

Title 17. California Code of Regulations
Division 1. State Department of Health Services
Chapter 4. Preventive Medical Services
Subchapter 15. Syringe Exchange Program (SEP) Certification

Designate new Article 1 to read:

Article 1. Definitions

Adopt Section 7000 to read:

7000. Syringe Exchange Program (SEP) Certification Definitions.

The California Department of Public Health proposes the following rules for certifying hypodermic needle and syringe exchange programs (herein referred to as Syringe Exchange Programs or SEPs) to facilitate the prevention of HIV and other bloodborne pathogens.

(a) The following definitions used in these regulations shall have the meaning specified.

(1) "AIDS" means acquired immune deficiency syndrome.

(2) "Administrator" means a person having the authority and responsibility for the operation of the SEP and serves as the contact for communication with the department.

(3) "Applicant" means the entity applying for authorization under Health and Safety Code Section 121349, and includes the individual who signs the application for certification of the SEP.

(4) "Bloodborne pathogens" means pathogenic microorganisms that are present in human blood and can cause disease in humans. These pathogens include, but are not limited to, hepatitis B virus, hepatitis C virus and human immunodeficiency virus (HIV).

(5) "Certification" means departmental authorization of an SEP to operate for up to 2 years.

(6) "Core services" means the primary activities an entity undertakes in order to serve its clients.

(7) "Department" means the California Department of Public Health, Office of AIDS.

(8) "Fixed site" means a building or single location, not a mobile site, where syringe exchange services are provided on a regular basis.

(9) "HIV" means the etiologic virus of AIDS.

(10) "Injection drug user" means a person who uses a syringe to self-administer drugs, referred to in Health and Safety Code Section 121349 as an intravenous drug user.

(11) "Local Health Jurisdiction" means a California county or city with a local health department.

(12) "Local Law Enforcement Official" means the individual designated by the sheriff or police chief in the district in which the SEP operates who has authority to receive communications from state and local public health agencies.

(13) "Location" means a site within a Local Health Jurisdiction. For this Subchapter, location can be a fixed or mobile site.

(14) "Mobile site" means a location where syringe exchange is conducted using a vehicle such as a van, or by foot in a location that is not a fixed indoor setting.

(15) “Needlestick Injury” means a penetrating wound from a needle that may result in exposure to blood.

(16) “Needlestick Injury Protocol” means policies and procedures, in adherence with the California Occupational Safety and Health Administration protocol as provided in California Code of Regulations, Title 8, Section 5193, to prevent needlestick injury to SEP staff, including volunteers, and to SEP participants, and that outline both immediate and subsequent remedial and prophylactic actions to take in the event of a needlestick injury.

(17) “Needs Statement” means a paragraph that provides the rationale for the request for certification in the location specified and uses data and other objective sources to document the need. Examples include statistics on HIV infection and/or viral hepatitis among injection drug users in the Local Health Jurisdiction, the presence of injection drug users in the location, and the presence or absence of other syringe exchange services in the Local Health Jurisdiction.

(18) “Participant” means a person who uses syringe exchange services, a client of the SEP.

(19) “Participant Confidentiality Protocols” means written protocols that strictly limit the disclosure of participant identification information.

(20) “Program” means an SEP.

(21) “Protocols” means written guidelines that define the limits and extent of practice of the staff of an SEP.

(22) "Public Comment Period" means a 90-day period, commencing from the date the department posts information about an application on its website, in which the public may use the website to comment on an application for SEP certification.

(23) "Sharps Waste" means used needles, syringes and lancets.

(24) "Site" means the location(s) where syringe exchange services are offered to participants.

(25) "Staff" means anyone who provides syringe exchange services on behalf of a program.

(26) "Syringe" means both the needle and syringe used to inject fluids into the body, referred to in Health and Safety Code Section 121349 as a hypodermic needle and syringe.

(27) "Syringe Exchange Program (SEP)" means a program that provides sterile needles and syringes and collects used sharps waste from injection drug users free of charge as part of efforts to reduce the spread of HIV/AIDS, viral hepatitis and other bloodborne pathogens.

(28) "Viral hepatitis" means any of the forms of hepatitis caused by a virus, including hepatitis B virus and hepatitis C virus.

NOTE: Authority cited: Sections 121349, 121349.1, 121349.2, 121349.3, 131000, 131005, 131019, 131050, 131051, 131052, and 131200, Health and Safety Code.

Reference: Sections 4150, 4145, and 4170, Business and Professions Code; and Sections 11364, 121285, 121349, 121349.1, 121349.2, 121349.3, and 131019, Health and Safety Code.

Designate new Article 2 to read:

Article 2: SEP Certification Process.

Adopt Section 7002 to read:

Section 7002. Application Requirements for SEP Certification.

An applicant desiring state authorization to operate an SEP shall, pursuant to Health and Safety Code Section 121349, file an application for certification with the California Department of Public Health, Office of AIDS, through its website or by mail.

(a) Each application shall contain the following information:

(1) The name of the applicant organization, the name under which it will be providing syringe exchange services, if different, and the date the application is submitted.

(2) The full name, title, email address and telephone number of the individual designated by the applicant as the administrator of the SEP.

(3) A description of the applicant organization's mission and core services, including a list of services the applicant currently provides to injection drug users. Services offered shall include all services listed in Health and Safety Code Section 121349(d)(1) and may be offered directly or by referral. These are:

(A) Drug abuse treatment services,

(B) HIV or hepatitis screening,

(C) Hepatitis A and hepatitis B vaccination,

(D) Screening for sexually transmitted infections,

(E) Housing services for the homeless, for victims of domestic violence, or other similar housing services, and

(F) Services related to provision of education and materials for the reduction of sexual risk behaviors, including, but not limited to, the distribution of condoms.

(4) A needs statement as defined in Section 7000(a)(17) and that includes information about the presence or absence of other syringe exchange services in the proposed location.

(5) A description of the proposed syringe exchange services, the anticipated number of participants to be served each year and the estimated number of syringes to be dispensed and collected each year. SEP services include all those listed in Health and Safety Code Section 121349(d)(3) which requires certified SEPs to:

(A) Provide needles and syringe exchange services for all of its participants;

(B) Provide HIV and viral hepatitis prevention education services for all of its participants; and

(C) Provide for the safe recovery and disposal of used syringes and sharps waste from all of its participants.

(6) A description of the service delivery mode(s) to be employed, whether fixed or mobile site, and:

(A) The number of locations at which syringe exchange services will be provided.

(B) A description of the location(s) where syringe exchange services will be provided that includes the full address (street number, street name, city and zip code) and county of the fixed or mobile site location(s).

(7) A description of additional services that will accompany syringe exchange, such as overdose prevention supplies and education.

(8) The SEP hours of operation in the location(s) and staffing. The description of hours of operation shall include the specific days the SEP is open, opening and closing times, and frequency of syringe exchange services. The description of staffing shall include number of staff, titles of positions and descriptions of duties.

(9) A paragraph, not to exceed 150 words and which will be posted on the department website, which summarizes the proposed program and includes the name of the applicant organization, the name of the SEP, location(s), hours of service, and types of services to be delivered.

(10) A copy of the following plans that guide the SEP's operations:

(A) Syringe Dispensing Plan as described in Section 7012(a);

(B) Syringe Collection and Disposal Plan as described in Section 7012(b);

(C) Service Delivery Plan as described in Section 7012(c);

(D) Data Collection and Program Evaluation Plan as described in Section 7012(d);

(E) Community Relations Plan as described in Section 7012(e).

(11) A budget for the program which includes at minimum projected income and costs for personnel, outside services, and operating expenses, including but not limited to rent, utilities, equipment, materials including syringes and disposal containers, transportation, insurance, training, meetings, syringe disposal services, and indirect costs.

(12) Contact name, phone number and email for the neighborhood association of the location, if one exists.

(13) A signed statement attesting to:

(A) The applicant's compliance with state laws, regulations and local ordinances;

(B) The capacity of the applicant to begin syringe exchange services within 90 days of certification;

(C) The involvement of program participant input into SEP design, implementation and evaluation.

(b) The public may comment online about an application during the 90-day public comment period, which commences on the date information about the application is posted on the department website.

(c) Pursuant to Health and Safety Code Section 121349, the department, after consultation with the local health officer and local law enforcement leadership, shall issue a final decision to certify or not to certify within 30 business days after the close of the 90-day public comment

period. Pursuant to Health and Safety Code Section 121349 of certification shall be valid for no more than two years, subject to possible renewal.

NOTE: Authority cited: Sections 121349, 121349.1, 121349.2, 121349.3, 131000, 131005, 131019, 131050, 131051, 131052, and 131200, Health and Safety Code.

Reference: Sections 11364, 121285, 121349, 121349.1, 121349.2, 121349.3, 131019; and 4150, 4145, and 4170, Business and Professions Code

Designate new Article 3 to read:

Article 3: Standards for Refusal to Certify an SEP Application.

Adopt Section 7004 to read:

Section 7004. Standards for Refusal to Certify an SEP Application.

An applicant whose application contains the deficiencies in this Section shall receive department notification to re-apply to address the deficiency and the applicant shall have 60-days thereafter to do so. The department shall reject an application if any of the following deficiencies exist:

(a) Information submitted in the application is incorrect or incomplete,

(b) The applicant does not meet all the requirements listed in Health and Safety Code Section 121349,

(c) Evidence of projected harm to public safety, presented by local law enforcement official(s), is, in the department's judgment, greater than evidence of projected benefits to public health.

NOTE: Authority cited: Sections 121349, 121349.1, 121349.2, 121349.3, 131000, 131005, 131019, 131050, 131051, 131052, and 131200, Health and Safety Code.

Reference: Sections 4150, 4145, and 4170, Business and Professions Code; and Sections 11364, 121285, 121349, 121349.1, 121349.2, 121349.3, and 131019, Health and Safety Code.

Designate new Article 4 to read:

Article 4: Renewal of SEP Certification.

Adopt Section 7006 to read:

Section 7006. Renewal of SEP Certification.

Pursuant to Health and Safety Code Section 121349, certification shall be valid for no more than two years and may be renewed by the department.

(a) Before the end of the two-year certification period, the SEP administrator may communicate to the department by mail or email to request renewal of certification for an additional two years.

(b) Pursuant to Health and Safety Code Section 121349, the department will consult with the local health officer and local law enforcement leadership regarding reauthorization requests. The department shall have 30 business days to review and respond to the applicant's request for renewal of the certification. If the department does not respond in writing within 30 business days the request for renewal shall be deemed denied.

NOTE: Authority cited: Sections 121349, 121349.1, 121349.2, 121349.3, 131000, 131005, 131019, 131050, 131051, 131052, and 131200, Health and Safety Code.

Reference: Sections 11364, 121285, 121349, 121349.1, 121349.2, 121349.3, and, 131019, Health and Safety Code; and Sections 4150, 4145, and 4170, Business and Professions Code.

Designate new Article 5 to read:

Article 5: Denial of Certification Renewal or Revocation of SEP Certification

Adopt Section 7008 to read:

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

An SEP certification shall be revoked and an application for renewal of certification shall be denied by the department if the applicant or the SEP:

(a) Violates the terms of this Subchapter.

(b) Fails to comply with the provisions of Health and Safety Code Section 121349.

NOTE: Authority cited: Sections 121349, 121349.1, 121349.2, 121349.3, 131000, 131005, 131019, 131050, 131051, 131052, and 131200, Health and Safety Code.

Reference: Sections 4150, 4145, and 4170, Business and Professions Code; and Sections 11364, 121285, 121349, 121349.1, 121349.2, 121349.3, and 131019, Health and Safety Code.

Adopt Section 7010 to read:

Section 7010. Process to Request Review Following Denial or Revocation.

Any person aggrieved by the department's decision to deny, revoke or refuse to renew certification, or by the department's deemed denial resulting from the department's failure to respond to the applicant's request for renewal within 30 business days, may request a hearing.

(a) A request for a hearing must be made in writing within 30 days of the date that the department's notification of denial or revocation was issued, or after the date of the department's deemed denial, if applicable.

(b) The request for hearing must be made in writing to the address found on the department website for the Division Chief of the Office of AIDS in the California Department of Public Health, and must clearly state the reasons for the request.

(c) Hearings shall be conducted pursuant to Health and Safety Code Section 131071.

NOTE: Authority cited: Sections 121349, 121349.1, 121349.2, 121349.3, 131000, 131005, 131019, 131050, 131051, 131052, and 131200, Health and Safety Code.

Reference: Sections 4150, 4145, and 4170, Business and Professions Code; and Sections 11364, 121285, 121349, 121349.1, 121349.2, 121349.3, 131019 and 131071, Health and Safety Code.

Designate new Article 6 to read:

Article 6: Operational Requirements for Certified SEPs.

Adopt Section 7012 to read:

Section 7012. Operational Requirements for Certified SEPs.

A certified SEP shall include program participant input into program design, implementation and evaluation. Program design, implementation and evaluation shall be guided by the following plans:

(a) A syringe dispensing plan that:

(1) Is designed to provide new, sterile syringes to meet the needs of participants in accordance with the recommendations made by the U.S. Public Health Service, published in the Centers for Disease Control and Prevention's Medical Advice for Person Who Use Injection Drugs, 1997, to support the use of a new, sterile syringe for each injection,

(2) Tracks the number of syringes dispensed.

(b) A syringe collection and sharps waste disposal plan that:

(1) Is designed to maximize return of used syringes without increasing risk of needlestick injury to staff or program participants.

(2) Tracks number of syringes returned in a manner that eliminates direct handling of sharps waste and does not interfere with service provision,

(3) Includes a needlestick injury protocol and a plan for ensuring staff and participant familiarity with the protocol,

(4) Includes sharps waste disposal education that ensures staff and participants are familiar with state law regulating proper disposal of home-generated sharps waste as referenced in Health and Safety Code Section 118286,

(5) Includes a plan and budget for sharps waste disposal, or an explanation if no cost is associated with sharps waste disposal.

(c) A service delivery plan that includes:

(1) Direct provision of services listed in Health and Safety Code Section 121349(d)(3) and in Article 2, Section 7002(a)(5),

(2) Direct provision or referrals for services listed in Health and Safety Code Section 121349(d)(1) and in Article 2, Section 7002(a)(3),

(3) Education and supplies for safer sex practices,

(4) Participant confidentiality protocols,

(d) A data collection and program evaluation plan that:

(1) Incorporates evaluation data into program design,

(2) Uses the department-designated data reporting method to collect the data elements listed in Health and Safety Code Section 121349(d)(4) which include:

(A) The total number of persons served,

(B) The total number of syringes and needles dispensed, collected and disposed of,

(C) The total numbers and types of referrals made to drug treatment and other services.

(e) A community relations plan that:

(1) Records adverse incidents and positive interactions between local law enforcement and SEP staff, volunteers or participants in their role as program participants.

(2) Documents concerns and positive feedback expressed by program participants, community members, neighborhood associations and/or local law enforcement officials; and

(3) Documents steps the program has taken to address any reasonable concerns.

NOTE: Authority cited: Sections 121349, 121349.1, 121349.2, 121349.3, 131000, 131005, 131019, 131050, 131051, 131052, and 131200, Health and Safety Code.

Reference: Sections 4150, 4145, and 4170, Business and Professions Code; and Sections 11364, 118286, 121285, 121349, 121349.1, 121349.2, 121349.3, and 131019, Health and Safety Code.

Adopt Section 7014 to read:

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

The program and its staff shall operate and furnish services in compliance with all applicable state laws, regulations and local ordinances.

NOTE: Authority cited: Sections 121349, 121349.1, 121349.2, 121349.3, 131000, 131005, 131019, 131050, 131051, 131052, and 131200, Health and Safety Code.

Reference: Sections 4150, 4145, and 4170, Business and Professions Code; and Sections 11364, 121285, 121349, 121349.1, 121349.2, 121349.3, and 131019, Health and Safety Code.

Designate new Article 7 to read:

Article 7: Reporting Requirements for Certified SEPs.

Adopt Section 7016 to read:

Section 7016. Reporting Requirements for Certified SEPs.

SEPs certified by the department must return a report to the department, postmarked or delivered by email by the anniversary date of certification each and every year of the program's operation under the department's certification. The report shall include:

(a) The data elements listed in Health and Safety Code Section 121349(d)(4) and in Article 6, Section 7012(d)(2) above;

(b) A report on the events recorded under the community relations plan, listed in Article 6, Section 7012(e) above.

NOTE: Authority cited: Sections 121349, 121349.1, 121349.2, 121349.3, 131000, 131005, 131019, 131050, 131051, 131052, and 131200, Health and Safety Code.

Reference: Sections 4150, 4145, and 4170, Business and Professions Code; and Sections 11364, 121285, 121349, 121349.1, 121349.2, 121349.3, and 131019, Health and Safety Code.