

Clinical Laboratory Improvement Amendments of 1988

Changes resulting from the Taking Essential Steps for Testing (TEST) Act of 2012

Link to the TEST Act 2012: <http://www.gpo.gov/fdsys/pkg/PLAW-112publ202/pdf/PLAW-112publ202.pdf>

TEST Act 2012 Citation: 126 Stat. 1483, Public Law 112-202, Sec. 2

The Taking Essential Steps for Testing Act of 2012 (TEST Act) amended CLIA 1988's certificate requirements and enforcement options related to proficiency testing referral as stated in section 353 of the Public Health Service Act (42 U.S.C. 263a) as follows:

(d) REQUIREMENTS FOR CERTIFICATES.—

(1) IN GENERAL.—A laboratory may be issued a certificate or have its certificate renewed if -

(E) the laboratory agrees to treat proficiency testing samples in the same manner as it treats materials derived from the human body referred to it for laboratory examinations or other procedures in the ordinary course of business, except that no proficiency testing sample shall be referred to another laboratory for analysis as prohibited under subsection (i)(4).

(i) SUSPENSION, REVOCATION, AND LIMITATION.—

(3) INELIGIBILITY TO OWN OR OPERATE LABORATORIES AFTER REVOCATION.—No person who has owned or operated a laboratory which has had its certificate revoked may, within 2 years of the revocation of the certificate, own or operate a laboratory for which a certificate has been issued under this section, except that if the revocation occurs pursuant to paragraph (4) the Secretary may substitute intermediate sanctions under subsection (h) instead of the 2-year prohibition against ownership or operation which would otherwise apply under this paragraph. The certificate of a laboratory which has been excluded from participation under the medicare program under title XVIII of the Social Security Act because of actions relating to the quality of the laboratory shall be suspended for the period the laboratory is so excluded.

(4) IMPROPER REFERRALS.—Any laboratory that the Secretary determines intentionally refers its proficiency testing samples to another laboratory for analysis ~~shall~~ may have its certificate revoked for at least one year and shall be subject to appropriate fines and penalties as provided for in subsection (h).

Note that this document is provided as a convenience and includes excerpts from the full CLIA '88 Law to demonstrate the changes. This document does not represent the full context or intent of the law. To view CLIA '88 in its entirety, please search for the current version of 42 USC 263a on the U.S. Government Printing Office (GPO) website.

Also, the December 4, 2012 TEST Act revisions may not be reflected in 42 USC 263a on the GPO's site prior to the edition of the United States Code pending publication in October 2013.

Link to the U.S. Government Printing Office search: <http://www.gpo.gov/fdsys/search/advanced/advsearchpage.action>

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