

# CMS Seeks Public Comment on CLIA

## Request for Information to Inform Future Rulemaking



Information summarized from: [Federal Register Notice 83 FR 1004](#)  
Last updated 01/09/18

### BACKGROUND

On January 9, 2018, the Centers for Medicare & Medicaid Services (CMS) issued a request for information related to the Clinical Laboratory Improvement Amendments of 1988 (CLIA). Aside from minor modifications, CLIA has not been updated since it was originally written and CMS is soliciting public comment to assist in future rulemaking. Comments will be accepted by the agency until March 12, 2018.

### APHL ACTION

APHL will submit a comment to CMS and is currently gathering feedback from its membership and committees. Look for opportunities to provide your feedback on APHL's listservs, eUpdate and the Washington Weekly.

APHL also encourages individual members and laboratories to submit separate comments to CMS.

### SHORT SUMMARY

CMS seeks public comment on:

- A. Personnel requirements
- B. Proficiency testing (PT) referrals
- C. Histocompatibility requirements (not summarized in this issue brief. Refer to Federal Register notice for details)
- D. CLIA fees
- E. General feedback on other areas of CLIA

### MAJOR CHANGES

#### A. Personnel Requirements

1. Nursing Degrees: CMS seeks public comment to update the existing CLIA personnel recommendations. In Survey & Certification Letter 16-18-CLIA, CMS outlined that a bachelor's degree in nursing is equivalent to a bachelor's degree in biological sciences as the educational requirement for moderate and high complexity testing personnel (pg. 5-6).
  - CMS seeks public comment related to whether a bachelor's degree in nursing should be considered equivalent to a bachelor's degree in biological sciences or should be

considered a separate qualifying degree to meet the CLIA requirements for moderate and high complexity testing personnel and technical consultants.

- *NOTE: APHL has a [position statement](#) on nursing degree equivalency*
2. **Physical Science Degrees:** There is broad interpretation of the accepted definition of a “physical science degree” to fulfill CLIA’s educational requirements, with some definitions including degrees that do not relate to laboratory science (pg. 6-7).
    - CMS seeks public comment on what is considered a physical science degree and if physical science degrees provide the educational background needed such that all or some should be considered a qualifying degree to meet the intent of CLIA requirements at §§493.1405, 493.1411, 493.1423, 493.1443, 493.1449, 493.1461 and 493.1489
  3. **Personnel Competencies:** Current CLIA regulation allow general supervisors with associate’s degrees to perform competency assessment on high complexity testing personal; however, general supervisors cannot perform competency assessments on moderate complexity testing personnel unless they can meet the regulatory qualifications of a technical consultant (pg. 7).
    - CMS seeks public comment regarding whether general supervisors should be allowed to perform competency assessments for testing personnel performing moderate complexity testing in laboratories that perform both moderate and high complexity testing.
  4. **Personnel Experience, Training and Skills:** When CLIA refers to laboratory training it is assumed that the qualifying individual has training and experience in non-waived clinical laboratory testing and the experience is clinical in nature (pg. 8).
    - CMS seeks public comment on what is appropriate laboratory training, experience and skill when qualifying all personnel to meet CLIA requirements, and what comprises appropriate documentation to verify the training, experience and skills for all personnel positions in part 493, subpart M.
  5. **Non-Traditional Degrees:** CMS recognizes that non-traditional degrees that may be combined with job experience in lieu of coursework may be classified as general education degrees (pg. 8).
    - CMS seeks public comment related to non-traditional type degrees (for example, Regents Bachelor of Arts) specifically whether any of these types of degrees should be considered to meet the requirements for a chemical, physical, biological or clinical laboratory science and/or medical laboratory technology degree.

## **B. PT Referral**

Background: The Taking Essential Steps for Testing Act (TEST Act) (Pub. L. 112-202) gives the Secretary the ability to apply sanctions in the cases of intentional PT referral. There are three

categories of sanctions that apply under certain specified conditions depending on the extent of the violation.

1. Discretion for Category 1 PT Referral: reserved for the most egregious violations, including repeat PT referrals and cases where a laboratory reports out another laboratory's PT results, sanctions include loss of the laboratory's CLIA certificate for a minimum of a year and bans the owner or operator from running a CLIA-certified laboratory for a minimum of a year and may include a civil money penalty. There is no room for circumstantial review or review on a case by case basis (pg. 9).
  - CMS seeks public comment related to applying discretion in situations where CMS determines that a laboratory has referred its proficiency testing samples to another laboratory and has reported those results from another laboratory as their own, and under what circumstances should discretion be applied.
2. Alternative Sanctions for PT Referral by Certificate of Waiver (CoW) Laboratories: CoW laboratories are not exempt from the ban against PT referral; however, CLIA does state that CMS does not impose alternative sanctions on CoW laboratories because those laboratories are not inspected for compliance with condition-level requirements. Due to this, CMS' only recourse in cases of PT referral are revocation, suspension or limitation sanctions (pg. 11).
  - CMS seeks public comment regarding the feasibility of applying alternative sanctions in case of PT referral that involves waived testing.

### **C. Histocompatibility**

For the purposes of this issue brief, the changes to CLIA's histocompatibility regulations have not been summarized because public health laboratories do not conduct histocompatibility testing. For more details, please refer to the Federal Register notice.

### **D. CLIA Fees**

Background: CLIA fees have not been updated since 1992. CMS intends to update program compliance fees associated with a Certificate of Compliance, additional fee associated with a Certificate of Accreditation, fees for revised certificates, follow up visits, complaint investigations, and activities related to sanctions

1. Fees for Revised Certificates: CMS seeks to determine a fair and reasonable fee to support revised certificates (i.e. when there is a change in name, location, director, services offered or certificate type). This fee change would likely be nominal (pg. 15).
  - CMS seeks public comment on a methodology that would set a fair and reasonable fee for revised certificate requests. CMS also seeks comment as to whether fees should be nominal and, if nominal, whether such fee would cover the costs associated with the task.

2. Compliance Determination, Additional Fees and Methodology for Determining Fee Amounts: Fees associated with holding a Certificate of Compliance or a Certificate of Accreditation vary based on laboratory classification. The schedule used to determine the fee amount a laboratory is assessed will not be revised. Compliance determination fees have not been revised since 1992, though the cost of conducting reviews has increased. CMS seeks to determine a fair fee for compliance determination activities (pg. 16).
- CMS seeks public comment (including information such as evidence, research and trends) on an alternate method to calculate the average hourly rate for each entity as outlined in §493.649(b). CMS also seeks comment on whether the method should be standardized and updated annually or as needed.
  - CMS seeks public comments to update the fees for determination of program compliance as well as additional fees to accredited laboratories as outlined in §§493.643(b) and 493.645(b) respectively. CMS also seeks comment on whether fees collected should be subject to the same ten schedules as §493.643(c) and whether they should be changed based on any updates to methodology for determining the average hourly rate.
  - CMS seeks public comment on exploring an appropriate methodology for assessing a fair fee for other compliance determination activities to include performing follow-up visits, complaint investigation, and activities associated with imposition of sanctions.

#### **E. General feedback on other areas of CLIA**

CMS is also soliciting general feedback on other areas of CLIA that could be modified, revised or improved.

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