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AB-1120 Clinical laboratories: blood withdrawal. (2021-2022)

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Date Published: 09/29/2022 09:00 PM

Assembly Bill No. 1120

CHAPTER 685

An act to amend Section 1246 of the Business and Professions Code, relating to clinical laboratories.

[Approved by Governor September 28, 2022. Filed with Secretary of State September 28, 2022.]

LEGISLATIVE COUNSEL'S DIGEST

AB 1120, Irwin. Clinical laboratories: blood withdrawal.

Existing law provides for the licensure and regulation of clinical laboratories and clinical laboratory personnel and health professionals by the State Department of Public Health and makes a violation of these provisions a crime. Existing law authorizes an unlicensed person employed by a licensed clinical laboratory to perform venipuncture or skin puncture for the purpose of withdrawing blood or for clinical laboratory test purposes upon specific authorization from a licensed physician and surgeon, if that unlicensed person meets certain requirements. Existing law requires an unlicensed person performing these duties to possess a valid and current certification as a certified phlebotomy technician issued by the department.

This bill would authorize a certified phlebotomy technician to collect blood through a peripheral venous catheter under specified conditions, including that the blood collection procedure is performed under the general supervision of a physician and surgeon and the blood collection procedure is performed using a device or devices approved by the United States Food and Drug Administration.

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

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

SECTION 1. Section 1246 of the Business and Professions Code is amended to read:

1246. (a) (1) On and after the effective date of the regulations specified in paragraph (2), any unlicensed person employed by a clinical laboratory performing the duties described in this section shall possess a valid and current certification as a certified phlebotomy technician issued by the department.

(2) The department shall adopt regulations for certification by January 1, 2001, as a certified phlebotomy technician that shall include all of the following:

(A) The applicant shall hold a valid, current certification as a phlebotomist issued by a national accreditation agency approved by the department, and shall submit proof of that certification when applying for certification pursuant to this section.

(B) An applicant with fewer than 1,040 hours of work experience shall complete education, training, and experience requirements as specified by regulations that shall include, but not be limited to, the following:

- (i) At least 40 hours of didactic instruction.
- (ii) At least 40 hours of practical instruction.
- (iii) At least 50 successful venipunctures.

(C) An applicant who has at least 1,040 hours of work experience that includes at least 50 successful venipunctures shall complete at least 20 hours of didactic instruction, as specified in regulations adopted by the department.

(D) Each certified phlebotomy technician shall complete at least three hours per year or six hours every two years of continuing education or training. The department shall consider a variety of programs in determining the programs that meet the continuing education or training requirement.

(E) The applicant has been found to be competent in phlebotomy by a licensed physician and surgeon or person licensed pursuant to this chapter.

(F) The applicant works under the supervision of a licensed physician and surgeon, licensed registered nurse, or person licensed under this chapter, or the designee of a licensed physician and surgeon or the designee of a person licensed under this chapter.

(3) A certified phlebotomy technician may collect blood through a peripheral venous catheter if all of the following are met:

(A) The blood collection procedure is performed in a facility licensed under Division 2 (commencing with Section 1200) of the Health and Safety Code.

(B) The blood collection procedures or protocols are developed and approved by the facility's supervising physician and surgeon or licensed clinical laboratory director and approved by the licensed facility.

(C) The certified phlebotomy technician has received a minimum of three hours of training by the supervising physician and surgeon or their delegate in the proper procedures to be employed when collecting blood through a peripheral venous catheter.

(i) Training in the blood collection procedure through a peripheral venous catheter shall be conducted according to standardized training procedures developed and approved by the facility's supervising physician and surgeon or licensed clinical laboratory director. The facility shall make these standardized procedures available to the department upon request.

(ii) The instructor shall document the certified phlebotomy technician's successful completion of training. The facility shall maintain and make available to the department, upon request, documentation of training completed by a certified phlebotomy technician pursuant to this paragraph.

(D) The certified phlebotomy technician performs the blood collection procedure under the supervision of a physician and surgeon licensed under Chapter 5 (commencing with Section 2000). Notwithstanding subdivision (b), the physician and surgeon may only delegate the supervision duties in this subparagraph to a registered nurse. A physician and surgeon or a registered nurse may restrict or limit a certified phlebotomy technician's ability to collect blood from a patient's peripheral venous catheter.

(E) The certified phlebotomy technician performs the blood collection procedure using a device or devices approved by the licensed facility and the United States Food and Drug Administration.

(F) This paragraph does not authorize the certified phlebotomy technician to manage, stop, or restart a patient's active intravenous infusion or insert or remove a peripheral intravenous catheter.

(4) Paragraph (3) does not authorize a certified phlebotomy technician to withdraw blood through a peripherally inserted central catheter or central venous catheter.

(5) The department shall adopt regulations establishing standards for approving training programs designed to prepare applicants for certification pursuant to this section. The standards shall ensure that these programs meet the state's minimum education and training requirements for comparable programs.

(6) The department shall adopt regulations establishing standards for approving national accreditation agencies to administer certification examinations and tests pursuant to this section.

(7) The department shall charge fees for application for and renewal of the certificate authorized by this section of no more than one hundred dollars (\$100) for a two-year period.

(b) (1) (A) A certified phlebotomy technician may perform venipuncture or skin puncture to obtain a specimen for nondiagnostic tests assessing the health of an individual, for insurance purposes, provided that the technician works under the general supervision of a physician and surgeon licensed under Chapter 5 (commencing with Section 2000). The physician and surgeon may delegate the general supervision duties to a registered nurse or a person licensed under this chapter, but shall remain responsible for ensuring that all those duties and responsibilities are properly performed. The physician and surgeon shall make available to the department, upon request, records maintained documenting when a certified phlebotomy technician has performed venipuncture or skin puncture pursuant to this paragraph.

(B) As used in this paragraph, general supervision requires the supervisor of the technician to determine that the technician is competent to perform venipuncture or skin puncture, or to collect blood, before the technician's first blood withdrawal, and on an annual basis thereafter. The supervisor is also required to determine, on a monthly basis, that the technician complies with appropriate venipuncture, skin puncture, and blood collection policies and procedures approved by the medical director and required by state regulations. The supervisor, or another designated licensed physician and surgeon, registered nurse, or person licensed under this chapter, shall be available for consultation with the technician, either in person or through telephonic or electronic means, at the time of blood withdrawal.

(2) (A) Notwithstanding any other law, a person who has been issued a certified phlebotomy technician certificate pursuant to this section may draw blood following policies and procedures approved by a physician and surgeon licensed under Chapter 5 (commencing with Section 2000), appropriate to the location where the blood is being drawn and in accordance with state regulations. The blood collection shall be done at the request and in the presence of a peace officer for forensic purposes in a jail, law enforcement facility, or medical facility, with general supervision.

(B) As used in this paragraph, "general supervision" means that the supervisor of the technician is licensed under this code as a physician and surgeon, physician assistant, clinical laboratory bioanalyst, registered nurse, or clinical laboratory scientist, and reviews the competency of the technician before the technician may perform blood withdrawals without direct supervision, and on an annual basis thereafter. The supervisor is also required to review the work of the technician at least once a month to ensure compliance with venipuncture policies, procedures, and regulations. The supervisor, or another person licensed under this code as a physician and surgeon, physician assistant, clinical laboratory bioanalyst, registered nurse, or clinical laboratory scientist, shall be accessible to the location where the technician is working to provide onsite, telephone, or electronic consultation, within 30 minutes when needed.

(c) The department may adopt regulations providing for the issuance of a certificate to an unlicensed person employed by a clinical laboratory authorizing only the performance of skin punctures for test purposes.