CALIFORNIA BUSINESS AND PROFESSIONS CODE 1244

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 does not test for human immunodeficiency virus or any reportable disease or condition identified in Section 120130 of the Health and Safety Code or the regulations adopted under that section.
(4) 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.
(5) Blood collection is performed by skin puncture only.
(6) Testing of a urine specimen is performed by the dipstick method only.
(7) Testing is performed on site and reported directly to the person requesting the test.
(8) 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.
(9) 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 on-site 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.

1244.1. Thirty days prior to operating a program of nondiagnostic general health assessment, the entity or person operating that

program shall file the following documentation with the local health officer in each county in which the program shall operate:

(a) The location of the program, the type and kind of nondiagnostic general health assessments being conducted, the dates and times of operation of programs, and evidence that the program shall be operated in compliance with Section 1244.

(b) The local health officer shall be notified in writing of any changes to occur in locations, dates, or times indicated in the documentation required in subdivision (a). The local health officer shall be notified of any changes at least 24 hours prior to the program operating at the different locations, dates, or times.

1244.3. Responsibility for enforcement of Sections 1244 and 1244.1 shall be with the local health officer or his or her authorized designee, including public health laboratory directors. Nothing in this section shall prevent the department from using any necessary enforcement actions for the protection of the public health and safety.

1244.4. Any fee for the filing of documentation and related enforcement activities pursuant to Section 1244, 1244.1, and 1244.3 shall be determined by the local enforcement agency and shall not exceed one hundred dollars ($100) except that those fees shall be adjusted annually by any annual increase in the California Consumer Price Index as determined pursuant to Section 2212 of the Revenue and Taxation Code. All moneys collected as fees pursuant to this section shall be deposited in the appropriate city, county, or city and county treasury and shall only be expended in carrying out Sections 1244, 1244.1, and 1244.3.

1245. (a) Any individual may perform a blood gas analysis if all the following conditions exist:

(1) He or she has earned a high school diploma or equivalent, as determined by HCFA pursuant to CLIA.

(2) He or she performs the blood gas analysis in a clinic or a general acute care hospital, as defined respectively in Sections 1202 and 1250 of the Health and Safety Code.

(3) He or she has been instructed by a physician and surgeon licensed in this state, who is in charge of a department of pulmonary physiology or clinical pathology in licensed clinics or hospitals, as defined respectively in Sections 1202 and 1250 of the Health and Safety Code, in the proper procedure to be employed when performing a blood gas analysis.

(4) He or she performs the blood gas analysis under the direction and supervision of the physician and surgeon.

(5) He or she submits the analysis for interpretation to the physician and surgeon under whose direction and supervision he or she performed the analysis.

(b) After September 1, 1997, any person may perform a blood gas analysis classified as of high complexity under CLIA, if, in addition to the requirements of subdivision (a), he or she has earned an associate degree related to pulmonary function from an accredited institution as determined by HCFA pursuant to CLIA.

(c) Nothing contained in this section shall be construed as authorizing any individual, not otherwise authorized, to withdraw blood.

(d) Nothing contained in this section is applicable to a person

licensed as a respiratory care practitioner under Chapter 8.3 (commencing with Section 3700). Those persons are authorized to perform those functions set forth in that chapter.

1246. (a) Except as provided in subdivisions (b) and (c), and in Section 23158 of the Vehicle Code, an unlicensed person employed by a licensed clinical laboratory may 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 provided that he or she meets both of the following requirements:

(1) He or she works under the supervision of a person licensed under this chapter or of a licensed physician and surgeon or of a licensed registered nurse. A person licensed under this chapter, a licensed physician or surgeon, or a registered nurse shall be physically available to be summoned to the scene of the venipuncture within five minutes during the performance of those procedures.

(2) He or she has been trained by a licensed physician and surgeon or by a clinical laboratory bioanalyst in the proper procedure to be employed when withdrawing blood in accordance with training requirements established by the State Department of Public Health and has a statement signed by the instructing physician and surgeon or by the instructing clinical laboratory bioanalyst that the training has been successfully completed.

(b) (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. However, an unlicensed person employed by a clinical laboratory to perform these duties pursuant to subdivision (a) on that date shall have until January 1, 2007, to comply with this requirement, provided that he or she has submitted the application to the department on or before July 1, 2006.

(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) The applicant 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.

However, an applicant who has been performing these duties pursuant to subdivision (a) may be exempted from the requirements specified in clauses (ii) and (iii), and from 20 hours of the 40 hours of didactic instruction as specified in clause (i), if he or she has at least 1,040 hours of work experience, as specified in regulations adopted by the department.

It is the intent of the Legislature to permit persons performing these duties pursuant to subdivision (a) to use educational leave provided by their employers for purposes of meeting the requirements of this section.

(3) 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.

(4) He or she has been found to be competent in phlebotomy by a licensed physician and surgeon or person licensed pursuant to this chapter.

(5) He or she 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.

(6) 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.

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

(8) The department shall charge fees for application for and renewal of the certificate authorized by this section of no more than twenty-five dollars ($25).

(c) (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 prior to 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 or skin puncture 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 provision of 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.

(d) 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.

1246.5. Notwithstanding any other provision of law, any person may request, and any licensed clinical laboratory or public health laboratory may perform, the laboratory tests specified in this section. A registered clinical laboratory may perform the laboratory tests specified in this section if the test is subject to a certificate of waiver under CLIA and the laboratory has registered with the department under paragraph (2) of subdivision (a) of Section 1265. A program for nondiagnostic general health assessment that includes a laboratory test specified in this section shall comply with the provisions of Section 1244. The results from any test may be provided directly to the person requesting the test if the test is on or for his or her own body. These test results shall be provided in a manner that presents clear information and that identifies results indicating the need for referral to a physician and surgeon.

The tests that may be conducted pursuant to this section are: pregnancy, glucose level, cholesterol, occult blood, and any other test for which there is a test for a particular analyte approved by the federal Food and Drug Administration for sale to the public without a prescription in the form of an over-the-counter test kit. A test approved only as an over-the-counter collection device may not be conducted pursuant to this section.