



FACT SHEET

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Clinical Laboratory Improvement Amendments of 1988 Fees; Histocompatibility, Personnel, and Alternative Sanctions for Certificate of Waiver Laboratories Proposed Rule (CMS-3326-P)

In order to promote the continuing quality and safety of laboratory testing for the public, the Centers for Medicare & Medicaid Services (CMS) and the Centers for Disease Control and Prevention (CDC) are issuing a proposed rule that would update the Clinical Laboratory Improvement Amendments of 1988 (CLIA) fee regulations. This proposed rule, if finalized, would provide sustainable funding for the CLIA program through a biennial two-part increase of CLIA fees. We are proposing to incorporate limited/specific fees for laboratories, including fees for follow-up surveys, substantiated complaint surveys, and revised certificates.

CMS is also proposing to offset the administrative overhead costs of test complexity determination for waived tests with a nominal increase to Certificate of Waiver (CoW) fees. In addition, we are proposing to clarify the methodology used to determine program compliance fees.

This proposed rule would also amend histocompatibility and personnel regulations under CLIA to address obsolete regulations and incorporate changes in technology. In addition, this proposed rule would allow CMS to apply alternative sanctions, including civil money penalties, a directed plan of correction, a portion of a plan of correction, and onsite state monitoring, to CoW laboratories.

Summary of Proposed Changes:

CLIA Fees

The CLIA program is funded through user fees assessed on certified laboratories. In 2018, CMS issued the first fee increase in 20 years, partially addressing an earlier funding shortfall. Despite that increase, the level of carryover funding available to cover program expenses is projected to decline continuously. Without an additional fee increase, the CLIA program will no longer be self-supporting by the end of fiscal year 2023. CMS is proposing to increase CLIA user fees by:

- Assessing and collecting currently authorized fees that have not been previously assessed. Fees would be assessed when the following activities are performed:

- Follow-up surveys to confirm correction of deficiencies,
 - Review and approval of testing when a laboratory adds a new specialty or subspecialty of testing to its services,
 - Complaint surveys when the findings are substantiated,
 - Desk reviews to ensure successful laboratory proficiency testing; and
 - Issuing revised or replacement certificates.
- Proposing a 20 percent across the board increase to existing fees;
 - Collecting a one-time \$25 certificate fee increase on CoW laboratories to recover the cost of the categorizing waived tests (simple tests) by the Food and Drug Administration (FDA) at the termination of the public health emergency; and
 - Proposing a formula to increase user fees every two years to account for inflation as per the Consumer Price Index-Urban (CPI-U), if needed to meet program obligations.

Histocompatibility

Histocompatibility is a type of laboratory testing performed on the tissue of different individuals to determine if one person is able to accept cells, tissue, or organs from another person. This proposed rule would remove specific regulations already covered in the general requirements and laboratory director responsibilities. For example, we propose to remove specific quality control (QC) requirements related to both human leukocyte antigen typing and cross matching since a laboratory is required to have appropriate QC procedures and control materials under the general QC requirements and laboratory director responsibilities.

Personnel

The CLIA regulations for laboratory personnel qualifications (Subpart M) have not been updated since 2003. The current educational requirements are lower for a person qualified to assess the competency of high complexity testing personnel than the requirements for assessing moderate complexity testing personnel. High complexity testing is more complicated than moderate complexity testing; as such, the educational requirements for those personnel assessing the competency of high complexity testing personnel should be higher than for moderate complexity testing. This proposed rule would decrease the burden on laboratories by allowing one individual to fulfill multiple responsibilities while still maintaining the laboratory's ability to perform accurate and reliable testing.

Academic degree names and types have changed since the CLIA personnel requirements were finalized in 1992 and updated in 2003. As a result, there are academic degrees for which the study area may not be clear. This makes it challenging to determine what types of academic degrees are acceptable in order to qualify CLIA personnel. This rule proposes an additional mechanism, based on coursework, for individuals with nontraditional degrees to meet personnel education requirements.

Alternative Sanctions for Certificate of Waiver (CoW) Laboratories

Alternative sanctions (i.e., directed plan of correction, civil money penalty, state onsite monitoring) may be imposed in lieu of, or in addition to, principal sanctions for all CLIA-certified laboratories, except CoW laboratories. In response to a January 2018 request for information (83 FR 1004), commenters noted that the imposition of alternative sanctions as opposed to principal sanctions for non-compliance should be an option for all CLIA-certified laboratories. During the COVID-19 public health emergency, CMS included this regulatory change in an interim final rule, Medicare and Medicaid Programs, Clinical Laboratory

Improvement Amendments (CLIA), and Patient Protection and Affordable Care Act; Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency, CMS-3401-IFC (85 FR 54820). CMS is now proposing to finalize this change through the rulemaking process, and continue to allow CMS to levy alternative sanctions on CoW laboratories and strengthen CLIA's oversight and improve laboratory quality across the nation.

The proposed rule can be downloaded from the *Federal Register* at:
<https://www.federalregister.gov/>. (Search for CMS-3326-P)

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