

Nondiagnostic General Health Assessment

Section 4: Section 1244 is added to the Business and Professions code to read:

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.

(2) The purpose of the program is to refer individuals to licensed sources of care as indicated.

(3) 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.

(4) The program maintains a supervisory committee consisting of, at a minimum, a licensed physician and surgeon and a laboratory technologist licensed pursuant to this chapter.

(5) 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 drawing 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.

(E) Proper procedures to be employed in response to fainting, excessive bleeding, or other medical emergencies.

(F) Reporting of assessment results to the individual being assessed.

(G) 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 either:

(1) Authorized to perform skin puncture under this chapter.

(2) Any person who possesses a statement signed by a licensed physician and surgeon that attests that the named person has received adequate training in the proper procedure to be employed in skin puncture.

(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.

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.