improper PT referral.

These changes to waived testing rules ensure compliance with PT referral requirements found at **§ 493.801(b)(1) through (6)**. Changes to the rule will allow CMS to apply sanctions to those laboratories performing waived testing found participating in PT referral.

Please see full article for additional rule change proposals, including changes to proficiency testing acceptance limits, and changes to subparts H and I.

Comment period ends at 2 pm PDT on April 5, 2019.

Respond and Comment period:

1. Electronically: You may use this direct link to submit electronic comments on this regulation to. Follow the "Submit a comment" instructions.
2. Regular mail: You may mail written comments to the following address only: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-3355-P, P.O. Box 8016, Baltimore, MD 21244-8016.
3. Express/overnight mail: You may send written comments to the following address only: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-3355-P, Mail Stop C4-26-05, 7500 Security Boulevard, Baltimore, MD 21244-1850.

In commenting, please refer to file code CMS-3355-P. Because of staff and resource limitations, CMS does not accept comments by facsimile (fax) transmission.

For further information contact:

Sarah Bennett, CMS, 410-786-3531
Caecilia Blondiaux, CMS, 410-786-2190 or
Nancy Anderson, CDC, 404-498-2741

References:

CMS 41 CFR Part 493.
Federal Register Notifications.

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Comment period ends at 2 pm PDT on April 5, 2019.

See page 4 on how to respond and submit comments.

Calendar of Events

Training Classes:

2019 ASCLS-WA Spring Meeting
April 25-26 Olympia

2019 Northwest Medical Laboratory Symposium
October 9-12 Lynnwood, WA

26th Annual Clinical Laboratory Conference
November 12 Tukwila

Contact information for the events listed above can be found on page 2. The Calendar of Events is a list of upcoming conferences, deadlines, and other dates of interest to the clinical laboratory community. If you have events that you would like to have included, please mail them to ELABORATIONS at the address on page 2. Information must be received at least one month before the scheduled event. The editor reserves the right to make final decisions on inclusion.

Washington State Department of Health

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