

Assembly Bill No. 685

Passed the Assembly January 12, 2004

Chief Clerk of the Assembly

Passed the Senate August 27, 2003

Secretary of the Senate

This bill was received by the Governor this _____ day of
_____, 2004, at _____ o'clock __M.

Private Secretary of the Governor



CHAPTER _____

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, Leno. HIV counselors: education and training.

Existing law authorizes the State Department of Health Services, through its Office of AIDS, to 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.

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, in accordance with prescribed conditions, and to 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 provide that an HIV counselor acting in accordance with the above provisions who successfully completes the HIV counselor training shall be deemed to have demonstrated sufficient literacy and comprehension to advance to the limited phlebotomy technician (LPT) training and to substitute completion of the HIV counselor training for the requirement for a high school diploma or General Education Development (GED) equivalent for a limited phlebotomy technician, and would revise the conditions under which an HIV counselor may perform these HIV tests.

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 an LPT that meets the LPT training standards set forth in designated statutes and regulations.

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



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

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 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) The patient is informed that the preliminary result of the test is indicative of the likelihood of HIV infection and that the result must be confirmed by an additional more specific test, or, if approved by the federal Food and Drug Administration for that purpose, a second different rapid HIV test. 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 who successfully completes the HIV counselor training shall be deemed to have demonstrated sufficient literacy and comprehension to advance to the limited phlebotomy technician training and may substitute successful completion of the HIV counselor curriculum for the requirement for a high school diploma or General Education Development (GED) equivalent for a limited phlebotomy technician, as defined in Section 1029.116 of Title 17 of the California Code of Regulations pursuant to Section 1246 of the Business and Professions Code.

(d) An HIV counselor who meets the requirements of this section with respect to performing any HIV test that is classified as waived under the CLIA may not perform any other test unless that person meets the statutory and regulatory requirements for performing that other test.

SEC. 2. The Legislature finds and declares that the public health threat of the AIDS epidemic and the challenges of outreach



to certain target populations for testing and counseling justify steps to ensure rapid HIV testing is made available expeditiously and safely. The Legislature further finds and declares that it would be inefficient, costly, and an impediment to deployment of the rapid HIV test if an HIV counselor has to be trained, using partially redundant curricula, by the Office of AIDS in addition to an authorized training program for a limited phlebotomy technician, as defined in Section 1029.116 of Title 17 of the California Code of Regulations pursuant to Section 1246 of the Business and Professions Code. 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 for training HIV counselors that integrates appropriate training for an HIV counselor and a limited phlebotomy technician (LPT) and that meets the LPT education, training, and experience standards set forth in paragraph (1) of subdivision (a) of Section 1034 of Title 17 of the California Code of Regulations pursuant to Section 1246 of the Business and Professions Code, except as provided in subdivision (c) of Section 120917 of the Health and Safety Code.

SEC. 3. This act is an urgency statute necessary for the immediate preservation of the public peace, health, or safety 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 act take effect immediately.



Approved _____, 2004

Governor

