

AMENDED IN SENATE MARCH 28, 2016

SENATE BILL

No. 1418

Introduced by Senator ~~Galgiani~~ Lara

February 19, 2016

An act to ~~amend~~ *repeal and add* Section 1246.5 of the Business and Professions Code, relating to clinical laboratories.

LEGISLATIVE COUNSEL'S DIGEST

SB 1418, as amended, ~~Galgiani~~ *Lara*. Clinical laboratory testing.

Existing law provides for the regulation and licensure of clinical laboratories and clinical laboratory personnel by the State Department of Public Health and makes a violation of a provision under this law a misdemeanor. Existing law authorizes a person to request, and a licensed clinical laboratory or public health laboratory to ~~perform~~, *perform specified clinical laboratory tests, including pregnancy, glucose level, cholesterol, and occult blood, and other specified blood tests*. Existing law authorizes a registered clinical laboratory to perform these tests, ~~as specified~~. *tests if the test is subject to a certificate of waiver under the Clinical Laboratory Improvement Amendments of 1988 and the laboratory has registered with the State Department of Public Health.*

Existing law authorizes the results of the test to be provided directly to the person requesting the test if the test is on or for his or her own body. Existing law requires that those test results be provided in a manner that presents clear information and that identifies results indicating the need for referral to a physician.

This bill would ~~make technical, nonsubstantive changes to these provisions~~. *repeal those provisions and instead allow a person to request, and a licensed clinical laboratory or public health laboratory to perform, any laboratory test that the laboratory offers to the public*

on a direct access basis without a health care provider's request. If a laboratory test of a person is conducted by or under the supervision of a person other than a health care provider and not at the request or with the written authorization of a health care provider, the bill would require any report of the test results to be provided by the person conducting the test to the person who was the subject of the test. The bill would require the report to state in bold type that it is the responsibility of the person who was tested to arrange with the person's health care provider for consultation and interpretation of the test results. By changing the definition of an existing crime, this bill would impose a state-mandated local program.

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: ~~no~~-yes.
State-mandated local program: ~~no~~-yes.

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

1 SECTION 1. Section 1246.5 of the Business and Professions
2 Code is repealed.
3 ~~1246.5. Notwithstanding any other provision of law, any person~~
4 ~~may request, and any licensed clinical laboratory or public health~~
5 ~~laboratory may perform, the laboratory tests specified in this~~
6 ~~section. A registered clinical laboratory may perform the laboratory~~
7 ~~tests specified in this section if the test is subject to a certificate~~
8 ~~of waiver under CLIA and the laboratory has registered with the~~
9 ~~department under paragraph (2) of subdivision (a) of Section 1265.~~
10 ~~A program for nondiagnostic general health assessment that~~
11 ~~includes a laboratory test specified in this section shall comply~~
12 ~~with the provisions of Section 1244. The results from any test may~~
13 ~~be provided directly to the person requesting the test if the test is~~
14 ~~on or for his or her own body. These test results shall be provided~~
15 ~~in a manner that presents clear information and that identifies~~
16 ~~results indicating the need for referral to a physician and surgeon.~~
17 ~~The tests that may be conducted pursuant to this section are:~~
18 ~~pregnancy, glucose level, cholesterol, occult blood, and any other~~

1 ~~test for which there is a test for a particular analyte approved by~~
2 ~~the federal Food and Drug Administration for sale to the public~~
3 ~~without a prescription in the form of an over-the-counter test kit.~~
4 ~~A test approved only as an over-the-counter collection device may~~
5 ~~not be conducted pursuant to this section.~~

6 *SEC. 2. Section 1246.5 is added to the Business and Professions*
7 *Code, to read:*

8 *1246.5. (a) Notwithstanding any other law, a person may*
9 *request, and a licensed clinical laboratory or public health*
10 *laboratory may perform any laboratory test that the laboratory*
11 *offers to the public on a direct access basis without a health care*
12 *provider's request or written authorization.*

13 *(b) If a laboratory test of a person is conducted by or under the*
14 *supervision of a person other than a health care provider and not*
15 *at the request or with the written authorization of a health care*
16 *provider, any report of the test results shall be provided by the*
17 *person conducting the test to the person who was the subject of*
18 *the test. The report shall state in bold type that it is the*
19 *responsibility of the person who was tested to arrange with the*
20 *person's health care provider for consultation and interpretation*
21 *of the test results.*

22 *(c) A health care provider's duty of care to a patient does not*
23 *include any responsibility to review or act on the laboratory test*
24 *results of a patient if the health care provider did not request or*
25 *authorize the laboratory test. A health care provider is not subject*
26 *to liability or disciplinary actions for the failure to review or act*
27 *on the results of a laboratory test of any patient if the health care*
28 *provider did not request or authorize the laboratory test.*

29 *(d) This section does not require that a laboratory test be*
30 *covered by a health care service plan contract or health insurance*
31 *policy.*

32 *SEC. 3. No reimbursement is required by this act pursuant to*
33 *Section 6 of Article XIII B of the California Constitution because*
34 *the only costs that may be incurred by a local agency or school*
35 *district will be incurred because this act creates a new crime or*
36 *infraction, eliminates a crime or infraction, or changes the penalty*
37 *for a crime or infraction, within the meaning of Section 17556 of*
38 *the Government Code, or changes the definition of a crime within*
39 *the meaning of Section 6 of Article XIII B of the California*
40 *Constitution.*

1 SECTION 1. ~~Section 1246.5 of the Business and Professions~~
2 Code is amended to read:

3 1246.5. ~~(a) Notwithstanding any law, a person may request,~~
4 ~~and a licensed clinical laboratory or public health laboratory may~~
5 ~~perform, the laboratory tests specified in this section. A registered~~
6 ~~clinical laboratory may perform the laboratory tests specified in~~
7 ~~this section if the test is subject to a certificate of waiver under the~~
8 ~~federal Clinical Laboratory Improvement Amendments of 1988~~
9 ~~(42 U.S.C. 263a) (CLIA) and the laboratory has registered with~~
10 ~~the department under paragraph (2) of subdivision (a) of Section~~
11 ~~1265. A program for nondiagnostic general health assessment that~~
12 ~~includes a laboratory test specified in this section shall comply~~
13 ~~with the provisions of Section 1244. The results from any test may~~
14 ~~be provided directly to the person requesting the test if the test is~~
15 ~~on or for his or her own body. These test results shall be provided~~
16 ~~in a manner that presents clear information and that identifies~~
17 ~~results indicating the need for referral to a physician and surgeon.~~

18 ~~(b) (1) The tests that may be conducted pursuant to this section~~
19 ~~are all of the following:~~

20 ~~(A) Pregnancy.~~

21 ~~(B) Glucose level.~~

22 ~~(C) Cholesterol.~~

23 ~~(D) Occult blood.~~

24 ~~(E) Any other test for which there is a test for a particular analyte~~
25 ~~approved by the federal Food and Drug Administration for sale to~~
26 ~~the public without a prescription in the form of an over-the-counter~~
27 ~~test kit.~~

28 ~~(2) A test approved only as an over-the-counter collection device~~
29 ~~may not be conducted pursuant to this section.~~