State of California—Health and Human Services Agency
California Department of Public Health

MARK B HORTON, MD, MSPH
*Director*

ARNOLD SCHWARZENEGGER
*Governor*

December 2, 2010

TO: OA FUNDED LOCAL HEALTH JURISDICTIONS AND NON-FUNDED LOCAL HEALTH JURISIDICTIONS AND COMMUNITY BASED ORGANIZATIONS

**SUBJECT: IMPORTANT CHANGES TO HIV COUNSELOR REQUIREMENTS**

On October 19, 2010, Governor Arnold Schwarzenegger signed into law Senate Bill (SB) 853, which amended Health and Safety (H&S) Code Section 120917. This amendment allows HIV testing sites to provide rapid HIV testing with HIV counselors trained by the California Department of Public Health, Office of AIDS (CDPH/OA) regardless of funding source. The passage of this bill eliminated the barrier to non-OA-funded local public health jurisdictions (LHJs) and community based organizations (CBOs) providing HIV rapid testing services using OA-trained HIV counselors. This change took effect immediately upon the Governor's signature.

CDPH/OA is providing this guidance to assist OA-funded and non-OA-funded LHJs and CBOs in understanding how this legislative change impacts their HIV testing programs. A summary table and the current legislation have been included as a reference.

**HIV Counselor and Quality Assurance Requirements**

Previously, H&S Code Section 120917 dictated that only an **HIV counselor trained by CDPH/OA and working in an HIV testing site *funded by CDPH/OA*** could perform any HIV test classified as waived under the federal Clinical Laboratory Improvement Act (CLIA) and report HIV results to the patient. With reductions in State prevention funding in fiscal year 2009-10, many LHJs and CBOs had to discontinue rapid HIV testing when they were no longer funded by CDPH/OA.

Now H&S Code Section 120917 addresses this barrier by allowing LHJs and CBOs not funded by OA to utilize HIV counseling staff trained by OA or its training agents to provide rapid HIV testing, as long as there is an local health department (LHD)-approved quality assurance plan in place. Consequently, HIV testing sites previously funded by OA have the option to restore rapid HIV testing. New HIV testing sites would need to follow the specific requirements as outlined below.

MS 7700, P.O. Box 997426, Sacramento, CA 95899-7426
MS 7700, 1616 Capitol Avenue, Suite 616, Sacramento, CA 95814
Telephone: (916) 449-5900 / Fax: (916) 449-5909
Internet Address: www.cdph.ca.gov/programs/AIDS

The amended legislation (H&S Code Section 120917) requires that an HIV counselor must meet **one** of the following criteria:

1. Is trained by OA and working in an HIV testing site funded by the department through a local health jurisdiction, or its agents.

**OR**

2. Is working in an HIV testing site that meets **both** of the following criteria:

   (i) Utilizes HIV counseling staff who are trained by OA or its agents.

   (ii) Has a quality assurance plan approved by the LHD in the jurisdiction where the site is located and has HIV counseling and testing staff who comply with the quality assurance requirements specified in California Code of Regulations (CCR), Title 17, Section 1230.

The quality assurance requirements under CCR, Section 1230 require that an HIV testing site:

1. Establish and maintain a quality assurance program that includes all of the following:

   (A) Evaluation and documentation of testing personnel by direct observation, training, and competency testing to ensure tests are accurately performed and reported. This shall be done prior to testing, six months later and then yearly as long as assessment of test performance is acceptable. If the testing personnel fail any assessment of test performance given in subpart (B), the testing personnel shall be removed from testing, retrained and their competency re-evaluated.

   (B) Assessment and documentation of test performance by testing previously analyzed specimens, internal blind testing samples, or external proficiency testing samples at least twice yearly and monitored by the laboratory director.

Note: SB 853 allows fees to be charged for OA-training of HIV counseling staff and LHD approval of quality assurance plans.

**Impact on Non-OA-funded LHJs and CBOs**

LHJs and CBOs wanting to establish or reestablish HIV testing services will need to follow all of the requirements listed under H&S Code Section 120917, as well as all state and federal requirements. Sites can submit updated OA-approved quality assurance plans to their LHD. LHDs would be responsible for approving the quality assurance plan and may charge a fee for this approval. H&S Code Section 120917 allows OA's training agents to charge a fee for training HIV counseling staff in non-funded OA agencies. OA's training agent is UCSF/AIDS Health Project (AHP); other training agents will be identified and communicated to you in the near future. For the present time, LHJs and CBOs can contact AHP directly for training needs.

**Impact on OA-funded LHJs and CBOs**

For LHJs funded for counseling and testing services by OA, these changes do not impact your current counseling staff or current contracts with CBOs. OA will continue to provide your counselor training and approve quality assurance plans for no fee. LHDs would be responsible for approving the quality assurance plan for CBOs within your jurisdiction not funded by OA and may charge a fee for this approval.

If you have any questions regarding these changes, please contact Ms. Dennese Neal at (916) 440-7744 or e-mail her at Dennese.Neal@cdph.ca.gov.

Sincerely,

Michelle Roland, MD, Chief
Office of AIDS

## Senate Bill 853 Changes Rapid HIV Testing Laws (Effective 10/19/2010)

| New HIV Counselor Testing Laws | What This Means |
|---|---|
| An HIV counselor shall meet one of the following requirements.<br>• Is trained by OA and working in an HIV testing site funded by OA through a local health jurisdiction, or its agents. H&S Code §1209217(e)(1)(A).<br>• Is working in an HIV testing site that meets both of the following criteria: H&S Code §1209217(e)(1)(B).<br>o Utilizes HIV counseling staff who are trained by OA or its agents.<br>o Has a quality assurance plan approved by the local health department in the jurisdiction where the site is located and has HIV testing staff who comply with the quality assurance requirements specified in California Code of Regulations, Title 17, Section 1230. | **HIV Testing Sites Currently Funded by OA:**<br>• No changes.<br>**HIV Testing Sites Previously Funded by OA:**<br>• Sites with OA-trained staff must now get quality assurance plans approved by the local health department.<br>• These sites can choose to submit past OA-approved quality assurance plans to the local health department for approval and may pay a fee for these services.<br>• New counseling staff must get training through an OA-contracted training provider and may pay a fee for these services.<br>• Ensure trained staff comply with CCR, Section 1230 requirements (evaluation and documentation of testing personnel).<br>Entities wishing to become an HIV testing site must meet state and federal requirements. |
| **New Quality Assurance and Training Fees** | **What This Means** |
| OA or its agents may charge a fee for training HIV counseling staff. H&S Code §1209217(e)(2)(A).<br>The local health department may charge a fee for the quality assurance plan approval.<br>H&S Code §1209217(e)(2)(B). | **HIV Testing Sites Currently Funded by OA:**<br>• No changes or new fees. OA will continue to provide HIV counselor training.<br>• Quality assurance plans will continue to be approved by OA<br>**HIV TESTING Sites Previously Funded by OA:**<br>• May have to pay a fee for HIV counselor training to an OA-contracted training provider.<br>• May have to pay a fee to a local health department for quality assurance plan approval. |

**CALIFORNIA CODES**
**HEALTH AND SAFETY CODE**
**SECTION 120917**

SEC. 14. Section 120917 of the Health and Safety Code is amended to read:

120917. (a) 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,~~ *meets the requirements of subdivision (e)* 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, subject to subparagraph (B), Chapter 3 (commencing with Section 1200) of Division 2 of the Business and Professions Code.

(B) Notwithstanding Section 1246 of the Business and Professions Code, an HIV counselor may perform skin punctures for the purpose of withdrawing blood for HIV testing, upon specific authorization from a licensed physician and surgeon, provided that the person meets both of the following requirements:

(i) He or she works under the direction of a licensed physician and surgeon.

(ii) He or she has been trained in both rapid HIV test proficiency for skin puncture blood tests and oral swab tests and in universal infection control precautions, consistent with best infection control practices established by the Division of Occupational Safety and Health in the Department of Industrial Relations and the federal Centers for Disease Control and Prevention.

(C) 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~~ *who meets the requirements of subdivision (e)* 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.

(D) 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 Centers for Disease Control and Prevention 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.

(b) An HIV counselor who has been certified pursuant to subdivision (b) of Section 120871 prior to September 1, 2009, and who will administer rapid HIV skin puncture tests shall obtain training

required by clause (ii) of subparagraph (B) of paragraph (1) of subdivision (a) prior to September 1, 2011. The HIV counselor shall not, unless also certified as a limited phlebotomist technician, perform a skin puncture pursuant to this section until he or she has completed the training required by that clause.

(c) 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.

(d) This section shall not be construed to certify an HIV counselor as a phlebotomy technician or a limited phlebotomy technician, or to fulfill any requirements for certification as a phlebotomy technician or a limited phlebotomy technician, unless the HIV counselor has otherwise satisfied the certification requirements imposed pursuant to Section 1246 of the Business and Professions Code.

*(e) (1) An HIV counselor shall meet one of the following criteria:*

*(A) 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.*

*(B) Is working in an HIV counseling and testing site that meets both of the following criteria:*

*(i) Utilizes HIV counseling staff who are trained by the Office of AIDS or its agents.*

*(ii) Has a quality assurance plan approved by the local health department in the jurisdiction where the site is located and has HIV counseling and testing staff who comply with the quality assurance requirements specified in Section 1230 of Article 1 of Group 9 of Subchapter 1 of Chapter 2 of Division 1 of Title 17 of the California Code of Regulations.*

*(2) (A) The Office of AIDS or its agents may charge a fee for training HIV counseling staff.*

*(B) The local health department may charge a fee for the quality assurance plan approval.*