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AB-392 Clinical laboratories: total protein test: authorization. (2021-2022)

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Assembly Bill No. 392

CHAPTER 429

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

[Approved by Governor September 19, 2022. Filed with Secretary of State September 19, 2022.]

LEGISLATIVE COUNSEL'S DIGEST

AB 392, Nazarian. Clinical laboratories: total protein test: authorization.

Existing law generally requires the State Department of Public Health to license and regulate clinical laboratories and various clinical laboratory personnel, and makes a violation of the provisions relating to clinical laboratories and personnel a crime. Existing law, until January 1, 2023, authorizes a person to perform a total protein test using a digital refractometer in a licensed plasma collection center if the department determines that specified conditions are met, including that the person performs the test in accordance with standardized procedures developed and approved by the center's supervising physician and surgeon or licensed clinical laboratory director and verifies the test results in a specified manner.

This bill would instead require the department to determine that the person performs the test in accordance with standardized procedures approved by the center's supervising physician and surgeon or licensed clinical laboratory director, and to additionally determine that job descriptions for individuals responsible for process supervision of the total protein test include specified responsibilities. The bill would require the center to perform control procedures as specified by the manufacturer and consistent with federal regulations. The bill would delete the requirement that results be verified in a specified manner as a condition of a person being authorized to conduct a total protein test. The bill would also indefinitely extend the above-described authorization to perform a total protein test. By expanding the crime applicable to this extended authority, 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.

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

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

SECTION 1. Section 1246.7 of the Business and Professions Code is amended 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) The person 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) The person 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), the person has received five hours of training in the proper procedures to be employed when performing a total protein test using a digital refractometer, including evaluation of specimen acceptability and criteria for rejection of inadequate specimens, and the procedures for recording the test results pursuant to paragraph (9).

(B) Their 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) The person performs the total protein test using a digital refractometer under the supervision of one of the following individuals:

(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.

(E) A clinical laboratory scientist licensed pursuant to this chapter.

(4) The supervisor is physically onsite in the licensed plasma collection center and available for consultation during the entire time that the person is processing specimens and performing the test.

(5) The licensed plasma collection center's supervising physician and surgeon or licensed clinical laboratory director provides a written job description for each employee who performs a total protein test using a digital refractometer that specifies the responsibilities and supervision requirements as specified in this section.

(6) The person 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 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.

(7) The person does not draw the blood sample required for the test using a procedure that requires a registration, certification, or license under state law unless they are properly registered, certified, or licensed to perform the procedure.

(8) The person's 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.

(9) The person accurately records the results of the predonation total protein test in a federal FDA 510k-approved blood establishment computer system (BECS).

(10) For each protein refractometer test system in use at the licensed plasma collection center, the center shall perform control procedures using the number and frequency specified by the manufacturer that meet the requirements of Section 493.1256 of Title 42 of the Code of Federal Regulations and this chapter.

(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 CLIA.

(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 (9) of subdivision (a) shall be maintained for three years and made available to the department upon request.

SEC. 2. 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.