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NOTICE OF PROPOSED RULEMAKING
Title 17, California Code of Regulations

DPH-18-015 Syringe Exchange Program Regulatory Consistency
Published: February 19, 2021

Public Proceedings

The California Department of Public Health (Department) is conducting a 45-day written public proceeding 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 the Informative Digest/Policy Statement overview section of this notice.

Written Comment Period

Any written comments pertaining to these regulations, regardless of the method of transmittal, must be received by the Office of Regulations by April 5, 2021, which is hereby designated as the close of the written comment period. Comments received after this date will not be considered timely. Persons wishing to use the California Relay Service may do so at no cost by dialing 711.

Written comments may be submitted as follows:

1. By email: regulations@cdph.ca.gov. It is requested that email transmission of comments, particularly those with attachments, contain the regulation package identifier "**Syringe Exchange Program Regulatory Consistency**" in the subject line to facilitate timely identification and review of the comment;
2. By fax transmission: (916) 636-6220;
3. By Postal Service: California Department of Public Health, Office of Regulations, 1415 L Street, Suite 500, Sacramento, CA 95814;
4. Hand-delivered: California Department of Public Health, Office of Regulations, 1415 L Street, Suite 500, Sacramento, CA 95814.



All submitted comments should include the regulation package identifier, “**DPH-18-015 Syringe Exchange Program Regulatory Consistency**” author’s name and mailing address.

INFORMATIVE DIGEST

The California Department of Public Health (Department) proposes to make minor amendments to California Code of Regulations (CCR), Title 17, Sections 7000, 7002 and 7014. First, Assembly Bill (AB) 1810 (Ting, Chapter 34, Statutes of 2018) shortened the public comment period for state-authorized syringe exchange program (SEP) applications in Health and Safety Code (HSC) from 90 days to 45 days; the Department proposes to make the corresponding change in regulations. Second, the Department proposes to remove the words “local ordinances” from CCR Title 17, Section 7002(a)(13)(A) and Section 7014 to be in compliance with HSC 121349(c).

BACKGROUND AND SUMMARY OF EXISTING LAWS AND REGULATIONS

Authority and Reference

HSC Section 131200 authorizes the Department to adopt and enforce regulations for the execution of its duties. Per HSC Section 131019, the Office of AIDS is the lead agency within the state responsible for coordinating HIV/AIDS-related programs. HSC Section 121349 gives the Department the authority to authorize SEPs. AB 1810 removed all sunset provisions from the SEP authorization program and extended the operation of these provisions indefinitely.

Background and Existing Laws

The practice of sharing needles and syringes, which is common among people who inject drugs (PWID), poses a substantial risk for the spread of bloodborne diseases, including HIV and viral hepatitis. Paraphernalia possession laws in many states, including California, have in the past made it difficult or illegal for PWID to obtain and possess sterile syringes and difficult or illegal for agencies that serve them to provide them with sterile syringes. Such statutory barriers have consistently been found to be associated with increased sharing of syringes and increased prevalence of HIV. Removing those barriers is a key HIV prevention strategy endorsed by the California Legislature and the federal Centers for Disease Control and Prevention (CDC), which funds the prevention efforts of the Office of AIDS. Supporting syringe exchange programs is one of the strategies of the federal government’s current “Ending the HIV Epidemic” plan.

SEPs have been operating in California since the late 1980s, providing sterile injection equipment, disposing of used syringes and providing linkages to health care and social services. Since the passage of AB 136 (Mazzoni, Chapter 762, Statutes of 1999), organizations in California that provide syringe exchange services have been permitted to apply for authorization to local (city or county) governments. AB 604 (Skinner, Chapter 744, Statutes of 2011) amended California code to allow the Department to also authorize SEP providers. According to the bill’s author, Assemblymember Skinner introduced the bill after the Fresno SEP lost its authorization due to a change in office holders on the Fresno County Board of Supervisors in 2011. A similar change to the San Diego City Council had previously resulted in the shutdown of an SEP run by a local

federally-qualified health center. The bill's author cited concern about lack of syringe exchange services in jurisdictions highly impacted by HIV, hepatitis C virus (HCV), and injection drug use, as well as concern that the Department lacked the authority "to fully respond to urgent public health concerns from HIV, hepatitis, and other blood-borne infections." AB 604 granted new authority to the Department to authorize SEPs, but did not impact the ability of local governments to continue to authorize SEPs if they chose.

HSC 121349 and Business and Professions Code Section 4145 outline the mechanisms by which an SEP may be authorized to operate. Regulations approved in 2014 allow the Department to authorize SEPs in locations where the Department determines that the conditions exist for rapid spread of HIV or viral hepatitis. Organizations that want to add syringe exchange services may apply directly to the Department's Office of AIDS for authorization, rather than to their local county or city government. Applications must meet minimal requirements outlined by the law to be considered. CCR, Title 17, Sections 7000-7016 define the application process, as well as the reauthorization process for state-authorized entities. All state-authorized SEPs are required to submit a yearly progress report. They may apply for reauthorization prior to the end of the two-year authorization period.

Effectiveness of Syringe Exchange Programs

The first SEP was established in California in 1988; there are currently 62 SEPs in the state. SEPs have been rigorously studied since they were first introduced in the mid-1980s in response to injection-related HIV transmission. As CDC has summarized, this evidence has shown that SEPs:

- Reduce HIV and viral hepatitis transmission;
- Reduce overdose mortality;
- Increase entry into substance use disorder treatment;
- Reduce needle-stick injuries;
- Save money; and
- Do not increase drug use or crime.

The impact of SEPs has been most notable in terms of controlling the HIV epidemic: between 2008 and 2014, the annual HIV diagnoses among PWID in the U.S. fell by half. In jurisdictions where SEPs were adopted early and publicly funded, injection-related HIV transmission has been steeply reduced, such as in San Francisco where the number of infections decreased by two-thirds¹, or New York City where HIV prevalence among PWID fell from 54% in 1990 to 3% in 2012.

SEPs also play an important role in preventing the transmission of HCV, in linking individuals to substance use disorder treatment, and in safe disposal of used syringes.

¹ San Francisco Department of Public Health, Population Health Division. *Syringe Access and Disposal Services*. (May 2018), <https://www.sfdph.org/dph/hc/HCCommPubHlth/Agendas/2018/May%2015/syringeprez.pdf>.

Studies have found, for example, that cities with SEPs have less syringe litter than those that don't have SEPs, and that syringes obtained from SEPs are more likely to be safely disposed than those acquired from other sources.

Unintended Conflict Between Law and Regulation

Some local governments that do not support the establishment of authorized SEPs within their jurisdictions are taking steps to circumvent the intent of HSC 121349 by blocking SEPs from operating through issuing restrictive local ordinances. However, the law is designed such that the state can authorize an SEP specifically because not all jurisdictions, even those who have a high need, support the operation of SEPs within their boundaries.

The law specifically provides preemption language to make clear that a state authorization under HSC 121349 overrides any other laws. The law provides:

“In order to reduce the spread of HIV infection, viral hepatitis, and other potentially deadly bloodborne infections, the State Department of Public Health may, *notwithstanding any other law*, authorize entities that provide services set forth in paragraph (1) of subdivision (d), and that have sufficient staff and capacity to provide the services described in Section 121349.1, as determined by the department, to apply for authorization under this chapter to provide hypodermic needle and syringe exchange services consistent with state standards in any location where the department determines that the conditions exist for the rapid spread of HIV, viral hepatitis, or any other potentially deadly or disabling infections that are spread through the sharing of used hypodermic needles and syringes [emphasis added].”

The improper inclusion of reference to local ordinances in CCR Title 17, Section 7002(a)(13)(A) and Section 7014 in the 2014 regulations has created a direct conflict with the law and had the effect of subverting the Legislature's stated intent of the preemption language in HSC Section 121349. This error in the regulations opened an opportunity for local ordinances to improperly shut down an SEP² that was otherwise approved through the legal mechanism in HSC 121349, could cause many communities deemed to be in need of SEP services to be denied access.

Policy Statement Overview

Problem Statement:

In 2018, AB 1810 was signed into law, amending HSC 121349(e). This changed the public comment period for state-authorized SEP applications from 90 days to 45 days. It is required that CCR, Title 17, Sections 7000 and 7002 be updated to reflect that change.

CCR, Title 17, Section 7002(a)(13)(A) defines one of the steps for state-authorized applicants. It states that SEP applicants must provide a signed statement attesting to “compliance with state laws, regulations and local ordinances.” Section 7014 states “the

² County of Orange, Orange County Flood Control District, City of Costa Mesa, City of Orange and City of Anaheim v. California Department of Public Health and Orange County Needle Exchange Program Case No. 37-2018-00039176-CU-MC-CTL Consolidated with 37-2018-00042617-CU-TT-CLT Superior Court of the State of California, County of San Diego.

program and its staff shall operate and furnish services in compliance with all applicable state laws, regulations and local ordinances.” CCR, Title 17, Section 7002(a)(13)(A) and Section 7014 should not have included “local ordinances” as part of the regulations. This has caused numerous issues. First, it has given some local governments the impression that they have authority over the approval and oversight of state-authorized SEPs. This occurred when the City of Santa Ana moved to close Orange County Needle Exchange Program (OCNEP), a state-authorized SEP. The Department then followed all requirements in HSC 121349 and authorized OCNEP to operate a mobile outreach program. The County of Orange along with several local jurisdictions subsequently filed suit against OCNEP and the Department to void the authorization. A second issue is that some community groups applying for authorization with the state are under the mistaken impression they must be approved by local government as well as the Department in order to be authorized. As a result, community groups may be hesitant to apply for authorization if their local government has indicated that they are not interested in approving an SEP. This misunderstanding is being communicated to the public and creating false expectations for community members opposed to SEPs, who may believe that local government can halt Department authorization of syringe services in their jurisdictions.

Objectives (Goals):

The objectives of this regulatory proposal are to:

- Create consistency between HSC and CCR in defining the public comment period; and
- Correct the current regulations by removing “local ordinances” from the regulations to be in compliance with AB 604.

Benefits

Regulations are required to clarify and implement statute: these changes will improve both clarity and implementation. Additional benefits of this proposal are as follows:

- Amended regulations will be in compliance with changes to HSC 121349 made by AB 1810; and
- Will remove ambiguity and clearly define the authority of the Department to authorize and oversee state-authorized SEPs notwithstanding any other law.

Evaluation as to Whether the Regulations are Inconsistent or Incompatible with Existing State Regulations

The Department has made a determination that these regulations are neither inconsistent nor incompatible with other state regulations.

Substantial Difference from Federal Regulation or Statute

State regulations are required, as there are no federal regulations governing the authorization of SEPs.

Incorporation by Reference

None.

Documents Relied Upon

1. Assembly Bill 1810 (Ting, Chapter 34, Statutes of 2018), http://leginfo.legislature.ca.gov/faces/billTextClient.xhtml?bill_id=201720180AB1810.
2. Assembly Bill 604 (Skinner, Chapter 744, Statutes of 2011), http://leginfo.legislature.ca.gov/faces/billNavClient.xhtml?bill_id=201120120AB604
3. California Health and Safety Code Section 121349, http://leginfo.legislature.ca.gov/faces/codes_displaySection.xhtml?sectionNum=121349.&lawCode=HSC.
4. California Code of Regulations, Title 17, Section 7000, [https://govt.westlaw.com/calregs/Document/IACE1B100F70711E2A418DBA4AAEF658?viewType=FullText&originationContext=documenttoc&transitionType=CategoryPageItem&contextData=\(sc.Default\)](https://govt.westlaw.com/calregs/Document/IACE1B100F70711E2A418DBA4AAEF658?viewType=FullText&originationContext=documenttoc&transitionType=CategoryPageItem&contextData=(sc.Default)).
5. California Code of Regulations, Title 17, Section 7002, [https://govt.westlaw.com/calregs/Document/IAD1CE540F70711E2A418DBA4AAEF658?viewType=FullText&originationContext=documenttoc&transitionType=CategoryPageItem&contextData=\(sc.Default\)](https://govt.westlaw.com/calregs/Document/IAD1CE540F70711E2A418DBA4AAEF658?viewType=FullText&originationContext=documenttoc&transitionType=CategoryPageItem&contextData=(sc.Default)).
6. U.S. Department of Health and Human Services. Federal Response – Ending the HIV Epidemic: A Plan for America, <https://www.hhs.gov/blog/2019/02/05/ending-the-hiv-epidemic-a-plan-for-america.html>, (as of October 2019).
7. Centers for Disease Control and Prevention. Summary of Information on the Safety and Effectiveness of Syringe Services Programs, (July, 2019), <https://www.cdc.gov/ssp/docs/SSP-Summary.pdf> (as of October 2019).
8. Centers for Disease Control and Prevention. Reducing Harms from Injection Drug Use & Opioid Use Disorder with Syringe Services Programs, (August, 2017), <https://www.cdc.gov/hiv/pdf/risk/cdchiv-fs-syringe-services.pdf> (as of October 2019).
9. California Department of Public Health (CDPH). [Issue Brief: Syringe Access Policies for California Syringe Exchange Programs](https://www.cdph.ca.gov/Programs/CID/DOA/CDPH%20Document%20Library/CDPH%20SEP%20Distribution%20Policy%20Issue%20Brief%20(Aproved%20w%20Logos).pdf), April 2017, [https://www.cdph.ca.gov/Programs/CID/DOA/CDPH%20Document%20Library/CDPH%20SEP%20Distribution%20Policy%20Issue%20Brief%20\(Aproved%20w%20Logos\).pdf](https://www.cdph.ca.gov/Programs/CID/DOA/CDPH%20Document%20Library/CDPH%20SEP%20Distribution%20Policy%20Issue%20Brief%20(Aproved%20w%20Logos).pdf) (as of October 2019).
10. San Francisco Department of Public Health, Population Health Division. Syringe Access and Disposal Services, (May 2018), <https://www.sfdph.org/dph/hc/HCCommPubHlth/Agendas/2018/May%2015/syringeprez.pdf> (as of October 2019).
11. County of Orange, Orange County Flood Control District, City of Costa Mesa, City of Orange and City of Anaheim v. CDPH and Orange County Needle Exchange Program Case No. 37-2018-00039176-CU-MC-CTL Consolidated with 37-2018-00042617-CU-TT-CLT Superior Court of the State of California, County of San Diego.
12. Doherty MC, Junge B, Rathouz P, Garfein RS, Riley E, Vlahov D. The effect of a needle exchange program on numbers of discarded needles: a 2-year follow-up. *Am J Public Health*. 2000;90(6):936–939.
13. Belani HK, Muennig PA. Cost-effectiveness of needle and syringe exchange for the prevention of HIV in New York City. *Journal of HIV/AIDS Social Services*. 2008;7:229–40.

14. Kong D, et al. Patient Costs, Characteristics, and Outcomes Associated with Hepatitis B and Hepatitis C Hospitalizations – California – 2011. Poster presentation at Conference of State and Territorial Epidemiologists Conference, Pasadena, California, June 2013.

Business reporting requirements

None.

Authority and Reference

HSC Section 131200 authorizes the Department to adopt and enforce regulations for the execution of its duties. Per HSC Section 131019, the Office of AIDS is the lead agency within the state responsible for coordinating HIV/AIDS-related programs. HSC Section 121349 gives the Department the authority to authorize SEPs. AB 1810 removed all sunset provisions from the SEP authorization program and extended the operation of these provisions indefinitely.

Mandated by Federal Law or Regulations

State regulations are required, as there are no federal regulations governing the authorization of SEPs.

Other Statutory Requirements

Health and Safety Code 121349, California Code of Regulations (CCR) Title 17, Sections 7000-7016, Business & Professions Code Section 4145.

Local Mandate

The Department has determined that this regulatory action 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 Statement

- The estimated cost to any local agency or school district requiring reimbursement: no costs.
- The estimated cost or savings to any state agency: If the Department certifies 5 additional SEPs, each of which averts an average of 6 HIV infections (for a statewide total of 30 infections averted) then SEP certification results in a yearly benefit to the state of \$596,074 per year (\$19,870 cost per year x 5 SEP x 6 averted infections). Subtract the estimated overall operating cost of an SEP per year (\$250,003) and the overall savings is \$346,071. More savings will be realized if additional programs are certified each year and if already-certified programs are re-certified and continue to operate.
- An estimate of any other non-discretionary cost or savings imposed upon local agencies: none.
- An estimate of any cost or savings in federal funding to the state: none.

Cost Impacts on Representative Person or Business

The agency is not aware of any cost impacts that a representative private person or

business would necessarily incur in reasonable compliance with the proposed action.

Effect on Small Business

This proposal makes two small changes to ensure current regulations are in compliance

Contact Person

Inquiries regarding the subject matter in this notice may be directed to Marjorie Katz, Department's Center for Infectious Diseases, Office of AIDS, Harm Reduction Unit, (916) 449-5964. Inquiries regarding the regulatory process described in this notice should be directed to Dawn Basciano, Office of Regulations, at (916) 440-7367, or to the designated backup contact person, Linda Cortez (916) 440-7807.

Public Hearing

The Department has not scheduled a public hearing on this proposed action. However, the Department will hold a hearing if it receives a written request for a public hearing from any interested person, or his or her duly authorized representative, no later than 15 days prior to the close of the written comment period.

Availability of Statement of Reasons and Text of Regulations

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, at the address noted above, 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) 558-1710 (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.

Final Statement of Reasons

A copy of the final statement of reasons (when prepared) will be available upon request from the Office of Regulations.

Internet Access

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 <https://oal.ca.gov/proposed-regulations/>.

Reasonable Alternatives

This regulation makes only technical, non-substantive or clarifying changes to current regulations. The Department has made the initial determination that no reasonable alternative considered by the Department or that has otherwise been identified and brought to the attention of the Department would be more effective in carrying out the purpose for which the action is proposed.

Significant Statewide Adverse Economic Impact Directly Affecting Business, Including Ability to Compete

The Department has made an initial determination that the proposed regulatory action would have no significant, statewide adverse economic impact directly affecting business, including the ability of California businesses to compete with businesses in other states.

Statements of Determination

The Department, based on the following, has made the determination 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.

Housing Costs

The Department has determined that the regulation will not have an impact on housing costs.

Economic Impact Assessment

The Department analyzed whether and to what extent this proposal affects the following:

1. The creation or elimination of jobs within the State of California: these proposed regulations do not create or eliminate jobs but may create new job opportunities as they may provide additional opportunities for new SEPs to form.
2. The creation of new businesses or the elimination of existing businesses within the State of California: these proposed regulations do not create new businesses or eliminate existing ones but may provide additional opportunities for new SEPs to form.
3. The expansion of businesses currently doing business within the State of California: these proposed regulations may allow existing SEPs to expand into other geographic areas to respond to public health need.
4. The benefits of the regulation to the health and welfare of California residents, and increases to worker safety: these proposed regulations will not affect worker safety. They may improve the health and welfare of California residents by affording the creation of new SEPs, which have been found to reduce the transmission of HIV, HCV and other bloodborne pathogens.