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Center for Clinical Standards and Quality

Ref: QSO-24-03-CLIA

DATE: December 28, 2023

TO: State Survey Agency Directors

FROM: Directors, Quality, Safety & Oversight Group (QSOG)

SUBJECT: Final Rule- Clinical Laboratory Improvement Amendments of 1988 (CLIA) Fees, Histocompatibility, Personnel, and Alternative Sanctions for Certificate of Waiver Laboratories (CMS-3326-F)

Memorandum Summary

- **Publication of Final Rule: CMS-3326-F was published on December 28, 2023.** This final rule updates the Clinical Laboratory Improvement Amendments of 1988 (CLIA) fees and clarifies the CLIA fee regulations. Specifically, the final rule will: 1) implement a process for sustainable funding for the CLIA program through a biennial two-part increase of CLIA fees; 2) amend histocompatibility and personnel regulations under CLIA to address obsolete regulations and update the regulations to incorporate technological changes; and 3) amend the provisions governing alternative sanctions (including civil money penalties, a directed plan of correction, a directed portion of a plan of correction, and onsite State monitoring) to allow for the imposition of such sanctions against non-compliant laboratories operating under Certificates of Waiver, rather than being limited only to imposing principal sanctions of revocation, suspension or limitation of a laboratory's CLIA certificate.

- **Effective Dates:** These regulations are effective January 27, 2024, except for instruction 3, amending § 493.2; instructions 14 through 19, amending §§ 493.945, 493.1273, 493.1274, 493.1278, 493.1359, and 493.1405; instruction 20 removing § 493.1406; instructions 21 through 30, amending §§ 493.1407, 493.1411, 493.1417, 493.1423, 493.1443, 493.1445, 493.1449, 493.1451, 493.1455, and 493.1461; instruction 31 removing § 493.1462; and instructions 32 through 36, amending §§ 493.1463, 493.1469, 493.1483, 493.1483, 493.1489, and 493.1491, which are effective December 28, 2024.

Background:

This final rule updates the Clinical Laboratory Improvement Amendments of 1988 (CLIA) fees and clarifies the CLIA fee regulations. This rule implements a process for sustainable funding for the CLIA program through a biennial two-part increase of CLIA fees. The CLIA fees incorporate limited/specific laboratory fees, including fees for follow-up surveys, substantiated complaint surveys, and revised certificates. The rule also includes a nominal increase in Certificate of Waiver (CoW) fees for the administrative overhead costs of test complexity determination for waived tests and test systems. In addition, CMS provides clarification of the methodology used to determine program compliance fees.

This final rule also amends the histocompatibility and personnel regulations under CLIA to address obsolete regulations and update the regulations to incorporate technological changes and changes in laboratory practices, and amends the provisions governing alternative sanctions (including civil money penalties, a directed plan of correction, a directed portion of a plan of correction, and onsite state monitoring) to allow for the imposition of such sanctions against non-compliant laboratories operating under Certificates of Waiver, rather than being limited only to imposing principal sanctions of revocation, suspension or limitation of a laboratory's CLIA certificate.

Discussion:

CLIA Definitions, at § 493.2

The final rule includes new definitions for the following:

1. *Continuing education (CE) credit hours* means either continuing medical education (CME) or continuing education units (CEUs). The CE credit hours must cover the applicable laboratory director responsibilities and be obtained prior to qualifying as a laboratory director.
2. *Doctoral degree* means an earned post-baccalaureate degree with at least 3 years of graduate level study, including research related to clinical laboratory testing or advanced study in clinical laboratory science, medical laboratory science, or medical technology. For purposes of this part, doctoral degrees do not include doctors of medicine (MD), doctors of osteopathy (DO), doctors of podiatric medicine (DPM), doctors of veterinary medicine (DVM) degrees, or honorary degrees.
3. *Experience directing or supervising* means that the director or supervisory experience must be obtained in a facility that meets the definition of a laboratory under this section and is not excepted under § 493.3(b).
4. *Laboratory training or experience* means that the training or experience must be obtained in a facility that meets the definition of a laboratory under this section and is not excepted under § 493.3(b).
5. *Midlevel practitioner* means a nurse midwife, nurse practitioner, nurse anesthetist, clinical nurse specialist, or physician assistant licensed by the state within which the individual practices, if such licensing is required in the state in which the laboratory is located.
6. *Replacement certificate* means an active CLIA certificate that is reissued with no changes made.

7. *Revised certificate* means an active CLIA certificate that is reissued with changes to one or more fields displayed on the certificate, such as the laboratory's name, address, laboratory director, or approved specialties/subspecialties. For purposes of this part, revised certificates do not include the issuance, renewal, change in certificate type, or reinstatement of a terminated certificate with a gap in service.

CLIA Fees, at §§ 493.557, 493.575, 493.638, 493.639, 493.643, 493.645, 493.649, 493.655, 493.680

By statute, the CLIA program is funded through user fees assessed on certified laboratories. CLIA ensures that patients have access to quality laboratory testing across the nation. In 2018, CMS issued the first fee increase in 20 years, partially addressing an earlier funding shortfall[1]. This 20 percent increase was a temporary solution to stabilize the program while CMS considered the changes below. Despite that increase, the level of carryover funding available to cover program expenses is projected to decline continuously. As such, the CLIA program will not be self-supporting without an additional fee increase.

CMS is finalizing the increase of CLIA user fees as follows:

1) Establishing new but currently authorized fees that have not been previously assessed; including the following authorized fees to cover administrative program costs when:
    - Performing follow-up -- i.e., revisit -- surveys to determine correction of the deficient practices found in either a CoC survey or a CoA validation survey;
    - Adding a specialties survey fee when it is necessary to determine compliance of testing in one or more additional specialties outside of the Certificate of Compliance (CoC) survey cycle;
    - Performing a substantiated complaint survey;
    - Performing desk review of unsuccessful PT performance to ensure successful laboratory proficiency testing; and
    - Issuing a revised or replacement certificate; refer to the new definitions above.
2) Imposing an 18 percent across-the-board increase to existing fees to stabilize the overall program;
3) Increasing the certificate fee for CoW laboratories by $25 to offset program obligations to FDA for its role in determining if tests and test systems meet criteria to be categorized as waived tests/test systems; and
4) Increasing fees every two years based on a two-part calculation of the Consumer Price Index-Urban (CPI-U) inflation adjustment, and, if applicable, an additional across the board increase.

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Histocompatibility, § 493.1278

The CLIA regulations include requirements specific to certain laboratory specialties such as microbiology and subspecialties such as endocrinology. The CLIA regulatory requirements for the specialty of histocompatibility at § 493.1278, including the crossmatching requirements, address laboratory testing associated with organ transplantation and transfusion and testing on prospective donors and recipients. As of January 2023, 247 CLIA-certified laboratories perform testing in this specialty. The CLIA regulations governing the specialty of histocompatibility

[1] 83 FR 67723.

have not been updated since 1992. Many of the changes finalized in this rule remove histocompatibility-specific requirements that we have determined are addressed by the general quality control (QC) requirements. We believe that removing specific requirements for obsolete methods and practices and eliminating redundant requirements will decrease the burden on laboratories performing histocompatibility testing.

This final rule addresses recommendations provided by the Clinical Laboratory Improvement Advisory Committee (CLIAC)[2]. CMS and CDC incorporated changes in this rulemaking to remove specific regulations already covered in the general requirements and laboratory director responsibilities.

CMS and CDC are finalizing the proposed updates to the CLIA regulations for the specialty of Histocompatibility, with the following modifications:

1) Update the name of the World Health Organization (WHO) committee that determines HLA nomenclature to "Nomenclature Committee for Factors of the HLA System," in the regulatory text;
2) Remove "at the serologic level" from the proposed regulatory text in this final rule; and
3) Revise the proposed regulatory text related to obtaining a recipient specimen, if possible, for crossmatch on the day of the transplant by adding "and prior to transplantation" for clarification.

Personnel, §§ 493.1359 through 493.1489

The CLIA regulations related to personnel requirements were updated with minor changes to the doctoral high complexity laboratory director qualifications in the 2003 final rule, but otherwise have remained unchanged since we published the 1992 final rule with comment period. In the 2018 RFI, we sought public comment and information related to CLIA personnel requirements in the following areas: nursing degrees; physical science degrees; personnel competency assessment (CA); personnel training and experience; and non-traditional degrees. As we explained in the 2018 RFI, these are areas that the CDC, CMS, interested parties, and State agency surveyors identified as relevant to our efforts to update the CLIA personnel requirements to better reflect current knowledge, changes in the academic context, and advancements in laboratory testing. We also requested input from CLIAC for recommended changes to the CLIA personnel requirements found in subpart M – Personnel for Nonwaived Testing, §§ 493.1351 through 493.1495.

CMS and CDC are finalizing the proposed updates to the CLIA regulations for Personnel, with some modifications, including:

1) Remove the proposed addition of a nursing degree qualification for high complexity testing personnel;
2) Revise the language of the regulations addressing laboratory director qualifications, to specify that an individual qualifying under the doctoral degree algorithm must have an earned doctoral degree; and

[2] The CLIAC managed by the CDC, established under the Federal Advisory Committee Act, provides scientific and technical advice and guidance to the Department of Health and Human Services (HHS). The Committee includes diverse membership across laboratory specialties, professional roles, (laboratory management, technical, physicians, nurses) and practice settings (academic, clinical, public health), and includes a consumer representative.

3) Update the final rule regulatory text for the Personnel section to better reflect CMS's intent as expressed in the proposed rule, including making technical updates, reformatting the regulatory citations, and updating regulatory cross references.

Alternative Sanctions for CoW Laboratories, § 493.1804(c)(1)

In this final rule, we are updating the regulation at § 493.1804(c)(1) to allow CMS to impose alternative sanctions on CoW laboratories, as appropriate. CoW laboratories are laboratories that only perform waived tests, that is, simple laboratory examinations and procedures that have an insignificant risk of an erroneous result. For example, a urine dipstick pregnancy test is a waived test. The current regulations state that we do not impose alternative sanctions on CoW laboratories because those laboratories are not inspected for compliance with condition-level requirements (§ 493.1804(c)(1)). However, while not subject to the biennial routine surveys, CoW laboratories are surveyed as a result of a complaint, and based on the complaint survey, may be found to be out of compliance with a condition-level requirement. The ability to levy alternative sanctions (that is, civil money penalties, a directed plan of correction, a directed portion of a plan of correction, and onsite State monitoring) on CoW laboratories helps CMS ensure appropriate sanctions are applied to CoW laboratories, as in the case of other certificate types (certificate of PPM, CoR, CoC, CoA).

In addition, we believe that this finalized change will reduce burden on CoW laboratories. The ability to impose alternative sanctions will be particularly useful in instances in which we find PT referral violations. PT is the testing of unknown samples sent to a laboratory by an HHS-approved PT program to check the laboratory's ability to determine the correct testing results. This final rule amends the CoW regulations at § 493.1804(c)(1) to allow for the application of alternative sanctions where warranted, in addition to or in lieu of principal sanctions.

Other Conforming Amendments

In preparing this final rule, we identified regulatory cross-references in certain existing regulations that will be outdated as a result of our proposed and final changes to subpart M regulations. Accordingly, in this final rule we are updating the regulatory cross-references at §§ 493.945(b)(2), 493.945(b)(3)(i), 493.945(b)(3)(ii)(C), 493.945(b)(3)(ii)(F), 493.1273(b), and 493.1274(c)(1), 493.1417(a), 493.1451(c), 493.1455(a), 493.1469(a) to be consistent with the finalized regulations.

The final rule may be viewed at https://www.federalregister.gov/.(Search for CMS-3326-F)

Effective Dates of Final Rule

These regulations are effective January 27, 2024, except for instruction 3, amending § 493.2; instructions 14 through 19, amending §§ 493.945, 493.1273, 493.1274, 493.1278, 493.1359, and 493.1405; instruction 20 removing § 493.1406; instructions 21 through 30, amending §§ 493.1407, 493.1411, 493.1417, 493.1423, 493.1443, 493.1445, 493.1449, 493.1451, 493.1455, and 493.1461; instruction 31 removing § 493.1462; and instructions 32 through 36, amending §§ 493.1463, 493.1469, 493.1483, 493.1483, 493.1489, and 493.1491, which are effective December 28, 2024.

Contact:

For questions or concerns relating to this memorandum, please contact LabExcellence@cms.hhs.gov.

Effective Date:
Please communicate to all appropriate staff within 30 days. See "Effective Date of Final Rule" for effective dates of the final rule.

/s/
David R. Wright
Director, Quality, Safety & Oversight Group

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