

Laboratory Testing Under the Microscope: The Clinical Laboratory Improvement Amendments of 1988

Richard D. Raskin *

* Sidley & Austin, Chicago, Illinois. B.A., 1979, Brown University; J.D., 1985, University of Cincinnati College of Law.

Currently, most clinical laboratories in the United States are not subject to significant federal oversight. Beginning in 1992, however, the Clinical Laboratory Improvement Amendments of 1988 n1 (CLIA-88) will subject hundreds of thousands of large and small clinical laboratories to a complex assortment of federal requirements. In particular, CLIA-88 will require laboratories engaged in medical testing to obtain a certificate for each category of tests that the laboratory performs. n2 To obtain the certificate, the laboratory will be required to meet detailed performance requirements in each applicable category of testing. Performing services outside the scope of the certificate will expose the laboratory and its owners and operators to denial of Medicare and Medicaid reimbursement, civil monetary penalties and - in cases of intentional violations - potential criminal sanctions. n3

n1 Pub. L. 100-578, 102 Stat. 2903 (1988) (codified at 42 U.S.C. § 263a (1988)).

n2 *See infra* notes 29-45 and accompanying text.

n3 *See infra* notes 64-68 and accompanying text.

Although CLIA-88 was originally scheduled to go into effect over a year ago, n4 its implementation has been delayed by the enormity of the program and by controversy over the regulations proposed by the Department of Health and Human Services (HHS). Nevertheless, according to HHS officials, 1992 will be the year that every clinical laboratory in the United States - whether hospital-based, independent, or located in a physician's office - will be required to meet CLIA-88 requirements. n5 This article discusses the scope of CLIA-88, the status of its various sets of proposed regulations, and the substantive requirements of the CLIA-88 statute.

n4 *See* 55 Fed. Reg. 31,758 (1990) (noting several sections were to become effective in January 1991).

n5 *See, e.g.,* Laurie Jones, *New Year Brings New Lab Rules*, Am. Med. News, Jan. 13, 1992, at 1.

SCOPE OF CLIA-88

CLIA-88 supersedes and significantly expands upon the requirements of the Clinical Laboratory Improvement Act of 1967 n6 (CLIA-67). Under that law, only about 12,000 hospital-based and independent laboratories were subject to federal regulation. CLIA-67 applied only to labs that solicited or accepted specimens in interstate commerce. Further, it exempted most physician office laboratories from federal regulation.

n6 Pub. L. 90-174, 81 Stat. 536 (1967) (codified at 42 U.S.C. § 263a (1982)).

Under CLIA-88, by contrast, HHS estimates that between 300,000 and 600,000 laboratories will be regulated. n7 CLIA-88 contains no interstate commerce limitation and no exemption for physician office laboratories. Further, unlike most federal regulatory initiatives in the health care field, CLIA-88 is not limited to services covered by Medicare and Medicaid. n8 The Act applies, quite literally, to every clinical laboratory - that is, every laboratory engaged in testing of human specimens for purposes of medical diagnosis - regardless of whether the laboratory receives any federal funds. n9

n7 *See* Enforcement Procedures for Laboratories, 56 Fed. Reg. 13,430, 13,437 (proposed Apr. 2, 1991).

n8 *See* 42 U.S.C. § 1395dd(e)(3) (1988) (anti-dumping provisions applicable to hospitals that participate in the Medicare program).

n9 *See* 42 U.S.C. § 263a(a) (1988).

Laboratory settings that now will be required to comply with federal standards are expected to include:

- accredited, nonaccredited, and federal hospital laboratories;
- laboratories located in critical care facilities, including operating rooms;
- ambulatory surgical centers;
- laboratories located in skilled nursing facilities, end-stage renal disease facilities, and intermediate care facilities;
- independent laboratories;
- physician office laboratories;
- laboratories associated with tissue banks and tissue repositories;
- industrial laboratories;
- drug screening laboratories and mobile laboratories; and
- any other facility or entity, including pharmacies and health fairs, that perform quantitative, qualitative, or screening test procedures or examinations on materials derived from the human body. n10

Several states already have their own laws regulating clinical laboratories. n11 Under CLIA-88, these laws remain in effect as long as they are "not inconsistent with" CLIA-88. n12 Moreover, if a state enacts laws with requirements that are "equal to or more stringent than" those of CLIA-88, HHS may exempt laboratories in the state from compliance with CLIA-88. n13

n10 Regulations Implementing the Clinical Laboratory Improvement Amendments of 1988, 55 Fed. Reg. 20,896, 20,900 (proposed May 21, 1990).

n11 *See, e.g.*, Illinois Clinical Laboratory Act, ILL. ANN. STAT. ch. 111 1/2, PP621-101 - 631-103 (Smith-Hurd 1988).

n12 42 U.S.C. § 263a(p)(1) (1988).

n13 *Id.* § 263a(p)(2).

STATUS OF IMPLEMENTING REGULATIONS

HHS has planned four separate rulemaking proceedings to implement different portions of CLIA-88. These rulemakings deal with:

- 1) certification requirements and laboratory performance standards;
- 2) general administration, including fee collection;
- 3) requirements for approval of accrediting bodies and state licensure agencies; and
- 4) sanctions and enforcement.

To date, proposed rules have been published for each of these four areas. However, none of the four sets of proposed rules has been finalized.

Certification Requirements and Laboratory Performance Standards

HHS published proposed regulations concerning certification requirements and laboratory performance standards on May 21, 1990. n14 The proposed regulations dealt with CLIA-88's principal regulatory requirements - for example, proficiency testing, personnel, quality control, quality assurance, and

inspections. The proposal resulted in over 60,000 comments, most of them highly critical of the approach taken by HHS. n15

n14 *See supra* note 10.

n15 *See* EXECUTIVE OFFICE OF THE PRESIDENT OF THE UNITED STATES, OFFICE OF MANAGEMENT & BUDGET, BUDGET OF THE UNITED STATES GOVERNMENT - FISCAL YEAR 1992 Pt. II, at 376 (1991) (summarizing comments on proposed certification requirements and laboratory performance standards).

The proposal was faulted for setting unrealistic proficiency testing standards, failing to distinguish between sophisticated laboratories and those that performed more simple tests, and imposing burdensome costs - in the billions of dollars - in exchange for uncertain benefits. n16 Comments also included complaints that the rules would be likely to cause many larger laboratories to raise their prices and many smaller laboratories to close - with adverse effects on access to lab services. n17 Even the President's Office of Management and Budget urged that the proposal be reconsidered in light of its anticipated costs and the burdens that it would impose upon patients and laboratories. n18

n16 *Id.*

n17 *Id.*

n18 Letter from James B. MacRae, Jr., Office of Management and Budget, to Gail R. Wilensky, Administrator, Health Care Financing Administration, HHS, at 2 (Sept. 21, 1990) (on file with the DePaul University College of Law, Health Law Institute). The letter states: "the rule appears to have been crafted as if the goal of health care quality could be pursued without due consideration for cost containment and access." *Id.*

Subsequently, HHS indicated that it was undertaking a "major rewrite" of the proposed certification requirements and performance standards. n19 As of January, 1992, the regulations were scheduled to be issued in final form early in 1992, with an effective date of July 1, 1992. n20

n19 Memorandum from Congressman John D. Dingell, Chairman, to Subcommittee on Oversight and Investigations, House of Representatives, at 2 (May 1, 1991) (on file with the DePaul University College of Law, Health Law Institute).

n20 Jones, *supra* note 5, at 41.

Other CLIA-88 Regulations

In addition to the proposed certification requirements and laboratory performance standards, three other sets of CLIA-88 rules are still in proposed form. Proposed rules for general administration and fee collection were published in the Federal Register on August 3, 1990. n21 Proposed rules regarding accrediting bodies and state licensure agencies were published on August 20, 1990. n22 And proposed rules concerning enforcement procedures were published on April 2, 1991. n23

n21 *See* Fee Collection, 55 Fed. Reg. 31,758 (proposed Aug. 3, 1990).

n22 *See* Granting and Withdrawal of Deeming Authority to Private Nonprofit Accreditation Organizations and State Licensure Agencies, 55 Fed. Reg. 33,936 (proposed Aug. 20, 1990).

n23 *See* 56 Fed. Reg. 13,430 (1991).

An additional rulemaking resulted in final rules n24 applicable to the 12,000 laboratories regulated under CLIA-67. This rulemaking was initiated prior to the enactment of CLIA-88, but was completed after CLIA-88 became law. Accordingly, HHS included in the final rule provisions relating to the portions of CLIA-88 that did not require prior notice and comment. n25

n24 *See* Final Rulemaking, Revision of Laboratory Regulations, 55 Fed. Reg. 9,538 (1990).

n25 *Id.* at 9,539.

REQUIREMENTS OF CLIA-88

CLIA-88 was enacted following a year-long congressional investigation of clinical laboratories in 1987 and 1988. n26 During the course of its investigation, Congress became concerned about a reportedly high error rate in cytology (or Pap smear) screening, ineffective proficiency testing, and inadequate performance of unregulated laboratories. n27 Congress concluded that there were serious deficiencies in the existing system of regulation. n28 In an attempt to remedy these deficiencies, CLIA-88 both expanded the aggregate number of laboratories regulated and increased the rigor of the standards applicable to those laboratories. Although the precise requirements of the CLIA-88 program will not be known until the Secretary of HHS (Secretary) finalizes the regulations, the basic structure of the program is set forth in the statute itself.

n26 *See* H.R. Rep. No. 899, 100th Cong., 2d Sess. 10, *reprinted in* 1988 U.S.C.C.A.N. 3828, 3831.

n27 *See* Diane M. Gianelli, *Senators Hit HCFA Delay on Issuing Lab Standards*, AM. MED. NEWS, Mar. 23, 1990, at 1.

n28 *See* H.R. Rep. No. 899, 100th Cong., 2d Sess. 11-19, *reprinted in*, 1988 U.S.C.C.A.N. 3828, 3831-39.

Certification

CLIA-88 provides that, in order to "solicit or accept materials derived from the human body for laboratory examination or other procedure," a laboratory must have in effect a current certificate or certificate of waiver applicable to the particular category of examinations or procedures that the laboratory wants to perform. n29 Laboratories that obtain a certificate of waiver are exempt from CLIA-88's most burdensome regulatory requirements. n30 In particular, they are not subject to the Secretary's laboratory performance standards. n31 However, eligibility for a certificate of waiver is strictly limited.

n29 42 U.S.C. § 263a(b), (d)(4) (1988). The Act defines a laboratory as:

a facility for the biological, microbiological, serological, chemical, immuno-hematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings.

Id. § 263a(a).

n30 *See id.* § 263a(d)(2).

n31 *Id.* § 263a(d)(2)(f)-(g).

Specifically, a certificate of waiver is available only to laboratories that limit their testing to "simple laboratory examinations and procedures which, as determined by the Secretary, have an insignificant risk of an erroneous result." n32 In the proposed rules relating to certification requirements and performance standards, waived tests included dipstick or tablet reagent urinalysis for bilirubin, glucose, hemoglobin, or protein; fecal occult blood tests; ovulation tests; urine pregnancy tests; and sickle cell screening by methods other than electrophoresis. n33 The list was criticized, however, as being both underinclusive and overinclusive. n34 It is expected to be modified in the final rulemaking.

n32 *Id.* § 263a(d)(2), (3).

n33 *See* 55 Fed. Reg. at 20,918 (1990).

n34 Even before the proposed rules were published, a "leaked" draft of the rules containing the waived list resulted in considerable controversy. *See* Gianelli, *supra* note 27, at 37.

Laboratories that are not eligible for a certificate of waiver must obtain a certificate. n35 Laboratories may become certified in either of two ways. The first alternative is to provide the Secretary with

"satisfactory assurances that the laboratory will be operated in accordance with standards issued by the Secretary under subsection (f)." n36 Laboratories that choose this alternative (nonaccredited laboratories) are required to comply with the substantive requirements for laboratory performance developed by the Secretary. n37 Further, these laboratories are routinely inspected by the Secretary and submit their applications for certification directly to the Secretary. n38

n35 *See* 42 U.S.C. § 263a(b).

n36 *Id.* § 263a(d)(1)(B)(i).

n37 *Id.* § 263a(f).

n38 *Id.* § 263a(g)(2), (d)(1)(A).

The second alternative is to provide the Secretary with "proof of accreditation by an approved accrediting body under subsection (e)." n39 Laboratories that choose this alternative (accredited laboratories) must comply with the standards developed by an accrediting body approved by the Secretary. n40 To obtain approval by the Secretary, however, accrediting bodies must have substantive standards at least as stringent as those developed by the Secretary under subsection (f). n41 Accredited laboratories submit their applications for certification to the accrediting body. n42 They are routinely inspected by the accrediting body, but may also be inspected by the Secretary "on such basis as the Secretary determines is necessary." n43

n39 *Id.* § 263a(d)(1)(B)(ii).

n40 *See id.* § 263a(e).

n41 *Id.* § 263a(e)(2)(A)(ii).

n42 *Id.* § 263a(d)(1)(A).

n43 *Id.* § 263a(g)(2).

Similar to waived laboratories, certified laboratories (whether accredited or nonaccredited) must agree to make records available to the Secretary and to submit required reports. n44 In addition, however, they must agree to permit announced or unannounced inspections by the Secretary and to treat proficiency testing samples in the same manner as they treat specimens obtained in the ordinary course of business. n45

n44 *Id.* § 263a(d)(1)(D).

n45 *Id.* § 263a(d)(1)(C), (E).

Laboratory Performance Standards

Subsection (f) of CLIA-88 contains the Act's principal regulatory requirements. Subsection (f) requires the Secretary to develop "standards to assure consistent performance by laboratories . . . of valid and reliable laboratory examinations and other procedures." n46 These standards must include requirements for:

- 1) quality assurance and quality control, including requirements relating to the collection, transportation, and storage of specimens and the reporting of results;
- 2) maintenance of records, equipment, and facilities necessary for the effective operation of a laboratory;
- 3) qualifications of personnel, including competency, training, experience, job performance, and education; and
- 4) proficiency testing. n47

In developing these standards, the Secretary is required to consider such factors as the types of examinations and procedures performed, the amount of interpretation involved, and the difficulty of the calculations involved. n48

n46 *Id.* § 263a(f)(1).

n47 *Id.* § 263a(f)(1)(A)-(D).

n48 *Id.* § 263a(f)(2).

The Secretary's standards must require each nonwaivered laboratory to perform satisfactory proficiency testing "for each examination or procedure conducted within a category of examinations or procedures for which it has received a certificate." n49 The only exception is where the Secretary determines that a proficiency test cannot reasonably be developed. n50 Proficiency testing must be conducted on a quarterly basis, except where the Secretary determines "for technical and scientific reasons" that testing twice annually is sufficient. n51

n49 *Id.* § 263a(f)(3)(A). In the Conference Report that accompanied the legislation, Congress explained:

Proficiency testing is a method of externally validating the level of a laboratory's performance The standard testing methodology currently in use involves sample test specimens being sent by mail to a laboratory by the proficiency testing agency. The laboratory then analyzes the samples and returns the results of the test to the proficiency testing organization. The proficiency testing organization typically calculates the mean of the test results, determines an acceptable range variation based on standard deviations from the mean, and reports the results to the lab.

H.R. Rep. No. 899, 100th Cong., 2nd Sess. at 15-16, *reprinted in* 1988 U.S.C.C.A.N. 3828, 3836.

n50 42 U.S.C. § 263a(f)(3)(A).

n51 *Id.*

The Secretary is required to develop additional, highly specific substantive standards in the area of cytology services. n52 These standards must include limitations on the number of slides reviewed, maintenance of records, rescreening of slides, and the periodic confirmation and evaluation of the proficiency of individuals reviewing the slides. n53 The Secretary's cytology standards must also require that all cytological screening be done on the premises of a certified laboratory. n54

n52 *Id.* § 263a(f)(4).

n53 *Id.* § 263a(f)(4)(B).

n54 *Id.* § 263a(f)(4)(B)(vi).

Once the Secretary's subsection (f) standards are finalized, they will be binding upon all nonaccredited laboratories. Subsection (f) standards will also be indirectly binding upon accredited laboratories because, to obtain approval by the Secretary, an accrediting organization must have standards at least as stringent as the Secretary's subsection (f) standards. n55 Waivered laboratories are not required to comply with subsection (f) standards. n56

n55 *Id.* § 263a(e)(2)(A)(ii).

n56 *Id.* § 263a(d)(2)(C).

Inspections

The Secretary may conduct announced or unannounced inspections of certified laboratories. In conducting the inspections, the Secretary "may have access to all facilities, equipment, materials, records,

and information that the Secretary determines have a bearing on whether the laboratory" is in compliance. n57 Both nonaccredited and accredited labs will be inspected by the Secretary.

n57 *Id.* § 263a(g)(1).

Fees

The CLIA-88 program is designed to be self-funding. Thus, all laboratories will be assessed a fee for the issuance and renewal of certificates. n58 Fees must be sufficient, in the aggregate, to cover the full costs of administering CLIA-88. n59

n58 *Id.* § 263a(m)(1). Only a "nominal fee" will be assessed for the issuance and renewal of certificates of waiver. *Id.*

n59 *Id.* § 263a(m)(3)(A).

Accredited laboratories are charged certificate fees for the issuance and renewal of certificates. n60 Nonaccredited laboratories are charged certificate fees, plus additional fees for inspections and performance of proficiency testing if they do not participate in an approved proficiency testing program. n61 Both certificate fees and additional fees must "vary by group or classification of laboratory, based on such considerations as the Secretary determines are relevant." n62 These considerations "may include the dollar volume and scope of the testing being performed by the laboratories." n63

n60 *Id.* § 263a(m)(1).

n61 *Id.* § 263a(m)(2).

n62 *Id.* § 263a(m)(3)(C).

n63 *Id.*

Sanctions and Enforcement

CLIA-88 prescribes various sanctions for laboratories that fail to comply with the requirements of the Act. These sanctions also will apply to violations of HHS's regulations, once those regulations are finalized.

A laboratory that fails to comply with the requirements of the statute or regulations is subject to civil monetary penalties of up to \$10,000 for each violation. n64 In addition, the Secretary may suspend, revoke, or limit the laboratory's certificate. n65 A person who has owned or operated a laboratory that has had its certificate revoked is barred from owning or operating any certified laboratory for a period of two years. n66 Any person who intentionally violates any requirement of or regulation promulgated under CLIA-88 may be imprisoned for up to one year and fined. n67 In the event of a repeat violation, a person may be imprisoned for up to three years and fined. n68

n64 *Id.* § 263a(h)(2)(B).

n65 *Id.* § 263a(i)(1).

n66 *Id.* § 263a(i)(3).

n67 *Id.* § 263a(l).

n68 *Id.*

CONCLUSION

The implementation of CLIA-88 will mark the beginning of a new era for clinical laboratories. Before the law's enactment, most clinical laboratories were regulated by the federal government only in connection with their receipt of Medicare or Medicaid funds. Under CLIA-88, however, the performance and operations of all clinical laboratories will be subject to close federal scrutiny for the first time. With CLIA-88 implementation on the horizon, it is essential that all clinical laboratories familiarize themselves with the

statute and regulations. Noncompliance will expose the laboratory and its owners and operators to a risk of serious penalties. #LS930223SP# #LS930225LEufishmx#