CLIA Fees, Histocompatibility, Personnel, Alternative Sanctions Final Rule, CMS-3326-F

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Objectives

After the presentation, you will be able to:

- State the two effective dates of the CMS-3326-F Final Rule provisions
- Describe the finalized requirements:
  - CLIA Fees
  - Histocompatibility
  - Personnel
  - Alternative Sanctions for Certificate of Waiver (CoW) laboratories

CMS-3326-F Final Rule Is Published!

Clinical Laboratory Improvement Amendments of 1988 (CLIA) Fees, Histocompatibility, Personnel, and Alternative Sanctions final rule (CMS-3326-F) was published in the Federal Register on **December 28, 2023**.

- General *Federal Register* link: Federal Register
- Direct link to CMS-3326-F Final Rule: CMS-3326-F
- CLIA ListServ: CMS-3326-F final rule announcement
- QSO Memo: QSO-24-03-CLIA Fees/Histocompatibility/Personnel/Alternative Sanctions final rule (CMS-3326-F)
- Correction notices: CMS-3326-CN and CMS-3326-CN2

Two Effective Dates

1) Effective 30 days after the FRN publication date, on January 27, 2024:

- CLIA Fees and Alternative Sanctions regulations
- Also include definitions for *replacement certificate* and *revised certificate*

Two Effective Dates

2) One year after the FRN publication date; on December 28, 2024:

- Histocompatibility and Personnel regulations
- Also include definitions for *continuing education (CE) credit hours, doctoral degree, experience directing or supervising, laboratory training or experience, and midlevel practitioner*

CLIA FEES
SUBPART F, General Administration
§§ 493.638 thru 493.680

Finalized Requirements - CLIA Fees

§ 493.2 includes two new definitions:

1. "*Replacement certificate*" means an active CLIA certificate that is reissued with no changes made.
2. "*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.

Finalized Requirements - CLIA Fees

- Establishes new but currently authorized fees that have not been previously assessed.
- Fees will 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.
  - Complaint surveys when the findings are substantiated.
  - Desk reviews involving unsuccessful laboratory proficiency testing.
  - Issuing revised or replacement certificates.

Finalized Requirements - CLIA Fees

- Apply a 18 percent across-the-board increase to the current fee.
- Apply a $25 certificate fee increase on Certificate of Waiver (CoW) laboratories to recover the cost of categorizing waived tests by the FDA.
- Apply a formula to assess user fees every two years to account for inflation if needed to meet program obligations.

Finalized Requirements - CLIA Fees

TABLE 6: CMS Proposed Fee for Issuance of Revised Certificate

Certificate Type	Fee
CoW	$95.00
CoA	$95.00
CoR	$150.00
CoC	$150.00
PPM	$150.00

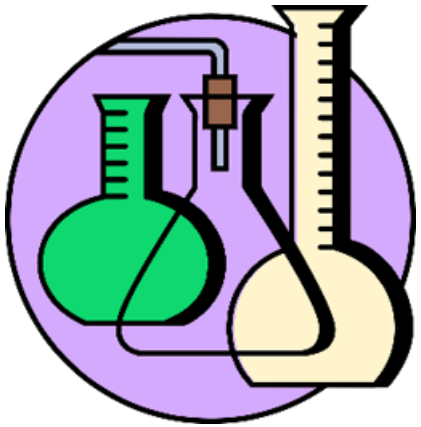
Finalized Requirements - CLIA Fees

CLIA website, CLIA Certificate Fee Schedule:

CLIA CERTIFICATE FEE SCHEDULE
Effective January 27th, 2024

Type of Lab	Number of Specialties	Annual Test Volume	Biennial Certificate Fee
Waived	N/A	N/A	$248
PPM	N/A	N/A	$297
Low Vol. A	N/A	2,000 or fewer	$223

HISTOCOMPATIBILITY
SUBPART K, QUALITY SYSTEMS
§ 493.1278



Finalized Requirements - Histocompatibility

- Remove histocompatibility-specific requirements that are already addressed by the general requirements regarding quality control materials and procedures for all test systems.
- Revise the name at § 493.1278(d) from “Antibody Screening” to “Antibody Screening and Identification” for clarification, as both processes apply to histocompatibility testing.
- Revise the words “transfusion” and “transfused” to “infusion” and “infused,” respectively.

Finalized Requirements - Histocompatibility

- Remove three requirements regarding the laboratory having crossmatch procedures and controls; already addressed by the general requirements for all test systems under §§ 493.1445(e)(1), 493.1251, and 493.1256.
- Modify the following terminologies to reflect current practices: “cadaver donor” is replaced by “deceased donor,” “transfused” is replaced by “infused,” and “combined” is replaced by “paired.”

Finalized Requirements- Histocompatibility

- 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.
- Add the requirement to obtain a recipient specimen prior to transplantation for crossmatch on the day of the transplant, if possible.

PERSONNEL
SUBPART M
§§ 493.1359, and 493.1405 thru 493.1491

Finalized Requirements - Personnel

§ 493.2 includes five new definitions:

1. "*Midlevel practitioner*" was amended by adding a nurse anesthetist and clinical nurse specialist.
2. "*Continuing education (CE) credit hours*" means either continuing medical education (CME) or continuing education (CE) units. The 20 CEs must be obtained before qualifying as a laboratory director.

Finalized Requirements - Personnel

§ 493.2 includes five new definitions :

3. *"Doctoral degree"* means an earned post-baccalaureate degree with at least 3 years of graduate-level study that includes research related to clinical laboratory testing or advanced study in clinical laboratory science or medical technology.

   - Doctoral degrees would not include doctors of medicine (MD), doctors of osteopathy (DO), doctors of podiatry, doctors of veterinary medicine (DVM), or honorary degrees
   - DCLS (Doctor of Clinical Laboratory Science) degrees would be included in doctoral degrees

Finalized Requirements - Personnel

§ 493.2 includes five new definitions:

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 § 493.2 and is not excepted from CLIA under § 493.3(b).

5. "*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 § 493.2 and is not excepted under § 493.3(b).

Finalized Requirements - Personnel

PPM laboratory director responsibilities (§ 493.1359):

- Modify the PPM laboratory director's responsibilities to include competency assessment (CA). The same CA intervals as in §§ 493.1413(b)(8) and 493.1451(b)(8) would apply.

Finalized Requirements - Personnel

Laboratory Director qualifications/responsibilities (§§ 493.1405, 1407, 1443, 1445):

- Remove “or possess qualifications that are equivalent to those required for such certification” related to the American Board of Pathology and American Osteopathic Board of Pathology.
- Include 20 CEs to moderate and high complexity laboratory director qualifications.
- Add “directing and supervising experience” to the high complexity, laboratory director’s doctoral degree qualification requirements.
- Remove the residency provision; however, relevant experience in a residency or fellowship would continue to be acceptable experience and training for qualifying individuals.

Finalized Requirements - Personnel

Laboratory Director qualifications/responsibilities (§§ 493.1405, 1407, 1443, 1445):

- Update the regulations addressing laboratory director responsibilities to require the director to be on-site at the laboratory at least once every six months, with at least a four month interval between the two on-site visits.
- Update 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.

Finalized Requirements - Personnel

Technical Supervisors qualifications (§ 493.1449):

- Combine the provisions with identical Technical Supervisor requirements into a combined requirement.
- Remove the reference to the American Society of Cytology as it has not provided certification for cytology since 1998.
- Update the *immunohematology* test specialty requirement to allow individuals with doctoral, master's, and bachelor's degrees with appropriate training and experience to qualify as a Technical Supervisor for immunohematology.

Finalized Requirements - Personnel

General Supervisor qualifications and responsibilities (§§ 493.1461, 1463):

- Revise the language to allow the delegation to the General Supervisor for performing all (semiannual and annual) CA.

Finalized Requirements - Personnel

Cytotechnologist qualifications (§ 493.1483):

- Replace “CAHEA” with CAAHEP (Commission on Accreditation of Allied Health Education Programs) and remove “or other organization approved by HHS” in the introductory regulatory text.

Finalized Requirements - Personnel

Testing Personnel qualifications (§§ 493.1423, 1489):

- Add the nursing degree for testing personnel, moderate complexity, as proposed for § 493.1423.
- However, for § 493.1489, a nursing degree does not automatically meet high complexity testing personnel qualifications.

Finalized Requirements - Personnel

Testing Personnel qualifications (§§ 493.1423, 1489):

- Add the blood gas testing personnel for moderate complexity.
- Move the military provision out of the April 24, 1995, grandfather provision for high complexity, and make it a mechanism that individuals will be able to qualify for high complexity testing personnel.
- Move Department of Health, Education and Welfare (HEW)-qualified individuals to 493.1489.

Finalized Requirements - Personnel

Degrees:

- Add an educational algorithm qualification option for both moderate and high complexity testing for bachelor's, master's, and doctoral degrees.
- Remove the reference to a physical science degree from subpart M.
- Add an approved thesis/research with the educational option.

Finalized Requirements - Personnel

Grandfathering:

- Remove the “grandfather” provisions at §§ 493.1406 (MC LD), 493.1443(b)(3)(ii) thru (b)(6) (HC LD), 493.1461(c)(5) and 493.1462 (HC GS), 493.1489(b)(5) and 493.1491 (HC TP).
- Add a new grandfather provision for all qualified individuals employed in a given personnel position before the date of the final rule. However, we intend to require all individuals becoming employed by a laboratory or changing assignments within a laboratory after the final rule's effective date to qualify under the new personnel provisions.

Finalized Requirements - Personnel related…

Other Conforming Amendments:

- Update 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 to the updated Personnel subpart M regulations.

Finalized Requirements - Personnel

Updated regulations:

- § 493.1359; (b)(2); (c); (d); Standard; PPM laboratory director responsibilities
- § 493.1405; (b); Standard; Laboratory director qualifications, moderate complexity
- § 493.1407; (c); Standard; Laboratory director responsibilities, moderate complexity
- § 493.1411; (b); Standard; Technical consultant qualifications, moderate complexity
- § 493.1423; (b); Standard; Testing personnel qualifications, moderate complexity
- § 493.1443; (b); Standard: Laboratory director qualifications, high complexity

Finalized Requirements - Personnel

Updated regulations:

- § 493.1445; (c); (e)(10); Standard; Laboratory director responsibilities, high complexity
- § 493.1449 Standard; Technical supervisor qualifications, high complexity
- § 493.1461; (c); (d)(3)(i); (e); Standard: General supervisor qualifications, high complexity
- § 493.1463; (b)(4); Standard: General supervisor responsibilities, high complexity
- § 493.1483; introductory text; (b); Standard: Cytotechnologist qualifications
- § 493.1489; (b); Standard: Testing personnel qualifications, high complexity

Finalized Requirements - Personnel

Remove “grandfather” provisions:

- § 493.1406 Laboratory Director qualifications on or before February 28, 1992
- § 493.1443 (b)(3)(ii) thru (b)(6) Laboratory Director qualifications on or before February 28, 1992 or February 24, 2003
- § 493.1461(c)(5) General supervisor qualifications on or before September 1, 1992
- § 493.1462 General supervisor qualifications on or before February 28, 1992
- § 493.1489(b)(5) Technologist qualifications on or before September 1, 1997
- § 493.1491 Technologist qualifications on or before February 28, 1992

ALTERNATIVE SANCTIONS
SUBPART R, ENFORCEMENT PROCEDURES
§ 493.1804(c)(1)

Finalized Requirements - Alternative Sanctions

Update the regulation at § 493.1804(c)(1) to allow CMS to impose alternative sanctions on Certificate of Waiver laboratories, as appropriate.

Summary

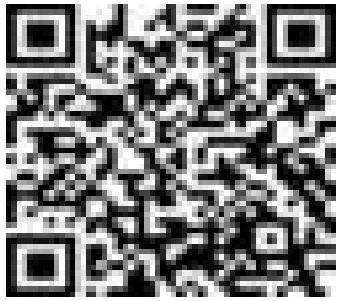
- Clinical Laboratory Improvement Amendments of 1988 (CLIA) Fees, Histocompatibility, Personnel, and Alternative Sanctions final rule (CMS-3326-F) was published in the Federal Register on **December 28, 2023**.
- Updated CLIA requirements include:
  - CLIA Fees
  - Histocompatibility
  - Personnel
  - Alternative Sanctions for CoW laboratories
- Effective dates of the CMS-3326-F Final Rule provisions:
  - January 27, 2024- CLIA fees and Alternative Sanctions for CoW laboratories
  - December 28, 2024- Histocompatibility and Personnel
- General *Federal Register* link: Federal Register

Resources

- **Email address**: LabExcellence@cms.hhs.gov

- **CLIA website**: https://www.cms.gov/medicare/quality/clinical-laboratory-improvement-amendments
    - Online Payment
    - CLIA Laboratory Lookup
    - CLIA Communications ListServ

- **QR code to CLIA website**:



Questions?