

# **Clinical Laboratory Improvement Act (CLIA)**

## **A Brief History of CLIA**

CLIA began in the late 1960's when problems arose in the cytology laboratories that read PAP smears. The personnel in these laboratories were overworked and had a very high error rate.

In 1967, the Clinical Laboratory Improvement Amendment was passed and the first laboratory regulations were born. These regulations primarily covered independent and hospital laboratories.

In 1988, a second amendment was passed providing oversight of all facility types, not just the hospitals and independent laboratories. Now physician offices, nursing homes and even health fairs are covered by CLIA '88.

## **What is CLIA-88?**

Congress passed CLIA-88, as a means for the Secretary of Health to develop comprehensive, quality standards for all laboratory testing to ensure the accuracy, reliability and timeliness of patient test results regardless of where the test was performed. A laboratory is defined as any facility which performs laboratory testing 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 is a user fee funded government program; therefore, all costs of administering the program must be covered by the regulated facilities. Facilities that do not accept Medicare or Medicaid or accept only cash must be certified under CLIA. It is the act of performing a laboratory test that defines the requirement of certification and not how the test is paid for.

The final CLIA regulations were published on February 28, 1992 and were based on the complexity of the test method; thus, the more complicated the test, the more stringent the requirements. Three categories of tests have been established: waived complexity, moderate complexity, including the subcategory of provider-performed microscopy (PPM), and high complexity. CLIA specifies quality standards for proficiency testing (PT), patient test management, quality control, personnel and quality assurance.

Data indicates that CLIA has improved the quality of testing in the United States. The total number of quality deficiencies has decreased approximately 40% from the first cycle of laboratory surveys to the second cycle of surveys. Current PT review data concurs with these earlier findings. Due to the educational value of PT in laboratories, CLIA-88 continues to address initial PT failures with an educational, rather than punitive, approach.

## **History of CLIA-88**

Beginning in 1987, a series of newspaper and magazine articles were published on the quality of laboratory testing. Also, simultaneously television programs were aired concerning the number of laboratories that were not subject to either federal or state regulations. Congress held hearings in 1988 and heard testimony from "victims" of faulty laboratory testing. Specific concerns were raised about the validity of cholesterol screening and the accuracy of Pap smear results.

Section 4064 of the Omnibus Budget Reconciliation Act of 1987 [OBRA-87 - Public Law 100-203], enacted on December 22, 1987 amended Section 1861(s)(11) to require physician offices that performed more than 5000 tests per year to meet regulations. Laboratory testing in both physicians' offices (POLs) and rural health clinics that did not accept and perform tests on referral specimens would not be subject to these revisions because both the Medicare and CLIA statutes [Section 1861(s)(11) of the Act and section 351(I) of the PHS Act] respectively precluded the regulation at that time of POLs and RHC that performed tests only for their own patients.

On October 31, 1988, Congress enacted Public Law 100-578 in response to the congressional hearings. PL 100-578 greatly revised the authority (PHS Act) for the regulation of laboratories.

This law revised section 353 of the PHS Act (42 U.S.C. 263a) amending CLIA-67 by expanding the

Department of HHS's authority from regulation of laboratories that only accepted and tested specimens in interstate commerce to the regulation of any laboratory that tested specimens for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of human beings.

Then on December 19, 1989, Congress enacted OBRA-89 (Public Law 101-239). Section 6141 removed the provision under section 4064 of OBRA-87, which would now require certification of all laboratories performing tests. In addition, it required laboratories participating in the Medicare/Medicaid programs to comply with CLIA-88 requirements.

On February 28, 1992, the final regulations for CLIA-88 were published with an implementation date of September 1, 1992. Sections of the CLIA requirements were to be phased in allowing previously non-regulated laboratories to become accustomed to the regulations. The regulations adding Provider-Performed Microscopy Procedures (PPMP) were published on March 24, 1995. Work is currently in progress with the CDC and CMS to develop final CLIA regulations, which will reflect all comments received since the September 1, 1992, Federal Register publication and the development of new technologies.

On April 24, 2003, the revised CLIA regulations went into effect. For more information, go to [www.cms.hhs.gov/clia](http://www.cms.hhs.gov/clia).

## **Legislative History**

### ***CLIA-67; Clinical Laboratory Improvement Act of 1967 [P.L. 90-174]:***

To implement CLIA-67, section 5(a) Part F of title III of the Public Health Service (PHS) Act (42 U.S.C. 262-3) was amended by changing the title to read: "Licensing -- Biological Products and Clinical Laboratories" and by adding section 353 (42 (U.S.C.) 263). Section 353 regulated any laboratory engaged in interstate commerce, that is, soliciting or accepting (directly or indirectly) any specimen for laboratory examination or other laboratory procedures and required CLIA-67 licensure. Laboratories were given a full, partial, or exempt CLIA-67 license, depending on the scope of laboratory testing. Regulations included Applicability; License - Application & Renewal; Quality Control; Personnel Standards; Proficiency Testing; Accreditation; General Provisions; and Sanctions.

### ***Medicare/Medicaid; Independent and Hospital Laboratories;***

Only independent and hospital laboratories seeking Medicare/Medicaid reimbursement were regulated under Title XVIII and Title XIX of the Social Security Act. Each facility type had their own regulations to follow.

### ***Medicare/Medicaid/CLIA-67 Regulations: August 5, 1988- Proposed [March 14, 1990 - Final and Effective 09/01/90]:***

In April 1986, a study [Final Report on Assessment of Clinical laboratory Regulations] on clinical laboratories recommended that HHS review the existing regulations to determine how to improve the assurance of quality laboratory testing and achieve program uniformity.

The August, 1988, proposal sought to recodify the regulations for these programs [Hospital Laboratories, Section 1861(e) of the Social Security Act (SSA); Independent Laboratories, 1861(s)(11) and 1861(s)(12) and (13) of the SSA; CLIA-67, 42 U.S.C. 263(a), Section 353 of the Public Health Service (PHS) Act, interstate commerce; Medicaid, Section 1902(a)(9)(C) of the SSA] into a new Part 493 in order to simplify administration and unify the health and safety requirements for all programs as much as possible.

In 2003, CMS revised the Interpretative Guidelines for Laboratories. This revision reorganized and clarified the previous guidelines into 3 new sections: Pre-Analytic, Analytic, and Post-Analytic. See [www.cms.hhs.gov/clia](http://www.cms.hhs.gov/clia) for more information.