DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Medicare & Medicaid Services

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Clinical Laboratory Improvement Amendments (CLIA)

The Clinical Laboratory Improvement Amendments (CLIA) establishes a program to regulate laboratories that perform testing on patient specimens to ensure accurate and reliable test results. This fact sheet discusses:

> **Please note:** The information in this publication applies to all laboratories specified, including those that submit claims to Medicare.

- ☐ Overview of the CLIA program;
- ☐ Test categories;
- ☐ How to enroll;
- ☐ Types of certificates;
- ☐ CLIA Proficiency Testing (PT); and
- ☐ Resources.

Overview

What Is CLIA?

Congress passed CLIA in 1988 to establish quality standards for all non-research laboratory testing performed on specimens derived from humans for the purpose of providing information for the diagnosis, prevention, treatment of disease, or impairment of, or assessment of health. CLIA regulations apply to laboratory testing in all settings including commercial, hospital, and physician office laboratories.
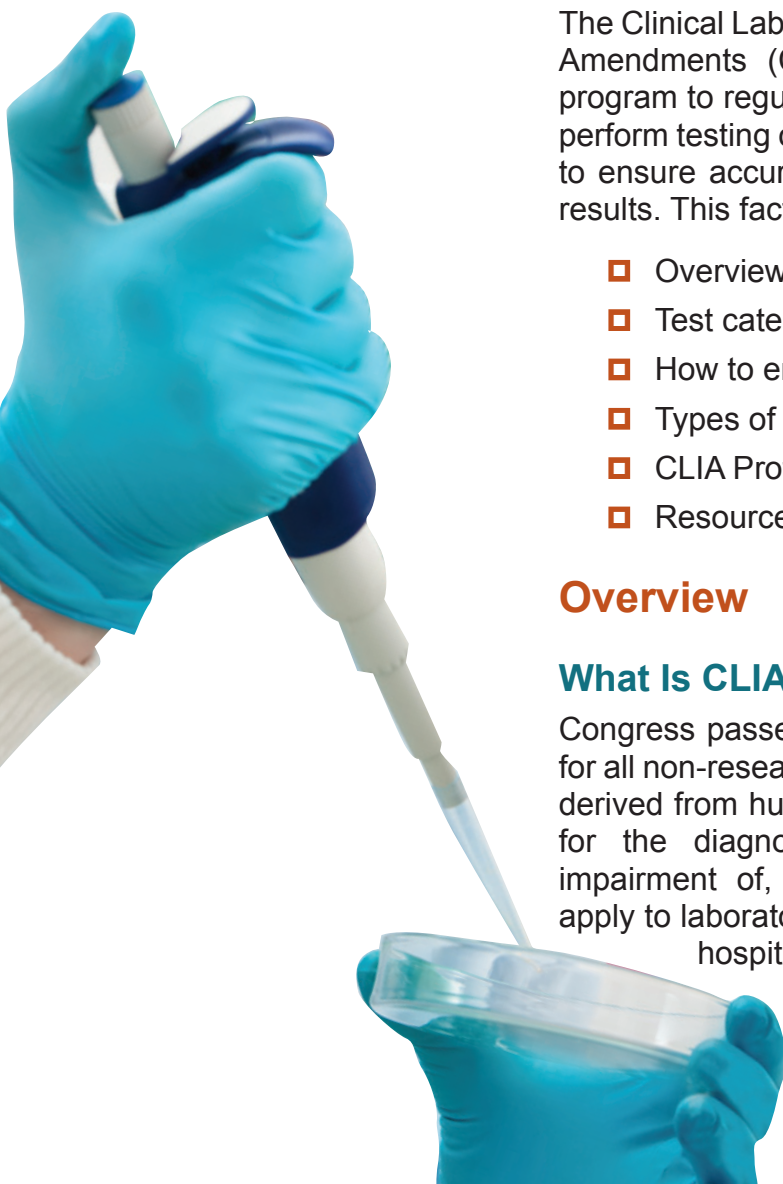
CLIA requires the Secretary of the U.S. Department of Health & Human Services (HHS) to certify laboratories performing non-research testing. The Centers for Medicare & Medicaid Services (CMS) administers the CLIA certification program for the Secretary along with the Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC). Fees collected from the regulated facilities cover all costs of administering the program, including certificate and survey costs.

Why Is CLIA Important?

CLIA establishes quality standards for laboratories to ensure the accuracy, reliability, and timeliness of the patient's test results. CMS data indicates that CLIA helped improve the quality of testing in the United States. The total number of quality deficiencies decreased approximately 40 percent from the first laboratory survey to the second under CLIA. Reviews of Proficiency Testing (PT) over time resulted in similar findings.

> **Did You Know?**
> Beginning in 2014, the CLIA regulations include the patient's right to access test reports directly through the testing laboratory.

How Does the Government Administer CLIA?

CMS, FDA, and CDC each carry out specific roles to assure quality laboratory services. Table 1 describes these roles.

Table 1. CLIA Administration

Federal Agency	Responsibilities	Website
CMS	■ Approves private accreditation organizations that perform inspections and approve State exemptions ■ Collects user fees ■ Conducts inspections ■ Enforces regulatory compliance ■ Issues laboratory certificates ■ Publishes CLIA rules and regulations ■ Monitors laboratory performance on PT and approves PT programs	http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA
FDA	■ Categorizes tests based on complexity ■ Develops rules and guidance for CLIA complexity categorization ■ Reviews requests for Waiver by Application	http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/IVDRegulatoryAssistance/ucm124105.htm
CDC	■ Conducts laboratory quality improvement studies ■ Develops and distributes professional information and educational resources ■ Develops technical standards and laboratory practice guidelines ■ Provides analysis, research, and technical assistance ■ Manages the CLIA Advisory Committee (CLIAC) ■ Monitors proficiency testing practices	http://www.cdc.gov/clia

Does CLIA Apply Only to Laboratories Obtaining Payment through Medicare?

CLIA standards apply nationally and not exclusively to Medicare. CLIA applies to all providers providing clinical laboratory services, whether or not they or another provider files Medicare claims for the tests.

Test Method Categorization

The FDA categorizes and grades each test based on the complexity of the test method. The FDA lists the category at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/IVDRegulatoryAssistance/ucm393285.htm on the FDA website. The FDA categorizes test methods into three levels of complexity:

1. Waived Complexity;
2. Moderate Complexity, including the subcategory of Provider-Performed Microscopy Procedures (PPMP); and
3. High Complexity.

When categorizing a test, the FDA considers the:

◻ Amount of interpretation involved;

◻ Calibration and quality control requirements of the instruments used;

◻ Degree of independent judgment involved;

◻ Difficulty of the calculations involved;

◻ Examinations and procedures performed and the methodologies employed; and

◻ Type of training required to operate the instruments used in the methodology.

The more complicated the test, the more stringent the requirements. CLIA specifies quality standards for:

◻ Facility administration;

◻ General laboratory systems;

◻ Personnel qualifications and responsibilities;

◻ Preanalytic, analytic, and postanalytic systems;

◻ PT;

◻ Quality assessment;

◻ Quality control; and

◻ Specific cytology provisions for laboratories performing moderate and/or high complexity tests.

Enrolling in the CLIA Program

To enroll in the CLIA program, laboratories must:

1. Complete an application;
2. Pay applicable fees;
3. Be surveyed, if applicable; and
4. Meet CLIA standards and become certified.

> **Fees**
>
> Fees are based on the type of certification requested, and for moderate and high complexity laboratories, the annual volume and types of testing performed.

Upon payment of fees, each laboratory receives an individual, unique CLIA number. For more information and the application form, visit http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/How_to_Apply_for_a_CLIA_Certificate_International_Laboratories.html on the CMS website.

> **CLIA Number on Medicare Claims**
>
> All Medicare claims for laboratory services must include the CLIA number for the laboratory.

Types of Certificates

The CLIA program grants five types of laboratory certificates:

1. Certificate of Waiver (CW);
2. Certificate for PPMP;
3. Certificate of Registration (COR);
4. Certificate of Compliance (COC); and
5. Certificate of Accreditation (COA).

What Is a Certificate of Waiver (CW)?

The CW permits a laboratory to perform only waived tests. Waived tests are so simple and accurate that little risk of error exists when done correctly. Examples of waived tests include:

- Certain testing methods for glucose and cholesterol;
- Pregnancy tests;
- Fecal occult blood tests; and
- Some urine tests.

> **Did You Know?**
>
> If the laboratory has a Certificate for PPMP, COR, COC, or COA, it can perform waived tests without a CW.

Routine on-site surveys are not required for a CW unless there is a complaint. Along with enrolling in the CLIA program and paying the fee, a laboratory must follow the manufacturer's instructions for test performance.

What Is a Certificate for Provider-Performed Microscopy Procedures (PPMP)?

A subset of the moderate complexity tests, PPMPs receive a unique classification and certification. A laboratory in which a physician, mid-level practitioner, or dentist performs **only** certain microscopy procedures and waived tests may receive this certificate.

> **Microscopy Procedures**
>
> A microscopy procedure is a moderately complex procedure performed using a microscope (for example, urine microscopic or potassium hydroxide [KOH] smear).

Routine on-site surveys are not required for a Certificate for PPMP. A laboratory may be surveyed as part of a routine survey for non-waived tests or if a complaint is alleged. Moderate complexity requirements apply.

What Is a Certificate of Registration (COR)?

A laboratory that applies for a COC or COA receives a COR. A COR provides temporary certification for the laboratory to conduct moderate and high complexity tests while it completes the certification process. The COR expires after two years or when the laboratory meets certification requirements (whichever is sooner).

The certification process includes an on-site survey or verification of accreditation. Laboratories may choose to achieve their full CLIA certification through a CMS survey or a CMS-approved accrediting organization.

What Is a Certificate of Compliance (COC)?

A laboratory may receive a COC after an on-site survey finds that it complies with all applicable CLIA requirements. Laboratories with a COC that perform moderate and high complexity tests must be surveyed every two years. The surveys:

- ☐ Determine a laboratory's regulatory compliance;
- ☐ Assist laboratories in improving patient care through education; and
- ☐ Assist laboratories in improving patient care by emphasizing standards that directly impact the laboratory's quality test performance.

The surveyor determines whether the laboratory meets CLIA requirements through:

- ☐ Interviews with the laboratory's personnel;
- ☐ Observation of the laboratory's (past and current) practices; and
- ☐ Review of the laboratory's relevant documented records.

What Is a Certificate of Accreditation (COA)?

A laboratory that performs moderate and high complexity tests and meets the standards of one of seven private non-profit accreditation organizations, approved by CMS, may receive a COA. To receive CMS approval, the non-profit accreditation organization's requirements must equal or exceed CLIA program requirements. Periodically, each organization must receive re-approval to ensure it maintains equivalent or more than equivalent requirements. Each year, CMS evaluates the organization's performance enforcing CLIA requirements.

The accreditation organization inspects the laboratory once every two years. CMS may perform a validation survey to evaluate the results of the most recent survey performed by the accreditation organization.

For a list of the seven private non-profit accreditation organizations, visit http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Accreditation_Organizations_and_Exempt_States.html on the CMS website.

CLIA Proficiency Testing (PT)

Laboratories conducting moderate and high complexity testing must participate in PT for certain tests. PT offers each laboratory performing non-waived tests a way to measure performance and verify its accuracy and reliability.

A CMS-approved PT program sends the laboratory a set of unknown samples about three times a year. The laboratory tests the samples in the same manner it tests patient specimens and reports the results back to the PT program. The PT program grades the results and sends the laboratory scores reflecting how accurately the laboratory performed the testing. PT programs undergo annual and ongoing regulatory review by CMS. For more information about PT programs, visit http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Proficiency_Testing_Providers.html on the CMS website.

Resources

For more information about CLIA, visit http://www.cms.gov/Regulations-and-Guidance/ Legislation/CLIA on the CMS website, or scan the Quick Response (QR) code on the right with your mobile device. Table 2 provides additional resources for clinical laboratory services. Additionally, CMS created a series of brochures to explain the CLIA regulation requirements at http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/CLIA_ Brochures.html on the CMS website.

Table 2. Laboratory Resources

Resource	Website
CLIA Application Information and Form	http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/How_to_Apply_for_a_ CLIA_Certificate_International_Laboratories.html
CLIA Database of Categorized Tests	http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/ IVDRegulatoryAssistance/ucm393285.htm
CLIA List of COA Accreditation Organizations	http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Accreditation_ Organizations_and_Exempt_States.html
CLIA PT	http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Proficiency_Testing_ Providers.html
CLIA Regulations	http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/CLIA_Regulations_ and_Federal_Register_Documents.html
Frequently Asked Questions	https://questions.cms.gov/faq.php?isDept=0&search=laboratory&searchType=keyword& submitSearch=1&id=5005
Medicare Information	Clinical Labs Center http://www.cms.gov/Center/Provider-Type/Clinical-Labs-Center.html Clinical Laboratory Fee Schedule (CLFS) http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/ MLNProducts/MLN-Publications-Items/CMS1243659.html "Medicare Benefit Policy Manual" Chapter 15, Sections 80.1 and 280 http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/ bp102c15.pdf "Medicare Claims Processing Manual" Chapters 16 and 18 http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs-Items/CMS018912.html Medicare Learning Network® (MLN) Guided Pathways (GPs), "Provider Specific Medicare Resources," Laboratory section http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/ MLNEdWebGuide/Downloads/Guided_Pathways_Provider_Specific_Booklet.pdf

This fact sheet was current at the time it was published or uploaded onto the web. Medicare policy changes frequently so links to the source documents have been provided within the document for your reference.

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