

AMENDED IN SENATE APRIL 13, 2016
AMENDED IN SENATE MARCH 28, 2016

SENATE BILL

No. 1418

Introduced by Senator Lara

February 19, 2016

An act to *amend Section 1288 of, and to repeal and add Section 1246.5 of* of, the Business and Professions Code, relating to clinical laboratories.

LEGISLATIVE COUNSEL'S DIGEST

SB 1418, as amended, 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 specified clinical laboratory tests, including pregnancy, glucose level, cholesterol, and occult blood tests. Existing law authorizes a registered clinical laboratory to perform these 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 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. healing arts licensee's order.~~ 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,~~ *without an order from a healing arts licensee,* 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~~ *his or her* health care provider for consultation and interpretation of the test results. *The bill would make additional conforming changes.* 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: yes.
State-mandated local program: 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 SEC. 2. Section 1246.5 is added to the Business and Professions
- 4 Code, to read:
- 5 1246.5. (a) Notwithstanding any other law, a person may
- 6 request, and a licensed clinical laboratory or public health
- 7 laboratory may ~~perform~~ *perform*, any laboratory test that the
- 8 laboratory offers to the public ~~on a direct access basis without a~~
- 9 ~~health care provider's request or written authorization. without an~~
- 10 ~~order from a healing arts licensee or his or her representative.~~
- 11 (b) If a laboratory test of a person is conducted ~~by or under the~~
- 12 ~~supervision of a person other than a health care provider and not~~
- 13 ~~at the request or with the written authorization of a health care~~
- 14 ~~provider, any report of the test without an order from a healing~~
- 15 ~~arts licensee or his or her representative, the test results shall be~~
- 16 ~~provided by the person conducting the test to the person who was~~

1 the subject of the test. The *test results* report shall state in bold
2 type that it is the responsibility of the person who was tested to
3 arrange with the person's *his or her* health care provider for
4 consultation and interpretation of the test results.

5 (c) ~~A health care provider's duty of care to a patient does not~~
6 ~~include any responsibility~~ *healing arts licensee is not required to*
7 ~~review or act on the a laboratory test results of a patient result if~~
8 ~~the health care provider~~ *healing arts licensee or his or her*
9 ~~representative did not request or authorize order the laboratory~~
10 ~~test. A health care provider~~ *healing arts licensee is not subject to*
11 ~~liability or disciplinary actions for the failure to review or act on~~
12 ~~the results of a laboratory test of any patient person if the health~~
13 ~~care provider did not request or authorize~~ *healing arts licensee or*
14 *his or her representative did not order the laboratory test.*

15 (d) This section does not require that a *any* laboratory test be
16 covered by a health care service plan contract or health insurance
17 policy.

18 *SEC. 3. Section 1288 of the Business and Professions Code is*
19 *amended to read:*

20 1288. ~~Any person conducting or operating a clinical laboratory~~
21 ~~may accept assignments for tests only from and make reports only~~
22 ~~to persons licensed under the provisions of law relating to the~~
23 ~~healing arts or their representatives. This section does not prohibit~~
24 ~~the acceptance of evaluation specimens for proficiency testing or~~
25 ~~referral of specimens or such assignment from one clinical~~
26 ~~laboratory to another clinical laboratory, either licensed or exempt~~
27 ~~under this chapter, providing the report indicates clearly the~~
28 ~~laboratory performing the test. A report of results issuing from a~~
29 ~~clinical laboratory shall show clearly the name and address of the~~
30 ~~laboratory and the name of the director.~~

31 ~~SEC. 3.~~

32 *SEC. 4.* 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

- 1 the meaning of Section 6 of Article XIII B of the California
- 2 Constitution.

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