

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



Clinical Laboratory Improvement Amendments (CLIA)



OVERVIEW



What Is CLIA?

Congress passed the **Clinical Laboratory Improvement Amendments (CLIA)** in 1988, establishing 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 requires that laboratories performing these types of tests be certified by the **Secretary of the Department of Health and Human Services (DHHS)**.

The Centers for Medicare & Medicaid Services (CMS) administers the CLIA laboratory certification program for the Secretary in conjunction with the Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC). The FDA is responsible for test categorization and the CDC is responsible for CLIA studies, convening the Clinical Laboratory Improvement Advisory Committee (CLIAC), and provides scientific and technical support to CMS. CLIA is user fee funded; therefore, all costs of administering the program must be covered by the regulated facilities, including certificate and survey costs.

Why Is CLIA Important?

CLIA established quality standards for laboratories to ensure the accuracy, reliability, and timeliness of patient test results regardless of where the test is performed. CMS data indicates that CLIA has helped to improve the quality of testing in the United States. The total number of quality deficiencies decreased approximately 40% from the first laboratory survey to the

second under CLIA. Similar findings were demonstrated in the review of proficiency testing (PT) data over time. CLIA regulations apply to laboratory testing in all settings including commercial, hospital, and physician office laboratories.

Does CLIA Only Apply to Laboratories Obtaining Payment through Medicare?

CLIA standards are national and are not Medicare-exclusive. CLIA applies to all providers rendering clinical laboratory services, whether or not Medicare claims are filed.

How Are Test Methods Categorized?

CLIA regulations are based on the complexity of the test method. Test methods are categorized into three levels of complexity:

- Waived Complexity;
- Moderate Complexity, including Provider-Performed Microscopy Procedures (PPMP); and
- High Complexity.

The more complicated the test, the more stringent the requirements. CLIA specifies quality standards for PT, facility administration, general laboratory systems, preanalytic, analytic, and postanalytic systems, personnel qualifications and responsibilities, quality control, quality assessment, and specific cytology provisions for laboratories performing moderate and/or high complexity tests.

How Does a Laboratory Enroll in the CLIA Program?

To enroll in the CLIA program, laboratories must:

- Complete an application;
- Pay applicable fees;
- Be surveyed, if applicable; and
- Become certified, if CLIA standards are met.

Fees are based on the type of certification requested, and for moderate and high complexity laboratories, the annual volume and types of testing performed. Specific information about enrolling in CLIA and the application form can be found at: <http://www.cms.hhs.gov/clia/>

Upon payment of fees, each laboratory is assigned an individual and unique CLIA number. For Medicare claims to be processed, the CLIA number must be reported on all claims for laboratory services.

TYPES OF CERTIFICATES

The CLIA program has five types of laboratory certificates: Certificate of Waiver, Certificate for Provider-Performed Microscopy Procedures, Certificate of Registration, Certificate of Compliance, and Certificate of Accreditation.

Certificate of Waiver (CW)

The Certificate of Waiver permits a laboratory to perform only waived tests. Waived tests are those tests that have been determined so simple and accurate that there is little risk of error if the test is performed incorrectly. Examples of waived tests include certain testing methods for glucose and cholesterol, pregnancy tests, fecal occult blood tests, and some urine tests. Routine on-site surveys are not required for a CW Certificate unless there is a complaint but the laboratory must follow the manufacturer's instructions for test performance.

Certificate for Provider-Performed Microscopy Procedures (PPMP)

A subset of the Moderate Complexity tests, PPMPs are given a unique classification and certification. This certificate is issued to a laboratory in which a physician, midlevel practitioner, or dentist performs no tests other than certain microscopy procedures (a moderately complex procedure which is performed using a microscope; e.g., urine microscopic or KOH smear) and waived tests. This certificate permits the laboratory to also perform waived tests. Routine on-site surveys are not required for a PPMP Certificate, but these laboratories are subject to moderate complexity requirements and can be surveyed as part of a routine survey for nonwaived tests or a complaint is alleged.

Certificate of Registration (COR)

A Certificate of Registration is issued to a laboratory that applies for a Certificate of Compliance or a Certificate of Accreditation. A COR enables the laboratory to conduct moderate or high complexity laboratory testing or both until it is determined that the laboratory has met all requirements (through an on-site survey or verification of accreditation). Laboratories have a choice to achieve their CLIA certification via a CMS survey or a CMS approved accrediting organization.

Certificate of Compliance (COC)

A **Certificate of Compliance** is issued to a laboratory after an on-site survey finds that the laboratory is in compliance with all applicable CLIA requirements.

Laboratories with a Certificate of Compliance that perform moderate and/or high complexity testing are required to be surveyed biennially. Surveys are conducted by CMS or its agent and are outcome-oriented. CMS conducts surveys to determine a laboratory's regulatory compliance and assist laboratories in improving patient care through education and by emphasizing those standards that will have a direct impact on the laboratory's quality test performance. The surveyor determines whether the laboratory is meeting the requirements of the CLIA regulations based on:

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

Certificate of Accreditation (COA)

A laboratory that performs moderate and/or high complexity testing and that meets the standards of a private non-profit accreditation program approved by CMS may file for a COA. Approved non-profit accreditation programs are programs that are determined by CMS to have requirements that are equal to or more stringent than those of the CLIA program. The accreditation program inspects the laboratory on a biennial basis. Currently there are six CMS approved accrediting organizations. Periodically, each organization must be re-approved to ensure equivalency is maintained and each year CMS evaluates their performance in enforcing CLIA requirements to verify that it is sustained.

CLIA PERFORMANCE MEASURES —PROFICIENCY TESTING (PT)

By law, laboratories conducting moderate and/or high complexity testing are required to participate in PT for certain tests they perform.

PT is also educational and involves sending samples with results unknown to the laboratory, three times per year to evaluate whether the laboratory's results are

accurate and compare to its peers. The CLIA regulation requires that the PT samples be tested in the same manner and by the same individuals as patient testing. PT samples are provided by private non-profit organizations, Federal, or State agencies. PT programs undergo an annual and ongoing regulatory review conducted by CMS.

WHERE CAN I FIND MORE INFORMATION

For more information on the Clinical Laboratory Improvement Amendments, please visit the following website: CMS CLIA Information Page
<http://www.cms.hhs.gov/clia/>

This page contains information and links to a variety of CLIA resources including: CLIA regulations, CLIA enrollment, CLIA certificates, CLIA fee schedules, CLIA-approved accrediting organizations, CMS' outcome oriented survey process, data reports, key projects, CLIA performance measures, CLIA State Agencies and CMS Regional Offices CLIA contacts, and the FDA test categorization lists.

The Medicare Learning Network (MLN) is the brand name for official CMS educational products and information for Medicare providers. For additional information visit the Medicare Learning Network's Medlearn web page at <http://www.cms.hhs.gov/MLNGenInfo/> on the CMS website.



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