



CLINICAL LABORATORY IMPROVEMENT AMENDMENTS OF 1988: HOW TO ASSURE QUALITY LABORATORY SERVICES

OVERVIEW

In response to public health concerns over largely unregulated laboratory services, Congress enacted Clinical Laboratory Improvement Amendments of 1988 (CLIA).¹ For a laboratory to conduct tests on human specimens it must obtain a certificate from the Department of Health and Human Services, which requires compliance with CLIA. CLIA established quality standards for laboratory testing to assure the accuracy, reliability, and efficiency of patient test results.

The regulations implementing this legislation impose several requirements for laboratories:² (1) the laboratories must use materials that provide accurate and reliable test results and which act in accordance with performance specifications;³ (2) it must have a written procedures manual;⁴ (3) the laboratory must perform maintenance and function checks as specified by the manufacturer of the equipment;⁵ (4) the equipment must be calibrated and the calibration verified according to the manufacturer's instructions;⁶ (5) the laboratory must employ quality control measures;⁷ and (6) personnel must meet certain educational and work experience standards.⁸

If a laboratory does not have a certificate yet nevertheless conducts a drug screen, or if a laboratory does not meet these standards and a positive drug test is wrong, the employee may have a potential actionable claim against the employer for negligently selecting the laboratory or against the laboratory for negligent testing.⁹ Revocation of a certificate disqualifies the owner of the laboratory from owning or operating any laboratory for two years.¹⁰

¹ Clinical Laboratory Improvement Amendments of 1988, Pub. L. No. 100-578, 102 Stat. 2903; 42 U.S.C. § 263a. A laboratory is defined as any facility that 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. 42 U.S.C. § 263a.

² 57 Fed. Reg. 7001-7186.

³ 42 C.F.R. § 493.1205.

⁴ 42 C.F.R. § 493.1211.

⁵ 42 C.F.R. § 493.1215.

⁶ 42 C.F.R. § 493.1217(b).

⁷ 42 C.F.R. § 493.1218(f).

⁸ 42 C.F.R. §§ 493.1401-493.1495.

⁹ *Elliot v. Lab. Specialists, Inc.*, 588 So. 2d 175 (La. App. 1991) (holding that the employer was not liable but the laboratory was); *but see Doe v. Smithkline Beecham Corp.*, 855 S.W.2d 248 (Tex. App. 1993) (applicant could sue laboratory for negligence but not at-will employer).

¹⁰ 42 U.S.C. § 263a(i)(3)

BACKGROUND FACTS AND REASONS FOR CLIA'S ENACTMENT

Clinical laboratory tests account for over \$30 billion in annual expenditures, which is about the equivalent of 4.5 percent of total national health care spending each year.¹¹ In the United States, more than 6 billion tests are conducted yearly, in over 200,000 testing sites.¹²

Several reasons prompted the enactment of CLIA. For one, CLIA sought to address the oft-criticized unreliability of certain laboratory test results, which posed a threat to public health. Cytology¹³ procedures, for example, and in particular Pap smears, often proved unreliable. False and negative Pap smears caused cervical cancer to go undiagnosed in many women.¹⁴ Thus, the amendments were made to implement adequate standards to eliminate such missed diagnoses.¹⁵ The inaccuracy and unreliability of test results also led to a loss in the quality of care and increased health care costs.¹⁶ CLIA provided that the Secretary of Health and Human Services would set minimum standards that would regulate almost all aspects of quality control as well as conduct periodic inspections to ensure compliance.¹⁷

An additional reason for CLIA's enactment was that the existing standards, the Clinical Laboratory Improvement Act of 1967 (Section 353 of the Public Health Services Act), were outdated and inadequate given changes in laboratory testing.¹⁸ Further, the 1967 standards only regulated interstate commerce related laboratory facilities.¹⁹ Title XVIII of the Social Security Act required that labs serving as providers in the Medicare program be subject to quality standards established by the Secretary.²⁰ Physician office-based testing, which constituted a large proportion of testing, lacked virtually all accountability as it was exempt from federal regulation.²¹ Intrastate labs that did not participate in Medicare were able to avoid all Federal

¹¹ H.R.Rep. No. 899, 100th Cong., 2d Sess. 16 (1988), *reprinted in* 1988 U.S.C.C.A.N. 3828, 3831; *see* Health Care Fin. Transactions Man. § 20:40 (2004).

¹² Health Care Fin. Transactions Man. § 20:40 (2004).

¹³ Cytology is the examination of cells to identify abnormalities which may indicate disease. H.R.Rep. No. 899, 100th Cong., 2d Sess. 16 (1988), *reprinted in* 1988 U.S.C.C.A.N. 3828, 3837.

¹⁴ 134 Cong. Rec. H9866-02, 1998 WL 179529. Evidence showed high numbers of false negative results being reported. Not only were women given a false sense of security and discouraged from seeking proper care, but also the false negatives caused unnecessary deaths. H.R.Rep. No. 899, 100th Cong., 2d Sess. 16 (1988), *reprinted in* 1988 U.S.C.C.A.N. 3828, 3837. Specifically, evidence pointed towards labs employing inadequately trained cytologists and requiring them to process tests at rates double or triple higher than the recommended maximum workload. S.Rep. No. 561, 100th Cong., 2d Sess. 5 (1998).

¹⁵ 134 Cong. Rec. H9866-02, 1998 WL 179529.

¹⁶ H.R. Rep. 100-899, 1988 U.S.C.C.A.N. 3828, 3831.

¹⁷ 134 Cong. Rec. H9866-02, 1998 WL 179529.

¹⁸ 134 Cong. Rec. H9866-02, 1998 WL 179529; *see* H.R.Rep. No. 899, 100th Cong., 2d Sess. 16 (1988), *reprinted in* 1988 U.S.C.C.A.N. 3828, 3832 (stating that "today's clinical laboratories would hardly be recognizable by the framers of the original CLIA").

¹⁹ S.Rep. No. 561, 100th Cong., 2d Sess. 3-4 (1988).

²⁰ 1988 U.S.C.C.A.N. 3828, 3831.

²¹ At the time of CLIA's enactment, research demonstrated that approximately half of all tests occurred in physician labs, and that the volume of physician office-based testing was increasing at 16 percent annually. 134 Cong. Rec. H9866-02, 1998 WL 179529. In a 1986 report entitled "The Final Report on Assessment of clinical Laboratory Regulation," authored by Michael Kenney, unregulated labs in physician and group practice offices consistently demonstrated lower accuracy and precision results than regulated labs. The report concluded that compliance with

regulations, and reports showed that these facilities were among the poorest performing labs in terms of inaccurate results.²²

Because 2 different statutes, Medicare and CLIA, governed the previous system, each statute had different standards and requirements. To deal with quality standards in a uniform manner, Congress decided that all clinical laboratories should be subject to federal oversight.

Finally, the lack of valuable and informative data concerning laboratory quality curbed progress in the accuracy and reliability of testing. CLIA aimed to rectify this problem by requiring that useful information on lab performance be circulated to physicians and to the public and conducting studies on the links between lab quality, regulation and patient health.²³

SUMMARY OF FINDINGS AND REASONS FOR CLIA²⁴

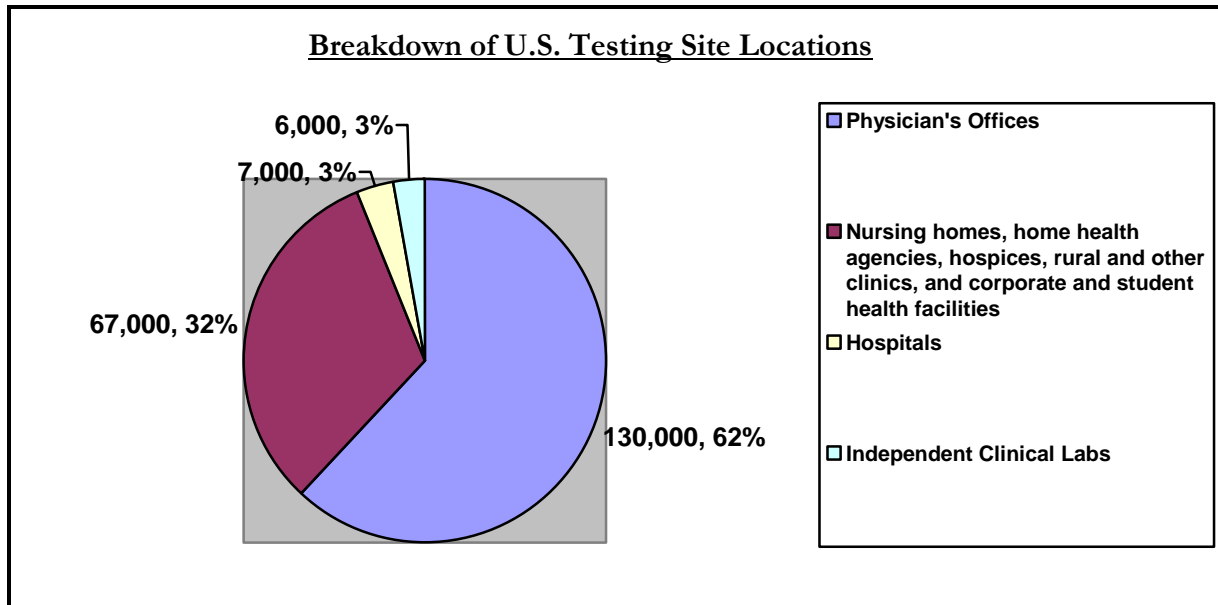
1. Laboratory Testing is a critical element in the delivery of good health care.
2. Accurate and reliable testing is vital to the public health of all Americans.
3. Current testing procedures and technology result in all lab testing either being done in interstate commerce or substantially affecting interstate assurances.
4. Unregulated labs can compete unfairly with regulated labs by performing tests at lower cost, but at risk of lower accuracy and reliability.
5. Unregulated labs impair the effectiveness of the health and safety regulations governing other labs
6. Current regulatory standards and procedures fail to protect public health and welfare and fail to eliminate burdens on interstate commerce; and
7. Federal regulation is reasonable and appropriate to promote public health and welfare and protect interstate commerce.

regulations would increase accurate results and thereby increase public health protection. H.R. Rep. 100-899, 1988 U.S.C.C.A.N. 382, 3836.

²² H.R.Rep. No. 899, 100th Cong., 2d Sess. 16 (1988), *reprinted in* 1988 U.S.C.C.A.N. 3828, 3834-3835.

²³ *Id.*

²⁴ H.R.Rep. No. 899, 100th Cong., 2d Sess. 16 (1988), *reprinted in* 1988 U.S.C.C.A.N. 3828, 3839.



OVERSIGHT AND ENFORCEMENT

Under CLIA, CMS regulates all laboratory testing (except research) performed on humans in the United States. Approximately 175,000 of these testing sites are subject to CLIA. The Division of Laboratory Services, within the Survey and Certification Group, under the Center for Medicaid and State Operations has the responsibility for implementing CLIA.²⁵ The Centers for Disease Control and Prevention is responsible for the CLIA studies, convening the CLIA Committee (CLIAC) and provides scientific and technical support to CMS.

The provisions give enforcement authority directly to the Attorney General and Secretary, and make no mention, either directly or implicitly, of an individual's right to seek damages or injunctive relief against a laboratory for its alleged violations. Legislative history of CLIA supports that Congress did not intend to give individual's a private right of action.²⁶

SANCTIONS FOR VIOLATION

1. In the case of noncompliance with the Secretary's standards, the Secretary may:
 - impose monetary civil penalties;²⁷
 - suspend, revoke, or limit certification of the laboratory;²⁸
 - seek to enjoin the laboratory from continuing activity which creates a significant hazard to the public health.²⁹
2. In the case of intentional violations of CLIA's provisions or regulations, the United States Attorney General may seek prosecution.³⁰

²⁵ CLIA Program, at <http://www.cms.hhs.gov/clia/>.

²⁶ H.R. Rep. 100-899, 1988 U.S.C.C.A.N. 3828, 3829, 3831.

²⁷ 28 U.S.C. § 263a(h)(1)-(2).

²⁸ 28 U.S.C. § 263a(i)(1)-(2).

²⁹ 28 U.S.C. § 263a(j).

³⁰ 28 U.S.C. § 263(a)(1).

EXEMPTIONS

Section 353(p) of the Public Health Service Act provides for the exemption of laboratories from the requirements of CLIA when the State in which they are located has requirements equal to or more stringent than those of CLIA.

Section 353(d)(2) provides that the Secretary can issue a certificate of waiver to laboratories meeting certain enumerated requirements and criteria. This exemption was intended for those laboratories that conducted tests with an insignificant risk of inaccurate results.