

Informative Digest

Background/Authority

A central goal of the 2010 National HIV/AIDS Strategy is to protect and improve the public health of the nation by significantly reducing the number of new HIV infections and the rate of HIV transmission by 2015. The California Legislature has found and declared that scientific data from syringe exchange programs (SEPs) have shown that SEPs can curtail the spread of HIV infection among injection drug users, that they do not increase drug use in the population and that SEPs can serve as an important bridge to treatment and recovery from substance use disorders. To act upon these findings, the Legislature passed and Governor Edmund G. Brown, Jr., signed into law Assembly Bill (AB) 604 (Skinner, Chapter 744, Statutes of 2011). AB 604 permits the California Department of Public Health, Centers for Infectious Diseases, Office of AIDS (Department) to establish a process through which qualified entities may apply directly to the Department for authorization to provide syringe exchange services, a process which the Department will term SEP "certification." Prior to passage of AB 604, only local governments had the legal standing to authorize SEPs. In his signing message for AB 604, Governor Edmund G. Brown, Jr., directed the Department to develop regulations to clarify the application process and criteria.

The Department proposes to adopt Subchapter 15, Sections 7000 through 7016 to California Code of Regulations, Title 17, Division 1, Chapter 4 to implement AB 604. California Health and Safety (H&S) Code Section 131200 authorizes the Department to adopt and enforce regulations for the execution of its duties. Per H&S Code Section 131019, the Office of AIDS is the lead agency within the state responsible for coordinating HIV/AIDS-related programs. H&S Code Section 121349 gives the Department the authority to authorize SEPs.

Policy Statement Overview

Problem Statement: In California, access to nonprescription sterile syringes through SEPs is concentrated in Northern California and Los Angeles County. Many California local health jurisdictions that have a high burden of HIV/AIDS have few or no providers of sterile syringes without a prescription. AB 604 permits, until January 1, 2019, the Department to authorize qualified applicants to provide syringe exchange services in locations where the Department determines that the conditions exist for rapid spread of HIV, viral hepatitis, or other bloodborne diseases.

The objectives of this proposed regulatory action are to:

- Implement AB 604 and achieve the goals set by H&S Code Section 121349 to reduce the spread of HIV, viral hepatitis, and other bloodborne diseases.
- Specify the application procedures for Department SEP certification.
- Provide quality assurance standards for State-certified SEPs.
- Protect the confidentiality of clients who participate in syringe exchange services.
- Protect the health and safety of SEP staff, volunteers, and clients.

- Protect environmental health by keeping used needles and syringes, known as sharps waste, out of the environment.

Benefits: Anticipated benefits from this proposed regulatory action are:

- Protection of public health where conditions exist for the rapid spread of HIV, viral hepatitis, or other bloodborne pathogens.
- Protection of environmental health through support of proper disposal of sharps waste.
- Reduction in the disparity between areas of California where local government has moved to increase access to sterile syringes and those, such as the Central Valley, that have high rates of injection drug use and currently have little or no legal access to sterile syringes without a prescription.
- Saving California funds that would otherwise be allocated to medical and social service costs to care for those infected by HIV and viral hepatitis through the sharing of contaminated syringes.

Based on scientific evidence of cost-effectiveness, the Department projects that the total statewide benefit of allowing the Department to certify SEPs will be significant compared to the cost. Total discounted costs associated with the lifetime care of a person with HIV are estimated at \$385,200. Given that the average annual budget of California SEPs is less than \$230,000, averting even one HIV infection results in cost savings, but potential cost savings may be much larger. Similarly, a reduction in the number of injection drug use-related cases of viral hepatitis would substantially reduce the associated public costs of care and treatment for viral hepatitis.

Summary of Proposal

The purpose of these proposed regulations is to implement AB 604. The standards in these proposed regulations are limited to Department-certified SEPs. Local governments have the continued authority to authorize SEPs and set local standards as appropriate.

The Department proposes adoption of the following regulations:

Adopt **Section 7000, SEP Certification Definitions** to provide for uniform interpretation of the text of the regulations.

Adopt **Section 7002, Application Requirements for SEP Certification** to specify the application requirements and the steps involved in the SEP certification process.

Adopt **Section 7004, Standards for Refusal to Certify an SEP Application** to specify the standards by which applications will be evaluated and disapproved.

Adopt **Section 7006, Renewal of SEP Certification**, to identify how certification renewal shall be initiated, the party responsible for initiating the renewal process, and the timeframe during which the renewal must be requested.

Adopt **Section 7008, Reasons for Denial of SEP Certification Renewal or Revocation of Certification** to make explicit the reasons the Department may refuse to renew an SEP's certification or may revoke a certification.

Adopt **Section 7010, Process to Request Review Following Denial of Certification or Revocation** to specify the process by which applicants may request review of the Department's decision to deny or revoke certification.

Adopt **Section 7012, Operation Requirements for Certified SEPs** to specify the minimal operation requirements for certified SEPs in order to protect environmental health, worker safety, participant confidentiality and health, and ensure quality syringe exchange services.

Adopt **Section 7014, Compliance with State Laws, Regulations and Local Ordinances** to establish the requirement that Department-certified SEPs operate in compliance with the law.

Adopt **Section 7016, Reporting Requirements for Certified SEPs** to specify the information that must be reported by the SEPs to the Department, the frequency with which data must be reported, and the date by which the report must be returned in order to provide clear instructions to certified SEPs.

Authority and Reference

Authority: Sections 121349, 121349.1, 121349.2, 121349.3, 131000, 131005, 131019, 131050, 131051, 131052, and 131200, H&S Code.

Reference: Sections 4150, 4145, 4170, Business and Professions Code; and 11364, 118286, 121285, 121349, 121349.1, 121349.2, 121349.3, 131019, and 131071, H&S Code.

Comparable Federal Regulation or Statute

There are no comparable federal laws or regulations pertaining to the establishment or operation of SEPs.

FISCAL IMPACT ESTIMATE

- A. FISCAL IMPACT ON LOCAL GOVERNMENT:** None.
- B. FISCAL IMPACT ON STATE GOVERNMENT:** Administrative costs are estimated at \$69,000 from State General Fund monies in the current State fiscal year.

C. FISCAL IMPACTS ON FEDERAL FUNDING OF STATE PROGRAMS: None.

D. FISCAL IMPACT ON PRIVATE PERSONS OR BUSINESSES DIRECTLY AFFECTED: The Department estimates that approximately ten businesses will be impacted over the life of the legislation. These regulations are not a mandate and only provide the opportunity for small businesses and non-profit organizations to apply for Department certification to add syringe exchange services to their existing services. Entities that are certified by the Department to provide these services will assume all associated costs.

Associated costs include cost of operating an SEP, estimated at \$230,000 per year and initial costs to apply to the Department for certification, estimated at \$610.

It is estimated that there will be no costs for individuals.

E. MANDATE ON LOCAL AGENCIES OR SCHOOL DISTRICTS: None.