

Assembly Bill No. 512

CHAPTER 219

An act to amend Sections 1310 and 1320 of the Business and Professions Code, relating to clinical laboratories.

[Approved by Governor September 6, 2005. Filed with Secretary of State September 6, 2005.]

LEGISLATIVE COUNSEL'S DIGEST

AB 512, Richman. Clinical laboratories.

Under existing law, the State Department of Health Services licenses and regulates clinical laboratories and clinical laboratory personnel. A violation of these provisions is a misdemeanor. Under existing law, the department may deny, suspend, or revoke a license or registration for specified reasons.

This bill would also authorize the department to deny, suspend, or revoke a license or registration for failure to comply with specified disease reporting requirements.

Existing law authorizes the department to impose specified penalties in lieu of, or in addition to, revocation or suspension of a license or registration.

This bill would also authorize the department to impose civil monetary penalties for failure to comply with specified disease reporting requirements.

Because a violation of the bill would be a crime, it would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

The people of the State of California do enact as follows:

SECTION 1. Section 1310 of the Business and Professions Code is amended to read:

1310. If the department determines that a laboratory that has been issued a license or registration under this chapter, except for a laboratory only performing tests or examinations classified as waived under CLIA, no longer substantially meets the requirements of this chapter or the regulations adopted thereunder, the department, in lieu of, or in addition to, revocation or suspension of the license or registration under Section 1320 or 1323, may impose any of the following:

- (a) Directed plans of correction, as defined under CLIA.
- (b) Civil money penalties in an amount ranging from fifty dollars (\$50) to three thousand dollars (\$3,000) per day of noncompliance, or per violation, for a condition-level deficiency that does not pose immediate jeopardy, to an amount ranging from three thousand fifty dollars (\$3,050) to ten thousand dollars (\$10,000) per day of noncompliance, or per violation, for a condition-level deficiency that poses immediate jeopardy, but only after notice and an opportunity to respond in accordance with Section 100171 of the Health and Safety Code, and consideration of facts enumerated in CLIA in Section 493.1834 of Title 42 of the Code of Federal Regulations.
- (c) Civil money penalties in an amount ranging from fifty dollars (\$50) to three thousand dollars (\$3,000) per day of noncompliance, or per violation, for a violation of subdivision (t) of Section 1320, for failure to comply with disease reporting requirements, but only after notice and an opportunity to respond in accordance with Section 100171 of the Health and Safety Code.
- (d) Onsite monitoring, as defined under CLIA, and payment for the costs of onsite monitoring.
- (e) Any combination of the actions described in subdivisions (a), (b), (c), and (d).

SEC. 2. Section 1320 of the Business and Professions Code is amended to read:

1320. The department may deny, suspend, or revoke any license or registration issued under this chapter for any of the following reasons:

- (a) Conduct involving moral turpitude or dishonest reporting of tests.
- (b) Violation by the applicant, licensee, or registrant of this chapter or any rule or regulation adopted pursuant thereto.
- (c) Aiding, abetting, or permitting the violation of this chapter, the rules or regulations adopted under this chapter or the Medical Practice Act, Chapter 5 (commencing with Section 2000) of Division 2.
- (d) Permitting a licensed trainee to perform tests or procure specimens unless under the direct and responsible supervision of a person duly licensed under this chapter or physician and surgeon other than another licensed trainee.
- (e) Violation of any provision of this code governing the practice of medicine and surgery.
- (f) Proof that an applicant, licensee, or registrant has made false statements in any material regard on the application for a license, registration, or renewal issued under this chapter.
- (g) Conduct inimical to the public health, morals, welfare, or safety of the people of the State of California in the maintenance or operation of the premises or services for which a license or registration is issued under this chapter.
- (h) Proof that the applicant or licensee has used any degree, or certificate, as a means of qualifying for licensure that has been purchased or procured by barter or by any unlawful means or obtained from any

institution that at the time the degree, certificate, or title was obtained was not recognized or accredited by the department of education of the state where the institution is or was located to give training in the field of study in which the degree, certificate, or title is claimed.

(i) Violation of any of the prenatal laws or regulations pertaining thereto in Chapter 2 (commencing with Section 120675) of Part 3 of Division 105 of the Health and Safety Code and Article 1 (commencing with Section 1125) of Group 4 of Subchapter 1 of Chapter 2 of Part 1 of Title 17 of the California Code of Regulations.

(j) Knowingly accepting an assignment for clinical laboratory tests or specimens from and the rendering of a report thereon to persons not authorized by law to submit those specimens or assignments.

(k) Rendering a report on clinical laboratory work actually performed in another clinical laboratory without designating clearly the name and address of the laboratory in which the test was performed.

(l) Conviction of a felony or of any misdemeanor involving moral turpitude under the laws of any state or of the United States arising out of or in connection with the practice of clinical laboratory technology. The record of conviction or a certified copy thereof shall be conclusive evidence of that conviction.

(m) Unprofessional conduct.

(n) The use of drugs or alcoholic beverages to the extent or in a manner as to be dangerous to a person licensed under this chapter, or any other person to the extent that that use impairs the ability of the licensee to conduct with safety to the public the practice of clinical laboratory technology.

(o) Misrepresentation in obtaining a license or registration.

(p) Performance of, or representation of the laboratory as entitled to perform, a clinical laboratory test or examination or other procedure that is not within the specialties or subspecialties, or category of laboratory procedures authorized by the license or registration.

(q) Refusal of a reasonable request of HCFA, a HCFA agent, the department, or any employee, agent, or contractor of the department, for permission to inspect, pursuant to this chapter, the laboratory and its operations and pertinent records during the hours the laboratory is in operation.

(r) Failure to comply with reasonable requests of the department for any information, work, or materials that the department concludes is necessary to determine the laboratory's continued eligibility for its license or registration, or its continued compliance with this chapter or the regulations adopted under this chapter.

(s) Failure to comply with a sanction imposed under Section 1310.

(t) Failure to comply with the disease reporting requirements adopted pursuant to Section 120130 of the Health and Safety Code. However, when a laboratory is not able to obtain complete information for a patient within the reporting timeframes, it shall document that it made a good faith effort to do so and it shall submit the report with the available information

within the required reporting timeframes and, in that case, the laboratory shall not be subject to sanctions for failure to submit complete patient information.

SEC. 3. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.