

## INITIAL STATEMENT OF REASONS

### **Summary of Proposal**

The California Department of Public Health, Centers for Infectious Diseases, Office of AIDS (Department) proposes to adopt Subchapter 15, Sections 7000 through 7016 to California Code of Regulations (CCR), Title 17, Division 1, Chapter 4 to implement Assembly Bill (AB) 604 (Skinner, Chapter 744, Statutes of 2011) to reduce the spread of HIV, viral hepatitis, and other bloodborne pathogens. HIV is the etiologic virus of AIDS, and, like viral hepatitis and other bloodborne pathogens, may spread from person to person through the sharing of hypodermic needles and syringes (hereafter referred to as syringes).

AB 604 permits the 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 syringe exchange program (SEP) "certification." SEPs are programs that reduce the spread of HIV and other bloodborne pathogens by providing sterile syringes and collecting used ones from injection drug users free of charge.\* These programs also provide linkages to services ranging from drug treatment to HIV testing to housing assistance. 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.<sup>1</sup> The Department proposes to adopt regulations to define: 1) the certification procedures; 2) the operation requirements for State-certified SEPs; and 3) the reporting requirements for State-certified SEPs. Failure to adopt regulations will prohibit the Department from accepting applications from qualified applicants that wish to provide syringe exchange services and may result in additional new HIV and other bloodborne infections among injection drug users in California.

### **Policy Statement Overview**

*Problem Statement:* One of the central goals of the 2010 National HIV/AIDS Strategy (NHAS) is to reduce the number of new HIV infections and the rate of HIV transmission by 2015. In California, the sharing of contaminated syringes is a risk behavior associated with approximately 18 percent of all HIV/AIDS cases in the HIV/AIDS surveillance system. Syringe sharing is also the most frequently reported risk behavior among persons infected with hepatitis C, a type of viral hepatitis which affects an

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\* The term "injection drug user" is used by the medical community in place of the prior term intravenous drug user as it more accurately reflects the fact that the Injection drug users may inject substances intramuscularly and/or subcutaneously.

<sup>1</sup> Brown, Edmund G. Signing message to the California State Assembly regarding AB 604. October 9, 2011.

estimated 3.2 million Americans. Hepatitis C is the most common bloodborne infection in the United States.<sup>2</sup> The California Legislature has declared that scientific data show that syringe exchange services, designed to increase access to sterile injection equipment, also: 1) do not increase drug use in a population; 2) can serve as an important bridge to treatment and recovery; and 3) can curtail the spread of HIV among injection drug users.

The Legislature passed AB 604 and the Governor signed the bill into law on October 9, 2011. AB 604 permits, until January 1, 2019, the Department to authorize qualified applicants to provide hypodermic needle and syringe exchange services (hereafter referred to as 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 Department may certify qualified applicants to provide syringe exchange services after consultation with local health officers, local and law enforcement officials, and after a 90-day public comment period. In his signing message for AB 604, Governor Edmund G. Brown, Jr. also directed the Department to work with local neighborhood associations. AB 604 limits the period under which SEPs may operate under state authorization to two years. Before the end of the two-year period, the Department may reauthorize the SEP in consultation with the local health officer and local law enforcement officials.

The objectives of this proposed regulatory action are to:

- Implement AB 604 and achieve the goals set by the bill.
- 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 participants.
- 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

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<sup>2</sup> Centers for Disease Control and Prevention (CDC). 2009. Viral hepatitis statistics and surveillance: viral hepatitis surveillance – United States, 2009. September 22, 2011. <http://www.cdc.gov/hepatitis/Statistics/2009Surveillance/index.htm>.

have high rates of injection drug use and currently have little or no legal access to sterile syringes without a prescription.

- Saving State general 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. For example, 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. In their study of cost-effectiveness of SEPs, Belani and Muennig calculated that between four and seven infections would be averted by SEPs which served 1,000 clients each year.<sup>3</sup> If the Department certifies five such programs each year, each of which averts a minimum of four HIV infections (for a statewide total of 20 infections averted per year) then SEP certification results in a total savings of \$6,554,000 per year. This is calculated as 20 infections averted at a cost of \$385,200 each (\$7,704,000) minus the budgets of these five programs (average SEP budget of \$230,000 X 5 = \$1,150,000).

Costs associated with viral hepatitis are also considerable in California. For example, in 2010, hospitalization charges associated with hepatitis C-related liver disease, liver cancer, and liver transplantation in California exceeded \$2 billion. More than two-thirds of these charges were paid for by public insurance programs, such as Medi-Cal and Medicare. A reduction in the number of injection drug use-related cases of hepatitis C would substantially reduce the associated public costs of care and treatment for viral hepatitis.

### **Consistency Evaluation**

The Department evaluated this proposal as to whether the proposed regulations are inconsistent or incompatible with existing state regulations. This evaluation included a review of the Department's existing general regulations and an Internet search of regulations external to the Department. It was determined that no other state regulation addressed the same subject matter and that this proposal was not inconsistent or incompatible with other state regulations. The Department has therefore determined that this proposal, if adopted, would not be inconsistent or incompatible with existing state regulations.

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<sup>3</sup> Belani HK, Muennig PA. Cost-effectiveness of needle and syringe exchange for the prevention of HIV in New York City. J HIV AIDS SocServ 2008;7:229-40. [www.pceo.org/pubs/Harm%20reduction.pdf](http://www.pceo.org/pubs/Harm%20reduction.pdf).

### **Comparable Federal Regulation or Statute**

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

### **Background/Authority**

The practice of sharing needles and syringes, which is common among injection drug users, poses a substantial risk for the spread of bloodborne diseases, including HIV and viral hepatitis. Studies have shown that injection drug users share syringes because new, sterile syringes are scarce.<sup>4</sup> Paraphernalia possession laws in many states, including California, have made it difficult or illegal for injection drug users to obtain and possess sterile syringes and difficult or illegal for agencies that serve injection drug users to provide them with sterile syringes. Such statutory barriers have consistently been found to be associated with increased prevalence of HIV/AIDS, and removing those barriers is a key HIV prevention strategy endorsed by the NHAS and the Federal Centers for Disease Control and Prevention (CDC), which funds the prevention efforts of the Office of AIDS.<sup>5</sup>

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. This authorization protects SEP providers from prosecution under California Health and Safety Code (H&S) Code Section 11364.7, which lists syringes as drug paraphernalia and thus makes it illegal to provide syringes without a prescription to another individual for disease prevention or any other purposes. AB 604 amended California code to allow the Department to also authorize SEP providers, but does not impact the ability of local governments to continue to authorize SEPs if they choose.

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. The Department's initiative to authorize SEPs at the state level may be expected to increase access to sterile syringes through authorized sources, especially in areas in the state where local government has not taken steps to authorize SEPs.

### **Authority**

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.

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<sup>4</sup> CDC. Fact sheet series: State and local policies regarding IDUs' access to sterile syringes. December, 2005. [http://www.cdc.gov/idu/facts/AED\\_IDU\\_POL.pdf](http://www.cdc.gov/idu/facts/AED_IDU_POL.pdf).

<sup>5</sup> CDC. Syringe exchange programs---United States, 2008. MMWR 2010;59(45):1488--1491. <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5945a4.htm>

### **Necessity/Reasonable Alternative Standards**

The Department has determined that regulations are needed to provide specific instructions for the entities that apply for certification, to ensure consistency and fairness in the Department's implementation of the certification process, and consistency in the operations and reporting requirements for certified SEPs. If regulations are not adopted, applicants will have no direction regarding the specifics of the program, and stakeholders involved in the process, including local health officers, local law enforcement, and local neighborhood associations, will have no clear understanding of what is required of State-certified SEPs or the standards used to certify an SEP applicant. Without the specificity of these regulations, SEP certification and program operation may be not consistent, possibly resulting in the establishment of SEPs that do not meet the requirements established by AB 604.

The Department proposes adoption of the following regulations:

#### **Article 1. Definitions.**

Article 1, Section 7000 provides definitions of terms used in the body of the regulations thereby providing for uniform interpretation of the text of the regulations. Subsections (1) through (28) are proposed to be adopted because their definitions will clarify their specific use and meaning in the regulations.

Definitions 1, 4, 9, 10, 15, 23, 26 and 28 are provided to define medical and public health terms used in H&S Code Section 121349 and in the regulations.

Definitions 2, 3, 7, 12, 18, 20, 25, and 27 describe parties involved with aspects of the development, certification, operation and/or oversight of Department-certified SEPs. These definitions are necessary to clarify responsibility, authority, and restrictions if any.

Definition 5 is provided to distinguish SEP authorization by the Department from SEP authorization by local government. This definition will help to clarify that the standards and procedures set by this Chapter apply only to Department-certified SEPs, and not to SEPs that have already been authorized by local government, or to SEPs that may be authorized by local government in the future.

Definitions 6, 16, 17, 19, and 21 provide explanations of certain terms that are used in the application that may have other interpretations. These are necessary to ensure that their meaning within the context of the SEP application is clear to all applicants.

Definitions 8, 11, 13, 14, and 24 are provided in order to differentiate between locations where syringe exchange services may be offered.

Definition 22 is provided to define the starting date of the SEP certification public comment period required by H&S Code Section 121349(e).

## **Article 2. SEP Certification Process.**

Article 2 is adopted to inform applicants and local stakeholders about the steps involved in the SEP certification process, pursuant to H&S Code Section 121349.

Section 7002, Subsection (a)(1) is necessary to identify the applicant organization. In some instances, the SEP may operate under a different name than the applicant organization. For example, the Delta Health Center may operate the Safer Points Project, a syringe exchange program; in this case, the applicant must provide both names. This information will be posted on the Department website as a resource for consumers to locate SEP programs throughout the state, pursuant to H&S Code Section 121349(f). The date the application is submitted is necessary in order to track the progress of the application.

Subsection (a)(2) is necessary to identify contact information for the person acting as administrator of the program in the event that the Department needs to request or convey information to the SEP.

Subsection (a)(3) is duplicative of H&S Code Section 121349(d)(1) and is provided for the regulated public to locate the requirements easily in one place. The description of the mission of the applicant organization is necessary because it indicates what type of entity is applying, such as a drug treatment program, a homeless services agency, an AIDS service organization or another type of entity. Pursuant to the consultation required by H&S Code Section 121349(c), this information will be discussed with local health officers and law enforcement regarding proposed SEPs in their local jurisdiction and will be made available during the public comment period.

Subsection (a)(4) is necessary to provide data to assist the Department to determine whether or not conditions exist in the proposed location for the rapid spread of HIV, viral hepatitis or other bloodborne pathogens, as required by H&S Code Section 121349(c). This information is also necessary in order to determine if certification would contribute to an over-concentration of syringe exchange services in particular neighborhoods.

Subsection (a)(5) is necessary to help the Department understand the size and scope of the proposed program, in order to determine whether or not the applicant has sufficient staff and capacity to provide the required services. Subparagraphs (A), (B), and (C) duplicate H&S Code Section 121349(d)(3) and is provided for the regulated public to locate the requirements easily in one place.

Subsection (a)(6) is necessary in the event an SEP application is provisionally deemed appropriate. Pursuant to the consultation required by H&S Code Section 121349(c), this information will be discussed with local health officers and law enforcement regarding proposed SEPs in their local jurisdiction and will be made available during the public comment period.

Subparagraphs (A) and (B) are necessary to provide a precise description of the proposed location of services. This information will be shared in the consultation with local health officers and local law enforcement officials required by the statute, and the consultation with local neighborhood associations.

Subsection (a)(7) will be included in the description of the services the Department posts on its website, and is necessary to provide stakeholders and consumers with information about the range of services offered by Department-certified SEPs.

Subsection (a)(8) is necessary to provide details about proposed SEP operating locations and hours to include in the Department's consultations with local health officers, local law enforcement, and local neighborhood associations. The description of staffing will assist the Department to determine whether or not the applicant has sufficient staff and capacity to provide the required syringe exchange services.

Subsection (a)(9) is duplicative of other parts of the application, and will be posted on the Department's website in order to provide interested stakeholders and consumers with key information about the SEP, collected in one summary paragraph.

Subsection (a)(10) is necessary for the Department to ensure that the applicant will operate the program according to the requirements of the regulations, and will follow established best practices for program operation, participant confidentiality, health and safety of SEP staff, volunteers, and participants, environmental safety, and program evaluation and reporting. The five plans that must be submitted are described in detail in Article 8, Section 7012 and discussed below. The elements required in these plans are based on best practice recommendations made in several different documents: *Recommended Best Practices for Effective Syringe Exchange Programs in the United States: Results of a Consensus Meeting*; *Ontario Needle Exchange Programs: Best Practice Recommendations*; *Guide to Developing and Managing Syringe Access Programs*; and the *Framework for Injection Drug User Health and Wellness*.<sup>6,7,8,9</sup>

Subsection (a)(11) is necessary for the Department to determine whether or not the

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<sup>6</sup> Scott, G, Irwin, K, eds. Recommended best practices for effective syringe exchange programs in the United States: Results of a consensus meeting. New York City Department of Health and Mental Hygiene. 2009. <http://harmreduction.org/issues/syringe-access/tools-best-practices/manuals-and-best-practice-documents/additional-best-practice-documents/>

<sup>7</sup> Strike C, Leonard L, Millson M, Anstice S, Berkeley N, Medd E. Ontario needle exchange programs: Best practice recommendations. Toronto: Ontario Needle Exchange Coordinating Committee. 2006. [http://www.ohrdp.ca/wp-content/uploads/pdf/Best\\_Practices\\_Report.pdf](http://www.ohrdp.ca/wp-content/uploads/pdf/Best_Practices_Report.pdf)

<sup>8</sup> Winkelstein, E. Guide to developing and managing syringe access programs. New York: Harm Reduction Coalition. 2010. <http://harm.live.radicaldesigns.org/section.php?id=145>.

<sup>9</sup> California HIV/AIDS Planning Group (CHPG). Framework for injection drug user health and wellness. 2009. <http://www.harmreduction.org/article.php?id=1135>.

applicant has the resources, including staff and funding, to support the proposed program.

Subsection (a)(12) is necessary for the Department to contact and consult with the appropriate local neighborhood association.

Subsection (a)(13), Subparagraph (A) is necessary to elicit a commitment from the applicant to comply with SEP-related law and regulations at the state level, as well as SEP-related ordinances at the local level, such as those pertaining to zoning or sharps waste disposal, which may differ in different jurisdictions.

Subsection (a)(13), Subparagraph (B) will assist the Department to determine whether or not the applicant has the capacity to commence syringe exchange services within 90 days of certification, as required by H&S Code Section 121349(d)(2).

Subsection (a)(13) Subparagraph (C) is necessary to ensure that Department-certified SEPs follow established best practices in SEP design, implementation and evaluation. This requirement is based on best practices as outlined in the documents previously cited.

Section 7002, Subsection (b) is necessary to ensure that the public is informed on how to provide input into the Department's decision to certify or not to certify an SEP, and specifies when the public comment period starts in order to ensure that the start and end dates of the period are clearly defined.

Section 7002, Subsection (c) is necessary in order to provide applicants with a timely response that also allows the Department sufficient time to review the application, review public comments received, and prepare a response to the applicant. The 30-business day processing time includes the following steps (number of days to complete each step is approximate):

Ten business days – Analysis and fact checking of public comments.

Five business days – Preparation of response to applicant.

Ten business days – Management review.

Five business days – Department mailroom handling.

### **Article 3. Standards for Refusal to Certify an SEP Application.**

Article 3, Section 7004 identifies the steps that may be taken to rectify deficiencies in an application in order to assist qualified applicants to successfully complete the application process.

Subsection (a) is necessary to ensure that the information the Department shares with the consultants (local health officers, local law enforcement officials, and neighborhood associations) and the public is accurate and complete, and that the Department's

decision is similarly based on accurate, complete information. Subsection (b) is necessary to ensure that Department SEP certifications are lawful. Subsection (c) is necessary to conform to H&S Code Section 121349(c) which requires the Department to balance the concerns of law enforcement with the public health benefits in making its certification decisions.

**Article 4. Renewal of SEP Certification.**

Article 4, Section 7006 is necessary to provide an explanation of the steps that must be taken by the SEP to apply for renewal of its certification. Section 7006 is duplicative of H&S Code 121349(c) and is provided for the regulated public to locate the requirements easily in one place.

Subsection (a) is required in order to provide details to the regulated public on the process for renewal of certification.

Subsection (b) is necessary to provide applicants with a timely response to their request that also allows the Department sufficient time to review the request. The 30-business day review and response time includes the following steps (number of days to complete each step is approximate):

- Ten business days – Consultation with local law enforcement and local health officer.
- Five business days – Preparation of response to applicant.
- Ten business days – Management review.
- Five business days – Department mailroom handling.

Subsection (b) interprets lack of response from the Department as denial in order that any and all responses from the Department are explained to the regulated public.

**Article 5. Denial of SEP Certification Renewal or Revocation of Certification.**

Article 5 is necessary in order to make explicit the reasons the Department may refuse to renew an SEP certification or may revoke a certification, and in order to provide information to the regulated public on how applicants may request review of the Department's decision to deny or revoke certification.

**Section 7008. Reasons for Denial of SEP Certification Renewal or Revocation of Certification.**

Section 7008 is necessary to make explicit the reasons the Department may refuse to renew an SEP's certification or may revoke a certification.

**Section 7010. Process to Request Review Following Denial of Certification or Revocation.**

Subsections (a) and (b) are necessary to provide applicants with specific instructions on how, when and where to request a hearing if they wish to appeal a Departmental decision to deny or revoke certification.

Subsection (c) is necessary to ensure that hearings shall be conducted pursuant to H&S Code Section 131071, and thus in compliance with the law.

#### **Article 6. Operation Requirements for Certified SEPs.**

Section 7012 outlines the minimal operation requirements for certified SEPs in order to protect environmental health, worker safety, patient confidentiality and health, and ensure quality syringe exchange services. These recommendations are based on the best practice documents previously cited, as well as on the regulations of the states of Maine, Maryland, New Jersey, New Mexico, New York and Vermont.<sup>10,11,12,13,14,15</sup>

Section 7012 is necessary for reasons previously noted above in discussion of Article 2, Section 7002, Subsection (a)(13) Subparagraph (C).

Subsection (a)(1) is necessary to ensure that SEP participants receive new, sterile syringes in accordance with the recommendations made by the U.S. Public Health Service, published in CDC's Medical Advice for Persons Who Use Injection Drugs, 1997, to support the use of a new, sterile syringe for each injection.<sup>16</sup> This requirement is based on best practice recommendations for disease prevention. Subsection (a)(2) is necessary to meet the data collection requirements of the statute.

Subsection (b)(1) and (3) are necessary to protect worker and program participant safety by minimizing the risk of needle-stick injury. Subsection (b)(2) is necessary to collect data on syringe return that may be used as an indicator of proper syringe disposal, and to meet the data collection requirements of H&S Code Section 121349(d)(4). Subsection (b)(4) is necessary to protect environmental health by ensuring that syringes are properly disposed of.

Subsection (c)(1) is duplicative of H&S Code Section 121349(d)(3) and is provided for the regulated public to locate the requirements easily in one place. It is also necessary to ensure that syringe exchange services are delivered in accordance with the statute. Subsection (c)(2) duplicates H&S Code Section 121349(d)(1) for the same reasons. Subsection (c)(3) is necessary to ensure that certified SEPs provide education and supplies to support safer sex practices, which is recognized as standard best practice

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<sup>10</sup> Code of Maine Rules, tit.10-144, chap. 252

<sup>11</sup> Code of Maryland Regulations, tit. 24, sec. 24.

<sup>12</sup> New Jersey Administrative Code, tit. 8, chap. 63.

<sup>13</sup> New Mexico Administrative Code, tit.7, chap. 4, part 6.

<sup>14</sup> New York Codes, Rules and Regulations, tit.10, sec. 80.135.

<sup>15</sup> Vermont Department of Public Health. Operating guidelines for organized community-based safer injection support programs. July 2010.

<sup>16</sup> CDC, Health Resources and Services Administration, National Institute on Drug Abuse and Substance Abuse and Mental Health Services Administration. HIV prevention bulletin: Medical advice for persons who inject illicit drugs.1997. <http://www.cdcnpin.org/Reports/MedAdv.pdf>.

for HIV prevention. Subsection (c)(4) is necessary to protect program participant confidentiality, in keeping with established best practices for provision of preventive health and social services.

Subsection (d)(1) is based on best practice recommendations for program design and quality assurance found in the best practice documents previously cited, and is necessary to ensure that Department-certified SEPs use the data they collect about their program to improve their program. Subsection (d)(2) is necessary to help the Department comply with H&S Code Section 121349.3(a), which requires the Department to relay reports on State-certified SEPs to local health officers.

Subsection (e) is necessary to assist the Department to assess whether or not the Department is balancing the concerns of law enforcement with public health benefit, as required by the statute, by documenting any adverse incidents and positive interactions with law enforcement. These requirements will also assist the Department in its charge to work closely with local neighborhood associations, as required by Governor Brown's signing message, by documenting any and all complaints and positive feedback from neighborhood associations and residents, as well as positive feedback. These subsections also inform applicants that documenting concerns from program participants is part of quality assurance, and that addressing the reasonable concerns of law enforcement, neighborhood associations and program participants is a requirement of State-certified SEPs.

#### **Section 7014. Compliance with State Laws, Regulations and Local Ordinances.**

Section 7014 is necessary to help ensure that Department-certified SEPs operate in compliance with the law.

#### **Article 7. Reporting Requirements for Certified SEPs.**

Article 7, Section 7016 is necessary to provide clear instructions to certified SEPs on how to conform to the reporting requirements mandated by the statute.

Subsection (a) is necessary to ensure that the Department and certified SEPs in compliance with the statute's reporting requirements.

Subsection (b) is necessary to help the Department fulfill its obligation to balance the concerns of law enforcement with public health benefit, as required by H&S Code Section 121349(c), and to work closely with local neighborhood associations, as required by Governor Brown's signing message.

## STATEMENTS OF DETERMINATION

### Alternatives Determination

The Department has determined 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 this action is proposed, or would be effective as and less burdensome to affected private persons than the proposed action.

### Economic Impact Assessment

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.

**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.

**Local Mandate**

The Department has determined that the proposed regulation amendments will 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.

**Effect on 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.

**Housing Costs Determination**

The Department has made an initial determination that the regulations will have no impact on housing costs.

**Reporting Requirement**

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.

**Documents Relied Upon**

- 1) Brown, Jr., Edmund G. Signing message to the California State Assembly regarding AB 604. October 9, 2011. [http://gov.ca.gov/docs/SB\\_604\\_Signing\\_Message.pdf](http://gov.ca.gov/docs/SB_604_Signing_Message.pdf).
- 2) CDC. 2009. Viral hepatitis statistics and surveillance: viral hepatitis surveillance – United States, 2009. September 22, 2011. <http://www.cdc.gov/hepatitis/Statistics/2009Surveillance/index.htm>.

- 3) Belani HK, Muennig PA. Cost-effectiveness of needle and syringe exchange for the prevention of HIV in New York City. J HIV AIDS Soc Serv 2008;7:229–40. [www.pceo.org/pubs/Harm%20reduction.pdf](http://www.pceo.org/pubs/Harm%20reduction.pdf).
- 4) CDC. Fact sheet series: State and local policies regarding IDUs' access to sterile syringes. December, 2005. [http://www.cdc.gov/idu/facts/AED\\_IDU\\_POL.pdf](http://www.cdc.gov/idu/facts/AED_IDU_POL.pdf).
- 5) CDC. Syringe exchange programs---United States, 2008. MMWR 2010;59(45):1488--1491. <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5945a4.htm>
- 6) Scott, G, Irwin, K, eds. Recommended best practices for effective syringe exchange programs in the United States: Results of a consensus meeting. New York City Department of Health and Mental Hygiene. 2009. <http://harmreduction.org/issues/syringe-access/tools-best-practices/manuals-and-best-practice-documents/additional-best-practice-documents/>
- 7) Strike C, Leonard L, Millson M, Anstice S, Berkeley N, Medd E. Ontario needle exchange programs: Best practice recommendations. Toronto: Ontario Needle Exchange Coordinating Committee. 2006. 1-72. [http://www.ohrdp.ca/wp-content/uploads/pdf/Best\\_Practices\\_Report.pdf](http://www.ohrdp.ca/wp-content/uploads/pdf/Best_Practices_Report.pdf)
- 8) Winkelstein, E. Guide to developing and managing syringe access programs. New York: Harm Reduction Coalition. 2010. <http://harm.live.radicaldesigns.org/section.php?id=145>.
- 9) California HIV/AIDS Planning Group (CHPG). Framework for injection drug user health and wellness. 2009. <http://harmreduction.org/syringe-access/syringe-access-policy-advocacy/policy-briefs-and-reports/additional-policy-documents/framework-for-idu-health-wellness/>.
- 10) Code of Maine Rules, Tit.10-144, Chap. 252. [10 Maine.pdf](#)
- 11) Code of Maryland Regulations, Tit. 24, Sec. 24. [11 Maryland.pdf](#)
- 12) New Jersey Administrative Code, Tit. 8, Chap. 63. [12 New Jersey.pdf](#)
- 13) New Mexico Administrative Code, Tit.7, Chap. 4, Part 6. [13 New Mexico.pdf](#)
- 14) New York Codes, Rules and Regulations, Tit.10, Sec. 80.135. [14 New York.pdf](#)

- 15) Vermont Department of Public Health. Operating guidelines for organized community-based safer injection support programs. July 2010.  
[15\\_Vermont\\_SEP\\_Guidelines.pdf](#)
- 16) CDC, Health Resources and Services Administration, National Institute on Drug Abuse and Substance Abuse and Mental Health Services Administration. HIV prevention bulletin: Medical advice for persons who inject illicit drugs. 1997. 3-4. <http://www.cdcnpin.org/Reports/MedAdv.pdf>.
- 17) National Alliance of State and Territorial AIDS Directors (NASTAD). Health departments' role in expanding syringe access. 2010. [http://www.nastad.org/Docs/highlight/2010427\\_Syringe%20Access%20Fact%20Sheet.pdf](http://www.nastad.org/Docs/highlight/2010427_Syringe%20Access%20Fact%20Sheet.pdf).
- 18) Burris S, Ortiz S, Webster R, Silverman R, Ng M. The project on harm reduction in the health care system. 2008. Temple University's Beasley School of Law. Retrieved December 2, 2011 from <http://www.temple.edu/lawschool/aidspolicy/>.
- 19) California Department of Health Services, Office of AIDS, HIV Education and Prevention Services Branch. Request for applications number 2007-03, HIV prevention for injection drug users in California: syringe exchange programs. March 30, 2007.