

Introduced by Senator Negrete McLeod

February 24, 2012

An act to amend Sections 1241 and 4052.4 of the Business and Professions Code, relating to clinical laboratories.

LEGISLATIVE COUNSEL'S DIGEST

SB 1481, as introduced, Negrete McLeod. Clinical laboratories: community pharmacies.

Existing law provides for the licensure and regulation of clinical laboratories and various clinical laboratory personnel by the State Department of Public Health, subject to certain exceptions. Existing law, the Pharmacy Law, provides for the licensure and regulation of pharmacists by the California State Board of Pharmacy and authorizes a pharmacist to perform skin puncture in the course of performing clinical laboratory tests classified as waived pursuant to the federal Clinical Laboratory Improvement Amendments of 1988 (CLIA).

This bill would exempt a community pharmacy that solely provides certain tests classified as waived under CLIA from the clinical laboratory regulations, provided that the tests are performed by a pharmacist, as specified, and the pharmacy obtains a certificate of waiver and complies with all other requirements under CLIA.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

The people of the State of California do enact as follows:

- 1 SECTION 1. Section 1241 of the Business and Professions
- 2 Code is amended to read:

1 1241. (a) This chapter applies to all clinical laboratories in
2 California or receiving biological specimens originating in
3 California for the purpose of performing a clinical laboratory test
4 or examination, and to all persons performing clinical laboratory
5 tests or examinations or engaging in clinical laboratory practice
6 in California or on biological specimens originating in California,
7 except as provided in subdivision (b).

8 (b) This chapter shall not apply to any of the following clinical
9 laboratories, or to persons performing clinical laboratory tests or
10 examinations in any of the following clinical laboratories:

11 (1) Those owned and operated by the United States of America,
12 or any department, agency, or official thereof acting in his or her
13 official capacity to the extent that the Secretary of the federal
14 Department of Health and Human Services has modified the
15 application of CLIA requirements to those laboratories.

16 (2) Public health laboratories, as defined in Section 1206.

17 (3) Those that perform clinical laboratory tests or examinations
18 for forensic purposes only.

19 (4) Those that perform clinical laboratory tests or examinations
20 for research and teaching purposes only and do not report or use
21 patient-specific results for the diagnosis, prevention, or treatment
22 of any disease or impairment of, or for the assessment of the health
23 of, an individual.

24 (5) Those that perform clinical laboratory tests or examinations
25 certified by the National Institutes on Drug Abuse only for those
26 certified tests or examinations. However, all other clinical
27 laboratory tests or examinations conducted by the laboratory are
28 subject to this chapter.

29 (6) Those that register with the State Department of Health
30 Services pursuant to subdivision (c) to perform blood glucose
31 testing for the purposes of monitoring a minor child diagnosed
32 with diabetes if the person performing the test has been entrusted
33 with the care and control of the child by the child’s parent or legal
34 guardian and provided that all of the following occur:

35 (A) The blood glucose monitoring test is performed with a blood
36 glucose monitoring instrument that has been approved by the
37 federal Food and Drug Administration for sale over the counter to
38 the public without a prescription.

39 (B) The person has been provided written instructions by the
40 child’s health care provider or an agent of the child’s health care

1 provider in accordance with the manufacturer’s instructions on the
2 proper use of the monitoring instrument and the handling of any
3 lancets, test strips, cotton balls, or other items used during the
4 process of conducting a blood glucose test.

5 (C) The person, receiving written authorization from the minor’s
6 parent or legal guardian, complies with written instructions from
7 the child’s health care provider, or an agent of the child’s health
8 care provider, regarding the performance of the test and the
9 operation of the blood glucose monitoring instrument, including
10 how to determine if the results are within the normal or therapeutic
11 range for the child, and any restriction on activities or diet that
12 may be necessary.

13 (D) The person complies with specific written instructions from
14 the child’s health care provider or an agent of the child’s health
15 care provider regarding the identification of symptoms of
16 hypoglycemia or hyperglycemia, and actions to be taken when
17 results are not within the normal or therapeutic range for the child.
18 The instructions shall also contain the telephone number of the
19 child’s health care provider and the telephone number of the child’s
20 parent or legal guardian.

21 (E) The person records the results of the blood glucose tests and
22 provides them to the child’s parent or legal guardian on a daily
23 basis.

24 (F) The person complies with universal precautions when
25 performing the testing and posts a list of the universal precautions
26 in a prominent place within the proximity where the test is
27 conducted.

28 (7) Those individuals who perform clinical laboratory tests or
29 examinations, approved by the federal Food and Drug
30 Administration for sale to the public without a prescription in the
31 form of an over-the-counter test kit, on their own bodies or on their
32 minor children or legal wards.

33 (8) Those certified emergency medical technicians and licensed
34 paramedics providing basic life support services or advanced life
35 support services as defined in Section 1797.52 of the Health and
36 Safety Code who perform only blood glucose tests that are
37 classified as waived clinical laboratory tests under CLIA, if the
38 provider of those services obtains a valid certificate of waiver and
39 complies with all other requirements for the performance of waived
40 clinical laboratory tests under applicable federal regulations.

1 (9) A community pharmacy that is providing only those tests
2 identified in Section 1246.5, provided that both of the following
3 requirements are satisfied:

4 (A) The pharmacy obtains a valid certificate of waiver and
5 complies with all other requirements for the performance of waived
6 clinical laboratory tests under applicable federal regulations.

7 (B) The tests are performed by a pharmacist, as defined in
8 Section 4036, in the course of performing routine patient
9 assessment procedures in compliance with Section 4052.4.

10 (c) Any place where blood glucose testing is performed pursuant
11 to paragraph (6) of subdivision (b) shall register by notifying the
12 State Department of Health Services in writing no later than 30
13 days after testing has commenced. Registrants pursuant to this
14 subdivision shall not be required to pay any registration or renewal
15 fees nor shall they be subject to routine inspection by the State
16 Department of Health Services.

17 SEC. 2. Section 4052.4 of the Business and Professions Code
18 is amended to read:

19 4052.4. Notwithstanding Section 2038 or any other provision
20 of law, a pharmacist may perform skin puncture in the course of
21 performing routine patient assessment procedures or in the course
22 of performing any procedure authorized under Section 1206.5 or
23 paragraph (9) of subdivision (b) of Section 1241. For purposes of
24 this section, “routine patient assessment procedures” means: (a)
25 procedures that a patient could, with or without a prescription,
26 perform for himself or herself, or (b) clinical laboratory tests that
27 are classified as waived pursuant to the federal Clinical Laboratory
28 Improvement Amendments of 1988 (42 U.S.C. Sec. 263a) and the
29 regulations adopted thereunder by the federal Health Care
30 Financing Administration, as authorized by paragraph (11) of
31 subdivision (a) of Section 1206.5 or paragraph (9) of subdivision
32 (b) of Section 1241. A pharmacist performing these functions shall
33 report the results obtained from a test to the patient and any
34 physician designated by the patient. Any pharmacist who performs
35 the service authorized by this section shall not be in violation of
36 Section 2052.

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