AMENDED IN ASSEMBLY APRIL 11, 2007

CALIFORNIA LEGISLATURE—2007–08 REGULAR SESSION

ASSEMBLY BILL No. 1442

Introduced by Assembly Member Feuer

February 23, 2007

An act to ~~amend Sections 1220 and 1244 of~~ *add Section 1220.2 to* the Business and Professions Code, relating to clinical laboratories.

LEGISLATIVE COUNSEL'S DIGEST

AB 1442, as amended, Feuer. Clinical laboratories.

Existing law provides for the licensure and regulation of clinical laboratories and various clinical laboratory personnel by the State Department of Public Health. Existing law authorizes the department to adopt or repeal any regulations necessary for the administration or enforcement of these provisions.

This bill would require the department to repeal certain regulations requiring approval of a laboratory for use of the human immunodeficiency virus (HIV) antibody test. The bill would require a clinical laboratory performing tests or examinations to screen for HIV antibodies to use only a United States Food and Drug Administration approved kit, to enroll in a proficiency testing program approved by the Centers for Medicare and Medicaid Services, to possess the appropriate license or registration, as specified, and to confirm all screened positive, inconclusive, or indeterminate results with a different, more specific confirmatory test prior to reporting the result.

Because the bill would revise requirements pertaining to clinical laboratories, a violation of which would be a crime, the bill 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.

~~Existing law provides for the licensure and regulation of clinical laboratories and various clinical laboratory health care professionals by the State Department of Public Health. Existing law requires a clinical laboratory to participate in a proficiency testing program approved by the department or by the Health Care Financing Administration (HCFA) for each specialty and subspecialty in which it performs clinical laboratory tests or examinations, as specified. Existing law also requires the department to conduct inspections of licensed clinical laboratories no less than once every 2 years, exempts registered clinical laboratories from the routine inspection requirements, and subjects a licensed or registered clinical laboratory to inspections by the HCFA or HCFA agents. Existing law provides that the regulations regarding clinical laboratories do not restrict, limit, or prevent a program of nondiagnostic general health assessment that meets certain requirements, including not testing for HIV or certain other reportable diseases or conditions, and testing is performed onsite and reported directly to the person requesting the test.~~

~~This bill would instead require the proficiency testing programs for specialties and subspecialties to be approved by the department or the Centers for Medicare and Medicaid Services (CMS). The bill would change the routine testing requirement to require random inspections of all clinical laboratories at least biennially and would subject licensed or registered clinical laboratories to inspections by the CMS or CMS agents. The bill would revise the requirements for a nondiagnostic general health assessment program to delete the requirement that the program not test for HIV or other reportable diseases and conditions, and to exclude from the onsite testing and direct reporting requirements confirmatory testing required pursuant to the manufacturer's directions. The bill would also repeal certain regulations requiring approval of a laboratory for use of the Human Immunodeficiency Virus Antibody Test.~~

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: ~~no~~ *yes*.

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

SECTION 1. Section 1220.2 is added to the Business and Professions Code, to read:

1220.2. All clinical laboratories that perform tests or examinations to screen for human immunodeficiency virus (HIV) antibodies shall do all of the following:

(a) Utilize only United States Food and Drug Administration approved kits used in accordance with the manufacturers' instructions.

(b) Enroll in a proficiency testing program approved by the Centers for Medicare and Medicaid Services.

(c) Possess the license or registration appropriate for the type and complexity of tests or examinations performed.

(d) Confirm all screened positive, inconclusive, or indeterminate results with a different, more specific confirmatory test prior to reporting the result.

SEC. 2. The department shall repeal Section 1230 of Title 17 of the California Code of Regulations.

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.

~~SECTION 1. Section 1220 of the Business and Professions Code is amended to read:~~

~~1220. (a) (1) Each clinical laboratory shall maintain records, equipment, and facilities that are adequate and appropriate for the services rendered.~~

~~(2) (A) Except for tests or examinations classified as waived under CLIA, each clinical laboratory shall enroll, and demonstrate successful participation, as defined under CLIA, for each specialty and subspecialty in which it performs clinical laboratory tests or examinations, in a proficiency testing program approved by the department or by the Centers for Medicare and Medicaid Services (CMS), to the same extent as required by CLIA in Subpart H~~

~~(commencing with Section 493.801) of Title 42 of the Code of Federal Regulations. This requirement shall not be interpreted to prohibit a clinical laboratory from performing clinical laboratory tests or examinations in a specialty or subspecialty for which there is no department or CMS approved proficiency testing program.~~

~~(B) Each clinical laboratory shall authorize its proficiency test results to be reported to the department in an electronic format that is compatible with the department's proficiency testing data monitoring system and shall authorize the release of proficiency tests results to the public to the same extent required by CLIA.~~

~~(b) Each clinical laboratory shall be conducted, maintained, and operated without injury to the public health.~~

~~(c) (1) The department shall conduct random inspections of clinical laboratories no less than once every two years. The department shall maintain a record of those inspections and shall ensure that every clinical laboratory in California is inspected at least that often.~~

~~(2) The department shall conduct an investigation of complaints received concerning any clinical laboratory, which may include an inspection of the laboratory.~~

~~(3) Each licensed or registered clinical laboratory shall be subject to inspections by CMS or CMS agents, as defined by CLIA, as a condition of licensure or registration.~~

~~(d) (1) Each clinical laboratory shall perform all clinical laboratory tests or examinations classified as waived under CLIA in conformity with the manufacturer's instructions.~~

~~(2) Except for those clinical laboratories performing only tests or examinations classified as waived under CLIA, each clinical laboratory shall establish and maintain all of the following:~~

~~(A) A patient test management system that meets the standards of CLIA in Subpart J (commencing with Section 493.1101) of Title 42 of the Code of Federal Regulations.~~

~~(B) A quality control program that meets the requirements of CLIA in Subpart K (commencing with Section 493.1201) of Title 42 of the Code of Federal Regulations.~~

~~(e) All of the provisions of Group 9 (commencing with Section 1230) of Subchapter 1 of Chapter 2 of Division 1 of Title 17 of the California Code of Regulations shall be repealed.~~

~~SEC. 2. Section 1244 of the Business and Professions Code is amended to read:~~

~~1244. (a) Nothing in this chapter shall restrict, limit, or prevent a program of nondiagnostic general health assessment provided that:~~

~~(1) The program meets the requirements of Section 1265 and complies with the requirements of CLIA for waived testing.~~

~~(2) The purpose of the program is to screen asymptomatic individuals for chronic health disorders and to refer individuals to licensed sources of care as indicated.~~

~~(3) The program utilizes only those devices that comply with all of the following:~~

~~(A) Meet all applicable state and federal performance standards pursuant to Section 111245 of the Health and Safety Code.~~

~~(B) Are not adulterated as specified in Article 2 (commencing with Section 111250) of Chapter 6 of Part 5 of Division 104 of the Health and Safety Code.~~

~~(C) Are not misbranded as specified in Article 3 (commencing with Section 111330) of Chapter 6 of Part 5 of Division 104 of the Health and Safety Code.~~

~~(D) Are not new devices unless they meet the requirements of Section 111550 of the Health and Safety Code.~~

~~(E) Are approved as waived tests and are used according to the manufacturer's instructions.~~

~~(4) Blood collection is performed by skin puncture only.~~

~~(5) Testing of a urine specimen is performed by the dipstick method only.~~

~~(6) Testing is performed onsite and reported directly to the person requesting the test, unless confirmatory testing is required pursuant to the manufacturer's instructions.~~

~~(7) The program maintains a supervisory committee consisting of, at a minimum, a licensed physician and surgeon and a clinical laboratory scientist licensed pursuant to this code.~~

~~(8) The supervisory committee for the program adopts written protocols that shall be followed in the program and that shall contain all of the following:~~

~~(A) Provision of written information to individuals to be assessed that shall include, but not be limited to, the following:~~

~~(i) The potential risks and benefits of assessment procedures to be performed in the program.~~

~~(ii) The limitations, including the nondiagnostic nature, of assessment examinations of biological specimens performed in the program.~~

~~(iii) Information regarding the risk factors or markers targeted by the program.~~

~~(iv) The need for followup with licensed sources of care for confirmation, diagnosis, and treatment as appropriate.~~

~~(B) Proper use of each device utilized in the program including the operation of analyzers, maintenance of equipment and supplies, and performance of quality control procedures including the determination of both accuracy and reproducibility of measurements in accordance with instructions provided by the manufacturer of the assessment device used.~~

~~(C) Proper procedures to be employed when collecting blood, if blood specimens are to be obtained.~~

~~(D) Proper procedures to be employed in handling and disposing of all biological specimens to be obtained and material contaminated by those biological specimens. These procedures shall comply with all county and city ordinances for medical waste management and blood-borne pathogen control that apply to the location where the program operates.~~

~~(E) Proper procedures to be employed in response to fainting, excessive bleeding, or other medical emergencies.~~

~~(F) Documentation that the testing personnel are following the instructions of the instrument's manufacturer, are trained in the performance of the test, and are competent to perform the testing without supervision.~~

~~(G) Reporting of assessment results to the individual being assessed.~~

~~(H) Referral and followup to licensed sources of care as indicated.~~

~~The written protocols adopted by the supervisory committee shall be maintained for at least one year following completion of the assessment program during which period they shall be subject to review by department personnel and the local health officer or his or her designee, including the public health laboratory director.~~

~~(b) If skin puncture to obtain a blood specimen is to be performed in a program of nondiagnostic general health assessment, the individual performing the skin puncture shall be authorized to perform skin puncture under this chapter.~~

~~(c) A program of nondiagnostic general health assessment that fails to meet the requirements set forth in subdivisions (a) and (b) shall not operate.~~

~~(d) For purposes of this section, "skin puncture" means the collection of a blood specimen by the finger prick method only and does not include venipuncture, arterial puncture, or any other procedure for obtaining a blood specimen.~~

~~(e) Nothing in this chapter shall be interpreted as prohibiting a licensed clinical laboratory from operating a program of nondiagnostic general health assessment provided that the clinical laboratory complies with the requirements of this section.~~

~~(f) A program for a health fair providing diagnostic or screening tests is not a nondiagnostic general health assessment program if all of the requirements of this chapter are met, and the laboratory performing the testing is licensed or registered under subdivision (a) of Section 1265. For a test that is not authorized for self-ordering pursuant to Section 1246.5 and that is not for a nondiagnostic general health assessment pursuant to this section, the licensed or registered clinical laboratory participating in the health fair shall assure that the test is ordered onsite only by a person licensed under this division who is authorized under his or her scope of practice to order the test or by a person authorized by that licensee. The results of a test performed at a health fair shall be provided to the test subject along with an explanation of the results.~~

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