

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

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Clinical Laboratory Improvement Amendments (CLIA) and Medicare Laboratory Services

The Clinical Laboratory Improvement Amendments (CLIA) establishes a program to regulate laboratories that test patient specimens to ensure the labs produce accurate and reliable test results. This fact sheet provides the following information about CLIA:

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.

It also discusses the coverage of Medicare laboratory services separate from CLIA.

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; **and**
- For providing information for the diagnosis, prevention, and treatment of disease or impairment, or assessment of health.

CLIA mandates that virtually all laboratories, including physician office laboratories, meet applicable Federal requirements and have a CLIA certificate to operate.

CLIA requires 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 HHS along with the Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC). Fees 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 number of quality deficiencies decreased about 40 percent from the first laboratory survey to the second under CLIA. Reviews of PT over time resulted in similar findings.

Did You Know?

In 2014, CLIA regulations added 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	<ul style="list-style-type: none"> ■ Approves private accreditation organizations that perform inspections and approve State exemptions ■ Collects user fees ■ Conducts inspections ■ Enforces regulatory compliance ■ Issues laboratory certificates ■ Monitors laboratory performance on PT and approves PT programs ■ Publishes CLIA rules and regulations 	https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA
FDA	<ul style="list-style-type: none"> ■ 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	<ul style="list-style-type: none"> ■ Conducts laboratory quality improvement studies ■ Develops and distributes professional information and educational resources ■ Develops technical standards and laboratory practice guidelines ■ Manages the CLIA Advisory Committee (CLIAC) ■ Monitors PT practices ■ Provides analysis, research, and technical assistance 	http://wwwn.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 entities providing clinical laboratory services, whether or not they or another provider files Medicare claims for the tests. Laboratories billing Medicare have additional responsibilities and requirements discussed in the Medicare Laboratory Services section.

Test Method Categorization

The FDA categorizes and grades each test based on the complexity of the test method. Find and search the FDA database at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/IVDRegulatoryAssistance/ucm393285.htm> on the Internet. 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;
- Calibration and quality control requirements of the instruments;
- Degree of independent judgment;
- Difficulty of the calculations;
- Examinations, procedures, and methodologies used; and
- Training required to operate the instruments for this particular 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;
- Pre-analytic, analytic, and post-analytic 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.

For more information and the application form, visit https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/How_to_Apply_for_a_CLIA_Certificate_International_Laboratories.html on the CMS website.

Fees

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

CLIA Number

Upon payment of fees, each laboratory receives a unique CLIA number. 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).

Did You Know?

If the laboratory has a Certificate for PPMP, COR, COC, or COA, it can perform waived tests without a CW.

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;
- ❑ Fecal occult blood tests;
- ❑ Pregnancy tests; and
- ❑ Some urine tests.

Waived Tests

For more information about CLIA-waived tests, visit https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Categorization_of_Tests.html and view the “List of Waived Tests” document in the Downloads section.

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 where 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 moderately complex 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 there is a complaint. 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 2 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 2 years. The surveys:

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

The surveyor determines whether the laboratory meets CLIA requirements through:

- ▣ Interviewing the laboratory's personnel;
- ▣ Observing the laboratory's past and current practices; and
- ▣ Reviewing the laboratory's relevant records.

What Is a Certificate of Accreditation (COA)?

A laboratory that performs moderate and high complexity tests and meets the standards of a private non-profit accreditation organization approved by CMS may receive a COA. To receive CMS approval, a 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 each organization's performance in enforcing CLIA requirements.

An accreditation organization inspects the laboratory once every 2 years, and CMS may perform a validation survey to evaluate the results of the most recent accreditation organization inspection.

For a list of the private non-profit accreditation organizations, visit https://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 just like patient specimens and reports the results to the PT program. The PT program grades the results and returns them to the laboratory so it sees how accurately it performed the testing. PT programs undergo annual and ongoing regulatory reviews by CMS. For more information about PT programs, visit https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Proficiency_Testing_Providers.html on the CMS website.

Did You Know?

A laboratory should **not** refer a PT sample to another laboratory for analysis even if that is protocol for patient specimens.

Medicare Laboratory Services

Medicare covers laboratory services and other diagnostic tests, including materials and the services of technicians, when:

1. The treating physician or a qualified Non-Physician Practitioner (NPP) orders/refers the service;
2. The service is medically reasonable and necessary; and
3. The service meets all CLIA requirements.

Medicare pays for laboratory services and other diagnostic tests in a variety of ways. Visit the CMS Clinical Labs Center web page at <https://www.cms.gov/Center/Provider-Type/Clinical-Labs-Center.html> for more information.

Ordering/Referring Requirements

Medicare Administrative Contractors (MACs) deny Medicare claims from clinical laboratories when they lack a valid individual National Provider Identifier (NPI) for the ordering/referring provider. For more information about the ordering/referring requirements, visit <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/MLN-Publications-Items/CMS1247538.html> on the CMS website.

Resources

For more information about CLIA, visit <https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA> on the CMS website, or scan the Quick Response (QR) code. Tables 2 and 3 provide additional resources for clinical laboratory services. CMS also created a series of brochures to explain the CLIA regulation requirements; find them at https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/CLIA_Brochures.html on the CMS website.

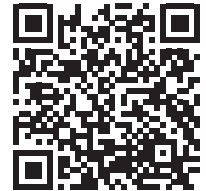


Table 2. CLIA Resources

Resource	Website
CLIA Application Information and Form	https://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 Frequently Asked Questions	https://questions.cms.gov/faq.php?id=5005&rdept=889
CLIA List of COA Accreditation Organizations	https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Accreditation_Organizations_and_Exempt_States.html
CLIA PT	https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Proficiency_Testing_Providers.html
CLIA Regulations	https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/CLIA_Regulations_and_Federal_Register_Documents.html

Table 3. Medicare Laboratory Services Resources

Resource	Website
Clinical Laboratory Fee Schedule (CLFS)	https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/MLN-Publications-Items/CMS1243659.html
Clinical Labs Center	https://www.cms.gov/Center/Provider-Type/Clinical-Labs-Center.html
Lab National Coverage Determinations (NCDs)	https://www.cms.gov/Medicare/Coverage/CoverageGenInfo/LabNCDs.html
Medicare Coverage Database – Including Lab Local Coverage Determinations (LCDs)	https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx
Medicare Laboratory Policy and Procedures	<p>“Medicare Benefit Policy Manual” Chapter 15, Sections 80.1 and 280 https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf</p> <p>“Medicare Claims Processing Manual” Chapters 16 and 18 https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs-Items/CMS018912.html</p>
Medicare Learning Network® (MLN) Guided Pathways (GPs)	<p>Provider Specific Medicare Resources, Laboratory section https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNEdWebGuide/Downloads/Guided_Pathways_Provider_Specific_Booklet.pdf</p> <p>All Other GP Resources https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNEdWebGuide/Guided_Pathways.html</p>



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