Clinical Laboratory Improvement Amendments (CLIA) 101

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DEPARTMENT OF PUBLIC HEALTH & HUMAN SERVICES

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The CLIA Federal/State Relationship

The Clinical Laboratory Improvement Amendments of 1988 (CLIA) establish a close and integrated relationship between the Federal government and State Agencies (SAs) responsible for implementing, maintaining, and enforcing federal requirements for clinical laboratories.

CMS (Centers for Medicare & Medicaid Services) runs the CLIA program

State Agencies (SAs) help CMS carry out inspections and enforcement; primary oversight of non-Federal Jurisdictional laboratories

Medicare State Operations Manual – Chapter 6

Presentation Objectives

Define CLIA:

- Differentiate test complexity levels
- Identify the types of CLIA certificates

Managing your CLIA Certificate:

- Review the application and update process
- Describe the renewal process
- Describe how to find your CLIA certificate

What is CLIA?

The Clinical Laboratory Improvement Amendments (CLIA) of 1988 are federal regulations that apply to all U.S. and CLIA-certified international laboratories that test human specimens (e.g., blood, tissue, fluids) to assess health or to diagnose, prevent, or treat disease.

- Title 42, Code of Federal Regulations (CFR), Part 493 – Laboratory Requirements

The CLIA program is supported by the Centers for Medicare & Medicaid Services (CMS), the Centers for Disease Control and Prevention (CDC), and the Food and Drug Administration (FDA).

Exceptions

CLIA regulations **do not** apply to the following:

- Facilities that only perform forensic testing
- Research laboratories that test human specimens but do not report patient-specific results for diagnosis, treatment, or health assessment
- Substance Abuse and Mental Health Services Administration (SAMHSA)-certified laboratories performing drug testing in accordance with SAMHSA guidelines
- Facilities that only collect or prepare specimens (or both) or serve as a mailing service
- Drug testing for purposes of employment; unless employment drug testing is done and individual treatment is offered or made available

Test Complexity

Waived

- A test that is FDA classified as waived
  - A simple test that has a low risk of producing an incorrect result
- CLIA Certificate of Waiver

Nonwaived

- A test that is FDA classified as moderate and high complexity
- CLIA Certificates:
  - Certificate for Provider-Performed Microscopy (PPM) procedures
  - Certificate of Compliance
  - Certificate of Accreditation
    - Certificate of Registration (New Applications)

Test Complexity

The test's complexity determines the type of CLIA certificate for the laboratory.

How can you find your test's complexity?

- The FDA CLIA database lists all categorized tests and their complexity level: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/search.cfm

Other sources:

- MLN Connects® Newsletter | CMS (link): https://www.cms.gov/training-education/medicare-learning-network/newsletter
- For a list of waived tests sorted by analyte name, visit the FDA website at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm

CLIA Certificate of Waiver

What tests are allowed?

- Only waived tests
- All testing must be performed **according to the manufacturer's instructions**
- Waived labs are not subject to routine CLIA inspections, but they can be inspected if there are complaints or concerns about test accuracy or patient safety

Who can hold a Certificate of Waiver (CoW)?

- A facility with a Certificate of Waiver must designate a laboratory director; however, there are no federal CLIA educational or experiential requirements for this role

CLIA Certificate of Waiver – Continued

Educational material:

***To Test or Not to Test?* Booklet**

- This booklet outlines considerations and preparations for performing waived tests

***Ready? Set? Test!* Booklet**

- This booklet outlines recommended practices
- CDC training OneLab REACH https://reach.cdc.gov/course/ready-set-test-patient-testing-important-get-right-results

Certificate for Provider-Performed Microscopy (PPM) Procedures

What Tests Are Allowed?

- A limited number of moderately complex microscopic exams and waived tests

Who Can Hold a PPMP Certificate?

- **Licensed physicians**
- **Midlevel practitioners** (nurse midwives, nurse practitioners, nurse anesthetist, clinical nurse specialist, or physician assistants)
- **Dentists**

These individuals must personally perform testing during a patient visit and within the context of a physical exam.

Certificate for PPM Procedures – Continued

- **Educational material:**
  - The *Provider-Performed Microscopy Procedures* booklet (link) describes regulatory requirements and recommended practices.
  - CDC training OneLab REACH

Certificate of Compliance/ Certificate of Accreditation

- **Certificate of Registration (CoR):** Issued to allow the laboratory to conduct nonwaived moderate and high complexity testing until the laboratory is surveyed. Only laboratories applying for a certificate of compliance or a certificate of accreditation will receive a CoR, which is valid until the initial survey is conducted and compliance with CLIA regulations is determined.

- **Certificate of Compliance (CoC):** Issued to a laboratory that performs nonwaived moderate and high complexity testing after the State Agency (SA) or CMS surveyors conduct a survey and determine the laboratory is in compliance with the applicable CLIA requirements.

- **Certificate of Accreditation (CoA):** Issued to a laboratory that performs nonwaived moderate and high complexity testing, based on accreditation by a CMS-approved Accreditation Organization (AO).

Certificate of Compliance/ Certificate of Accreditation – Continued

These laboratories are required to undergo biennial inspections, as outlined in 42 CFR Part 493, to ensure continued compliance with federal regulations.

eCFR :: 42 CFR Part 493 -- Laboratory Requirements

Specific Personnel Requirements: Subpart M—Personnel for Nonwaived Testing

A **moderate complexity laboratory** can perform:

- Moderate complexity tests
- PPMP tests
- Waived tests

Certificate of Compliance/ Certificate of Accreditation – Continued

A **high complexity laboratory** can perform:

- High complexity tests
- Moderate complexity tests
- PPMP tests
- Waived tests

CLIA Application for Certification

How to apply:

1. Fill out the CMS 116 Application Form in its entirety
- Link: https://www.cms.gov/medicare/cms-forms/cms-forms/downloads/cms116.pdf
  - **NOTE:** Laboratory directors performing non-waived testing (including PPM) must meet specific education, training and experience under subpart M of the CLIA regulations. Proof of these qualifications for the laboratory director must be submitted with this application.

2. Submit to the Montana State Survey Agency Director email at MTSSAD@mt.gov

Laboratories must switch to email notifications to start receiving electronic CLIA fee coupons and certificates. After March 1, 2026, paper fee coupons and CLIA certificates will no longer be available.

CLIA Certificate Updates

How to Update:

- Submit either:
  - A **CMS-116 form** (completed in full), or
  - A **Written Notification** (examples: termination, email, demographic)
    - **Written Notification must include:**
      - Laboratory name
      - CLIA number
      - Name of Laboratory Director and/or Owner
      - Description of the change(s)
      - Wet or certified electronic signature of the Laboratory Director and/or Owner

CLIA Certificate Updates – Continued

- Submit the **CMS-116** form or **Written Notification** to the Montana State Survey Agency Director email at MTSSAD@mt.gov
- **Accredited labs:** Contact your Accreditation Organization

- **Educational material:** Help with a new CLIA Certificate Application - Laboratory Quick Start Guide CMS CLIA Certificate
- **Information can also be found on the state website:** https://dphhs.mt.gov/qad/Certification/CLIA/index

Renewal Process

Renewal Notice (CLIA Fee Coupon) – Emailed **6 months before** expiration date
Update Your Certificate Information
Pay the CLIA Certification Fee
Pay online at **Pay.gov** using your **CLIA ID number**
Accepted payment methods:
Credit/debit card
Bank routing number
Automated Clearing House (ACH) payments
Receive Your New Certificate - Emailed about **two weeks** before your certificate expires

- **Exception: Certificates of Compliance**:
  Survey fee is sent **12 months** before expiration
  Certificate fee is sent **after the survey is completed**

Certificate Copies – Where Can I Get Another Certificate?

Additional copies of your certificate may be obtained from the QCOR website link: S&C QCOR Home Page (cms.gov) [qcor.cms.gov] by following these steps:

1. Under the Tool bar click ‘CLIA Laboratory Lookup’
2. Enter your CLIA ID and click ’Search’
3. Click the blue hyperlink for your laboratory
4. Follow the pop-up link to download your certificate

Note: If your changes are not reflected in the pop-up link, you will need to request a revised certificate. Please be aware that CMS charges a fee for issuing revised certificates.

Questions?

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