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AB-481 Healing arts: clinical laboratories: personnel. (2025-2026)

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AMENDED IN ASSEMBLY APRIL 02, 2025

CALIFORNIA LEGISLATURE— 2025–2026 REGULAR SESSION

ASSEMBLY BILL

NO. 481

Introduced by Assembly Member Blanca Rubio

February 10, 2025

An act to amend Section 1269 of, and to add Section 1206.8 to, the Business and Professions Code, relating to healing arts.

LEGISLATIVE COUNSEL'S DIGEST

AB 481, as amended, Blanca Rubio. Healing arts: clinical laboratories: personnel.

Existing law prohibits, except as specified, a person from performing a clinical laboratory test or examination classified as of moderate or high complexity under the federal Clinical Laboratory Improvement Amendments of 1988 (CLIA) unless the test or examination is performed under the overall operation and administration of the laboratory director, as specified. A violation of these provisions is a crime.

Existing law authorizes unlicensed laboratory personnel who have earned a high school diploma or its equivalent and who meet specified training requirements to perform specified activities under the supervision and control of a physician and surgeon or licensed person.

This bill would authorize a person to assist, as defined, in the performance of moderate or high complexity testing in a clinical laboratory if the ~~person~~ *person, in addition to the above requirements*, meets the requirements under CLIA for moderate or high complexity testing. *Prior to assisting in the performance of the specified activities, the bill would require the person, under direct and constant supervision, to demonstrate the skills and ability to satisfactorily perform the task. The bill would require the laboratory director to designate the supervisor and to maintain overall responsibility for the supervision and performance of the unlicensed laboratory personnel.*

By expanding the application of an existing crime, this bill would create a state-mandated local program.

~~Existing law authorizes unlicensed laboratory personnel who have earned a high school diploma or its equivalent and who meet specified training requirements to perform specified activities under the supervision and control of a physician and surgeon or licensed person.~~

This bill would define supervision and control, as used above, to mean direction, management, and awareness of the activity of unlicensed laboratory personnel by a physician and surgeon or licensed person, who must be physically present in the laboratory and readily available for consultation during the entire time that the unlicensed laboratory personnel are engaged in the duties.

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 1206.8 is added to the Business and Professions Code, to read:

~~1206.8.(a)Notwithstanding subdivision (b) of Section 1206.5, a person may assist in the performance of moderate complexity testing in a clinical laboratory if they meet the requirements under the federal Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. Sec. 263a) for moderate complexity testing.~~

~~(b)Notwithstanding subdivision (c) of Section 1206.5, a person may assist in the performance of high complexity testing in a clinical laboratory if they meet the requirements under the federal Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. Sec. 263a) for high complexity testing.~~

~~(c)"Assist" or "Assistance"~~

1206.8. For purposes of Section 1269, "assist" or "assisting" means activities performed by trained and competent personnel who follow specific instruction from a licensed physician and surgeon or personnel licensed under this chapter, other than a trainee, under direct and constant supervision, and includes the following activities prior to, during, and after the laboratory testing process:

~~(1)~~

(a) Load and unload barcoded specimens and barcoded quality control material onto automated instruments.

~~(2)~~

(b) Load and replenish premeasured reagents and supplies onto automated instruments.

~~(3)~~

(c) Load and unload samples and their ~~byproducts, such as extraction products,~~ *byproducts into or* onto shakers, incubators, refrigerators, freezers, thermal cyclers, and other automated equipment or instruments.

~~(4)~~

(d) Unload and store reagents from an automated instrument.

~~(5)~~

(e) Move assay from one piece of equipment to the next.

~~(6)~~

(f) Clean and disinfect laboratory equipment.

~~(7)~~

(g) Replacement of consumable laboratory equipment, supplies, and reagents.

~~(8)Activities permissible under paragraph (2) of subdivision (b) of Section 1269.~~

~~(9)Quantitatively measure sample;~~

(h) Transfer samples, quality control material, or reagents by the use of previously calibrated and approved automatic syringes, fixed volume pipettes, or other dispensers.

~~(10) Assist with sample dilutions.~~

SEC. 2. Section 1269 of the Business and Professions Code is amended to read:

1269. (a) Unlicensed laboratory personnel may perform any of the activities identified in subdivision ~~(b)~~, *(f)*, in a licensed clinical laboratory, under the direct and constant supervision of a physician and surgeon, or a person licensed under this chapter other than a trainee, upon meeting all of the following criteria:

- (1) Have earned a high school diploma, or its equivalent, as determined by HCFA under CLIA.
- (2) Have documentation of training appropriate to ensure that the individual has all of the following skills and abilities:
 - (A) The skills required for proper specimen collection, including patient preparation, labeling, handling, preservation or fixation, processing or preparation, and transportation and storage of specimens.
 - (B) The skills required for assisting a licensed physician and surgeon or personnel licensed under this chapter, other than trainees, in a licensed clinical laboratory.
 - (C) The skills required for performing preventive maintenance, and troubleshooting.
 - (D) A working knowledge of reagent stability and storage.
 - (E) The skills required for assisting in the performance of quality control procedures, and an understanding of the quality control policies of the laboratory.
 - (F) ~~An awareness~~ *A working knowledge* of the factors that influence test results.

(b) Training for unlicensed personnel includes, but is not limited to, reading and understanding of the procedures, receiving verbal instruction on how the task is performed by licensed personnel, and directly observing the task performed by licensed personnel.

(c) Prior to performing any of the activities identified in subdivision (f), unlicensed personnel shall, under direct and constant supervision, demonstrate the skills and ability to satisfactorily perform the task.

(d) In addition to the requirements of this section, an unlicensed person assisting in the performance of moderate complexity testing in a clinical laboratory shall meet the requirements under CLIA for moderate complexity testing.

(e) In addition to the requirements of this section, an unlicensed person assisting in the performance of high complexity testing in a clinical laboratory shall meet the requirements under CLIA for high complexity testing.

~~(b)~~

(f) The activities that may be performed are:

- (1) Biological specimen collection, including patient preparation, labeling, handling, preservation or fixation, processing or preparation, and transportation and storage of specimens.
- (2) Assisting a licensed physician and surgeon or personnel licensed under this chapter, other than trainees, in a licensed clinical laboratory.
- (3) Assisting in preventive maintenance, and troubleshooting.
- (4) Preparation and storage of reagents and culture media.
- (5) Assisting in the performance of quality control procedures.

~~(e)~~

(g) Notwithstanding subdivision (a), unlicensed laboratory personnel, other than a trainee, may, under the supervision and control of a physician and surgeon or person licensed under this chapter, perform specimen labeling, handling, preservation or fixation, processing or preparation, transportation, and storing if they meet the requirements of subparagraph (A) of paragraph (2) of, and paragraph (1) of, subdivision (a).

~~(d)~~

(h) Unlicensed laboratory personnel shall not do any of the following:

- (1) Record test results, but they may transcribe results that have been previously recorded, either manually by a physician and surgeon or personnel licensed under this chapter, or automatically by a testing instrument.
- (2) Perform any test or part thereof that involves the quantitative measurement of the specimen or test reagent, or any mathematical calculation relative to determining the results or the validity of a test procedure.
- (3) Perform any phase of clinical laboratory tests or examinations in the specialty of immunohematology beyond initial collection and centrifugation.

~~(e)~~

(f) When any of the following manual methods are employed, the activities of unlicensed laboratory personnel shall be limited as follows:

- (1) In the case of qualitative and semi-quantitative "spot, tablet, or stick" tests, the personnel may add the test reagent to the specimen or vice versa, but the results must be read by a physician and surgeon or person licensed under this chapter.
- (2) In the case of microbiological tests the unlicensed laboratory personnel may make primary inoculations of test material onto appropriate culture media, stain slide preparations for microscopic examination, and subculture from liquid media.

~~(f)~~

(g) When any of the following mechanical or electronic instruments are employed, unlicensed laboratory personnel shall not perform any of the following activities:

- (1) Standardizing or calibrating the instrument or assessing its performance by monitoring results of appropriate standards and control.
- (2) Reading or recording test results, except that the personnel may transcribe results that have been previously recorded automatically by a testing instrument.
- (3) Quantitatively measuring any sample or reagents unless done automatically by the instrument in the course of its normal operation or by the use of previously calibrated and approved automatic syringes or other dispensers.

~~(g)~~

(k) For purposes of this section, "supervision and control" means direction, management, and awareness of the activity of unlicensed laboratory personnel by a physician and surgeon or by a person licensed under this chapter other than a trainee, who must be physically present in the laboratory and readily available for consultation during the entire time that the unlicensed laboratory personnel are engaged in the duties.

(l) The laboratory director shall designate the supervisor and shall maintain overall responsibility for the supervision and performance of the unlicensed laboratory personnel.

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.