



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



RON CHAPMAN, MD, MPH
Director & State Health Officer

EDMUND G. BROWN JR.
Governor

ACTION: Notice of Proposed Rulemaking
Title 17, California Code of Regulations

SUBJECT: Syringe Exchange Program (SEP) Certification, DPH-11-021

PUBLIC PROCEEDINGS: Notice is hereby given that the California Department of Public Health will conduct written public proceedings during which time any interested person or such person's duly authorized representative may present statements, arguments or contentions (all of which are hereinafter referred to as comments) relevant to the action described in this notice.

HEARING: A public hearing regarding this proposal is scheduled for March 22, 2013 from 2:00 p.m. to 4:00 p.m., in Training Room C at 1500 Capitol Avenue, Sacramento, CA.

For individuals with disabilities, the Department can provide assistive services such as sign-language interpretation, real-time captioning, note takers, reading or writing assistance, and conversion of written public hearing materials into Braille, large print, audiocassette, or computer disk, if requested in advance. Note: the range of assistive services available may be limited if requests are received less than ten business days prior to a public hearing.

To request such services or copies of materials in an alternate format, please write to Laurel Prior, Office of Regulations, MS 0507, P.O. Box 997377, Sacramento, CA 95899-7377, or call (916) 440-7673, or use the California Relay Service by dialing 711.

WRITTEN COMMENT PERIOD: Written comments pertaining to these regulations, regardless of the method of transmittal, must be received by the Office of Regulations by 5 p.m. on March 18, 2013, which is hereby designated as the close of the written comment period. Comments received after this date will not be considered timely.

Written comments may be submitted as follows:

1. By email to: regulations@cdph.ca.gov. It is requested that email transmission of comments, particularly those with attachments, contain the regulation package identifier: "DPH-11-021" in the subject line to facilitate timely identification and review of the comment; or
2. By fax: (916) 440-5747; or

3. By mail to: Office of Regulations, California Department of Public Health, MS 0507, P.O. Box 997377, Sacramento, CA 95899-7377; or hand-delivered to: 1616 Capitol Avenue, Sacramento, CA 95814. It is requested but not required that written comments sent by mail or hand-delivered be submitted in triplicate.

All comments, including email or fax transmissions, should include the author's name and U.S. Postal Service mailing address in order for the Department to provide copies of any notices for proposed changes to the regulation text on which additional comments may be solicited.

AUTHORITY AND REFERENCE:

The Department is proposing to adopt the regulations sections identified under the authority provided in sections 121349, 131000, 131005, 131019, 131050, 131051, 131052, and 131200, of the Health and Safety Code. This proposal implements, interprets, or makes specific sections, 4150, 4145, 4170, Business and Professions Code; and 11364, 118286, 121285, 121349, 121349.1, 121349.2, 121349.3, 131019, and 131071, of the Health and Safety Code.

INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW:

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 AND EFFECT OF PROPOSED RULEMAKING

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.

The 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.

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 Sections 7000, 7002, 7004, 7006, 7008, 7010, 7012, 7014 and 7016.

EVALUATION AS TO WHETHER THE PROPOSED REGULATIONS ARE INCONSISTENT OR INCOMPATIBLE WITH EXISTING STATE REGULATIONS

The Department has determined that this proposal, if adopted, would not be inconsistent or incompatible with existing state regulations.

FORMS INCORPORATED BY REFERENCE: N/A

MANDATED BY FEDERAL LAW OR REGULATIONS: N/A

OTHER STATUTORY REQUIREMENTS: N/A

LOCAL MANDATE: The Department has determined that the regulations would not impose a mandate on local agencies or school districts, nor are there any costs for which reimbursement is required by Part 7 (commencing with Section 17500) of Division 4 of the Government Code.

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. **OTHER NON-DISCRETIONARY COST OR SAVINGS IMPOSED UPON LOCAL AGENCIES:** None.

HOUSING COSTS: The Department has determined that the regulations will have no impact on housing costs.

SIGNIFICANT STATEWIDE ADVERSE ECONOMIC IMPACT DIRECTLY AFFECTING BUSINESS, INCLUDING ABILITY TO COMPETE:

The Department has determined that the proposed regulatory action would have no significant adverse economic impact on California business enterprises and individuals, including the ability of California businesses to compete with businesses in other states. Thus, there will be no significant adverse economic impact on California businesses.

RESULTS OF ECONOMIC IMPACT ANALYSIS:

The Department has determined that the regulation would not significantly affect the following:

1. **The creation or elimination of jobs within the state of California.** The proposal may result in the creation of jobs but its extent cannot be estimated.
2. **The creation of new businesses or the elimination of existing businesses within the state of California.** The proposal is unlikely to result in the creation of new businesses, although it may result in the creation of new initiatives by existing businesses. The proposal should not result in the elimination of existing businesses.

3. **The expansion of businesses currently doing business within the state of California.** The proposal may result in the expansion of businesses currently doing business with the State of California but its extent cannot be estimated.
4. **The benefits of the regulation to the health and welfare of California residents, worker safety, and the state's environment.** This proposal increases the benefits to the health and welfare of California residents because it reduces the spread of bloodborne pathogens and the costs and suffering associated with HIV and viral hepatitis infection. This proposal further increases the benefits to the health and welfare of California residents and worker safety because it ensures that State-certified SEPs follow procedures to reduce the risk of needle-stick injury, to appropriately address needle-stick injury if it occurs, and reduce the risk of community-acquired needle-stick injury by educating SEP participants about proper syringe disposal. This proposal may also contribute to improvement of the state's environment by contributing to efforts to prevent used sharps waste from entering the waste stream, and from being discarded improperly in public environments.

COST IMPACTS ON REPRESENTATIVE PERSON OR BUSINESS:

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.

BUSINESS REPORT:

The regulation establishes a reporting requirement that applies to businesses that request SEP certification from the state. The Department has determined that it is necessary for the health, safety, or welfare of the people of the state that the regulations apply to businesses.

SMALL BUSINESS:

The Department has determined that there would be an effect on small businesses that choose to apply for SEP certification, because they will be legally required to comply with the regulation and may incur costs associated with compliance. These costs should not be unduly burdensome, given that similar costs would be incurred by small businesses that choose to be authorized by local governments, because most SEPs collect and report this same data, reporting either to their funders or to the local city or county government body, which authorized the program.

ALTERNATIVES STATEMENT:

In accordance with Government Code Section 11346.5(a)(13), the Department must determine that no reasonable alternative considered by the Department or that has otherwise been identified or brought to the attention of the Department would be more effective in carrying out the purpose for which the action is proposed or would be effective

as and less burdensome to affected private persons than the proposed action, or would be more cost-effective to affected private persons and equally effective in implementing the statutory policy or other provision of law.

CONTACT PERSON: Inquiries regarding the substance of the proposed regulations described in this notice may be directed to Alessandra Ross (916) 449-5796 or Maria Islas-Sevilla in the Office of AIDS, CDPH at (916) 449-5790.

Any inquiries concerning the action described in this regulatory Notice of Proposed Rulemaking may be directed to Laurel Prior, Office of Regulations, at (916) 440-7673.

In any inquiries or written comments, please identify the action by using the Department regulation package identifier, DPH-11-021.

AVAILABILITY OF STATEMENT OF REASONS, TEXT OF PROPOSED REGULATIONS AND RULEMAKING FILE: The Department has prepared and has available for public review an initial statement of reasons for the proposed regulations, all the information upon which the proposed regulations are based, and the text of the proposed regulations. The Office of Regulations, 1616 Capitol Avenue, Sacramento, CA 95814, will be the location of public records, including reports, documentation, and other material related to the proposed regulations (rulemaking file).

In order to request that a copy of this public notice, the regulation text, and the initial statement of reasons or alternate formats for these documents be mailed to you, please call (916) 440-7673 (or the California Relay Service at 711), send an email to regulations@cdph.ca.gov, or write to the Office of Regulations at the address previously noted. Upon specific request, these documents will be made available in Braille, large print, audiocassette, or computer disk.

AVAILABILITY OF CHANGED OR MODIFIED TEXT: The full text of any regulation, which is changed or modified from the express terms of the proposed action will be made available by the Department's Office of Regulations at least 15 days prior to the date on which the Department adopts, amends, or repeals the resulting regulation.

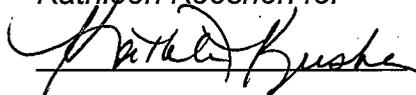
AVAILABILITY OF FINAL STATEMENT OF REASONS: A copy of the final statement of reasons (when prepared) will be available upon request from the Office of Regulations.

AVAILABILITY OF DOCUMENTS ON THE INTERNET: Materials regarding the action described in this notice (including this public notice, the regulation text, and the initial statement of reasons) that are available via the Internet may be accessed at www.cdph.ca.gov by clicking on these links, in the following order: Decisions Pending and Opportunity for Public Participation, Regulations, Proposed.

CALIFORNIA DEPARTMENT OF PUBLIC HEALTH

DPH-11-021

Kathleen Keeshen for



Ron Chapman, MD, MPH, Director

Date: 1/25/13