AMENDED IN ASSEMBLY MAY 19, 2003 AMENDED IN ASSEMBLY APRIL 1, 2003

CALIFORNIA LEGISLATURE—2003-04 REGULAR SESSION

ASSEMBLY BILL

No. 685

Introduced by Assembly Member Leno

February 19, 2003

An act to add Section 1246.3 to the Business and Professions Code An act to amend Section 120917 of the Health and Safety Code, relating to health care, and declaring the urgency thereof, to take effect immediately.

LEGISLATIVE COUNSEL'S DIGEST

AB 685, as amended, Leno. HIV counselors: HIV rapid tests education and training.

Under existing law it is unlawful for a person to perform venipuncture, skin puncture, or arterial puncture to collect a biological specimen, unless authorized to do so, and a violation of this prohibition is subject to criminal penalties. Existing

Existing law authorizes the State Department of Health Services, through its Office of Aids, to participate in a rapid immunodeficiency virus test research program conducted with the federal Centers for Disease Control and Prevention, involving innovative testing and counseling programs.

This bill would, notwithstanding any other law, authorize an unlicensed HIV counselor, as defined, to perform skin puncture for the purpose of performing a rapid human immunodeficiency virus test for the program.

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Existing law authorizes an HIV counselor who is trained by the Office of AIDS and working in an HIV counseling and testing site funded by the department through a local health jurisdiction to perform specified HIV tests and order and report these test results to patients without authorization from a licensed health care professional or his or her authorized representative.

This bill would exempt an HIV counselor acting in accordance with the above provisions from any requirement for a high school diploma or General Education Development (GED) equivalent if the person completes a literacy and comprehension protocol approved by the office. The bill would also exempt an HIV counselor from certain certification fees.

The bill would also declare that it is the intent of the Legislature that the office, in consultation with the Laboratory Science Division of the department, develop a comprehensive curriculum that integrates appropriate training for an HIV counselor and a limited phlebotomy technician.

The bill would declare that it is to take effect immediately as an urgency statute.

Vote: $^{2}/_{3}$. Appropriation: no. Fiscal committee: no. State-mandated local program: no.

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

- 1 SECTION 1. Section 1246.3 is added to the Business and 2 Professions Code, to read:
 - 1246.3. (a) Notwithstanding any other provision of law, an unlicensed HIV counselor may perform skin puncture for the purpose of performing a rapid human immunodeficiency virus test pursuant to Section 120917 of the Health and Safety Code.
 - (b) For purposes of this section, "HIV counselor" means a person who meets any one of the following requirements:
 - (1) He or she is trained by the Office of AIDS and is working in an HIV counseling and testing site funded by the department through a local health jurisdiction, or its agent.
- 12 (2) He or she is trained by programs that are funded by the 13 Centers for Disease Control and Prevention and use Office of 14 AIDS curriculum.
- 15 (3) He or she is trained by the Office of AIDS and works in another state agency.

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SEC. 2.

 SECTION 1. Section 120917 of the Health and Safety Code is amended to read:

- 120917. (a) The department, through its Office of AIDS and the authorized agents of the office, may participate in a rapid human immunodeficiency virus test research program conducted with the federal Centers for Disease Control and Prevention, involving innovative HIV testing and counseling programs. Under the rapid HIV test research program, as authorized by this section, the department may do the following:
- (1) Perform and report clinical test results using a rapid HIV test for diagnosis, prior to test approval by the federal Food and Drug Administration (FDA). However, test performance and reporting shall only be done to the extent allowed under that device's investigational approval by the FDA and pursuant to a California Health and Human Services Agency Institutional Review Board-approved research protocol.
- (2) Use a second independent HIV test to confirm initially reactive test results to the extent allowed under the investigational approval by the FDA. All rapid tests shall be confirmed using technology approved by the federal Food and Drug Administration. If the results from this confirmatory testing differ from the results of the rapid test, the subject shall be notified. No subject shall participate in the research protocol who does not provide appropriate contact information.
- (b) An HIV counselor who is trained by the Office of AIDS and working in an HIV counseling and testing site funded by the department through a local health jurisdiction, or its agents, may do all of the following:
- (1) Perform any HIV test that is classified as waived under the federal Clinical Laboratory Improvement Act (CLIA; 42 U.S.C. Sec. 263a and following) if all of the following conditions exist:
- (A) The performance of the HIV test meets the requirements of CLIA and Chapter 3 (commencing with Section 1200) of Division 2 of the Business and Professions Code.
- (B) The person performing the HIV test meets the requirements for the performance of waived laboratory testing pursuant to subdivision (a) of Section 1206.5 of the Business and Professions Code. For purposes of this subdivision and subdivision (a) of Section 1206.5 of the Business and Professions Code, an HIV

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counselor trained by the Office of AIDS shall be "other health care personnel providing direct patient care" as referred to in paragraph (12) of subdivision (a) of Section 1206.5 of the Business and Professions Code.

- (C) Prior to informing a patient of a test result indicative of HIV infection that was performed pursuant to this paragraph, a second independent HIV test is performed to confirm initially reactive test results. Nothing in this subdivision shall be construed to allow an HIV counselor trained by the Office of AIDS to perform any HIV test that is not classified as waived under the CLIA.
- (2) Notwithstanding Sections 1246.5 and 2053 of the Business and Professions Code, order and report HIV test results from tests performed pursuant to paragraph (1) to patients without authorization from a licensed health care professional or his or her authorized representative. Patients with indeterminate or positive test results from tests performed pursuant to paragraph (1) shall be referred to a licensed health care provider whose scope of practice includes the authority to refer patients for laboratory testing for further evaluation.
- (c) Notwithstanding any other provision of law, an HIV counselor acting in accordance with this section shall be exempt from any requirement for a high school diploma or General Education Development (GED) equivalent if the person completes a literacy and comprehension protocol approved by the Office of AIDS.
- (d) An HIV counselor shall not be subject to any certification fees pursuant to Section 1246 of the Business and Professions Code.
- SEC. 2. The Legislature finds and declares that it would be inefficient, costly, and an impediment to deployment of the HIV rapid test if an HIV counselor has to be trained by the Office of AIDS and an authorized training program for limited phlebotomy technicians. Therefore, it is the intent of the Legislature that the Office of AIDS, in consultation with the Laboratory Science Division of the State Department of Health Services, develop a comprehensive curriculum that integrates appropriate training for an HIV counselor and a limited phlebotomy technician.
- 38 SEC. 3. This act is an urgency statute necessary for the 39 immediate preservation of the public peace, health, or safety

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- within the meaning of Article IV of the Constitution and shall go into immediate effect. The facts constituting the necessity are:

 In order to authorize more personnel to participate in performing HIV tests as soon as possible, it is necessary that this

- 5 act take effect immediately.