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AB-613 Healing arts: clinical laboratories. (2017-2018)

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Assembly Bill No. 613

CHAPTER 799

An act to add and repeal Section 1246.7 of the Business and Professions Code, relating to clinical laboratories.

[Approved by Governor September 27, 2018. Filed with Secretary of State September 27, 2018.]

LEGISLATIVE COUNSEL'S DIGEST

AB 613, Nazarian. Healing arts: clinical laboratories.

Existing law provides for the licensure, registration, and regulation of clinical laboratories and various clinical laboratory personnel by the State Department of Public Health, with specified exceptions. A violation of those provisions is a crime. Existing law authorizes a person who is licensed under those provisions to perform certain laboratory tests.

This bill, until January 1, 2021, would authorize a person with specified qualifications to perform a total protein test using a digital refractometer in a licensed plasma collection center in this state if specified circumstances are met, as determined by the department, including that the person meets certain education and training requirements. The bill would require the digital refractometer used to perform a total protein test pursuant to these provisions to meet specific criteria, including that it be used within 30 feet of the donor for whom the test is being conducted. The bill would require a participating licensed plasma collection center to make specified information available to the department. The bill would exempt the information obtained pursuant to these provisions from the California Public Records Act. Because a violation of those provisions would be a crime, the bill would impose a state-mandated local program.

Existing constitutional provisions require that a statute that limits the right of access to the meetings of public bodies or the writings of public officials and agencies be adopted with findings demonstrating the interest protected by the limitation and the need for protecting that interest.

This bill would make legislative findings to that effect.

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.

Vote: majority Appropriation: no Fiscal Committee: yes Local Program: yes

THE PEOPLE OF THE STATE OF CALIFORNIA DO ENACT AS FOLLOWS:

SECTION 1. It is the intent of the Legislature to enact legislation to specify the qualifications of, and the limited circumstances in which, properly trained and supervised personnel may perform a total protein test using a digital refractometer in a licensed plasma collection center in this state.

SEC. 2. Section 1246.7 is added to the Business and Professions Code, to read:

1246.7. (a) Notwithstanding any other law, a person may perform a total protein test using a digital refractometer in a licensed plasma collection center in this state, if the department, as part of its routine, fee-supported inspection of the licensed plasma collection center, including its review of personnel reports for licensed and unlicensed personnel and job descriptions of all center positions for a licensed plasma collection center, determines that all of the following conditions are met:

(1) (A) He or she has earned a high school diploma or equivalent, as determined by the federal Centers for Medicare and Medicaid Services (CMS) pursuant to the federal Clinical Laboratory Improvement Amendments of 1988 (CLIA) (42 U.S.C. Sec. 263a).

(B) He or she has training sufficient to demonstrate that the individual has the skills and abilities described in paragraph (2) of subdivision (a) of Section 1269.

(2) (A) In addition to the education and training requirements specified in paragraph (1), he or she has received five hours of training in the proper procedures to be employed when performing a total protein test using a digital refractometer and the procedures for recording the test results pursuant to paragraph (7).

(B) His or her training in the proper procedure to be employed when performing a total protein test using a digital refractometer has been certified by a moderate complexity laboratory technical consultant as specified in Section 1036.2 of Title 17 of the California Code of Regulations, by a physician and surgeon licensed in this state, or by a licensed clinical laboratory director who is in charge of the licensed plasma collection center.

(C) The instructor documents, and the plasma collection center maintains the documentation of, the individual's successful completion of training in the performance of the total protein test using a digital refractometer. This documentation shall be made available to the department upon request.

(3) He or she performs the total protein test using a digital refractometer under the supervision of one of the following individuals who is physically onsite in the licensed plasma collection center and is available for consultation and direction while the person is processing specimens and performing the test:

(A) A moderate complexity laboratory technical consultant as specified in Section 1036.2 of Title 17 of the California Code of Regulations.

(B) A registered nurse licensed pursuant to Chapter 6 of Division 2.

(C) A physician or surgeon licensed pursuant to Chapter 5 of Division 2.

(D) A clinical laboratory director licensed pursuant to this chapter.

(4) He or she performs the total protein test using a digital refractometer in accordance with both of the following:

(A) Standardized operating procedures required by the licensed plasma collection center's license.

(B) Standardized procedures developed and approved by the licensed plasma collection center's supervising physician and surgeon or licensed clinical laboratory director for administration of the total protein test by the persons authorized to perform the total protein test pursuant to this section. These standardized procedures shall be made available to the department upon request.

(5) He or she does not draw the blood sample required for the test using a procedure that requires a registration, certification, or license under state law unless he or she is properly registered, certified, or licensed to perform the procedure.

(6) His or her competency in performing total protein tests using a digital refractometer is evaluated before testing on donors, and every six months thereafter, by the CLIA lab director or technical consultant by direct observation. A licensed plasma collection center shall maintain documentation of the competency evaluation, which shall be made available to the department upon request.

(7) He or she accurately records the results of the total protein test in a federal FDA 510k-approved blood establishment computer system (BECS), which shall be verified in one of the following ways:

(A) Using a digital refractometer that creates an electronic record of the test results.

(B) Having each record entered by the individual verified for accuracy at the time the test result is recorded and while the result remains visible on the digital refractometer by a registered nurse or by the individual described in paragraph (4) who

is supervising the individual performing the test. The individual certifying the accuracy shall affix his or her name to the record verifying the accuracy of the entries.

(C) Affixing a date- and time-stamped photograph of the digital refractometer test results to the spreadsheet.

(D) The plasma collection center utilizing a double blind computer entry system that requires the test results to be accurately entered into the record twice before the results are recorded as final.

(b) The digital refractometer used to perform a total protein test pursuant to this section shall meet all of the following criteria:

(1) Is used within 30 feet of the donor for whom the test is being conducted.

(2) Is used in accordance with the donor test management system, the quality control program, and the comprehensive quality assurance program established and maintained by the laboratory pursuant to paragraph (2) of subdivision (d) of Section 1220, if applicable to the licensed plasma collection center under federal law.

(3) Performs total protein tests classified as waived or of moderate complexity under the federal Clinical Laboratory Improvement Amendments of 1988 (CLIA) (42 U.S.C. Sec. 263a).

(4) Performs total protein tests using a digital refractometer on biological specimens that require manual blood collection, centrifugation to separate the blood cells from the plasma, pipetting the plasma from the cells, and application of the plasma into the refractometer.

(5) Provides total protein test results without calculation or discretionary intervention by the testing personnel.

(6) Performs total protein tests without the necessity for testing personnel to perform calibration or maintenance, except basic cleaning, resetting, and daily standardization pursuant to the manufacturer's instructions.

(c) To assess the competency and performance of persons authorized to perform the total protein test pursuant to this section, a licensed plasma collection center utilizing this section shall make available to the department any information required by statute or regulation to be collected or maintained by the licensed plasma collection center, and the results of any testing required by statute or regulation to be performed by the licensed plasma collection center, related to assessing the competency and performance of persons using a digital refractometer, as determined by the department. Information obtained pursuant to this subdivision shall be confidential and is not a public record. The department may contract for collection and review of the information required by this subdivision. The contract shall be exempt from Part 2 (commencing with Section 10100) of Division 2 of the Public Contract Code and shall be exempt from review or approval by any division of the Department of General Services.

(d) Records of digital refractometer test results collected pursuant to paragraph (7) of subdivision (a) shall be maintained for three years and made available to the department upon request.

(e) This section shall remain in effect only until January 1, 2021, and as of that date is repealed, unless a later enacted statute that is enacted before January 1, 2021, deletes or extends that date.

SEC. 3. The Legislature finds and declares that Section 2 of this act, which adds Section 1246.7 to the Business and Professions Code, imposes a limitation on the public's right of access to the meetings of public bodies or the writings of public officials and agencies within the meaning of Section 3 of Article I of the California Constitution. Pursuant to that constitutional provision, the Legislature makes the following findings to demonstrate the interest protected by this limitation and the need for protecting that interest:

In order to protect against an unwarranted invasion of personal privacy as a result of the disclosure of personnel, medical, or similar files, it is necessary that this act limit the public's right of access to that information.

SEC. 4. 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.