

**State of California  
Office of Administrative Law**

**In re:**  
Department of Public Health

**NOTICE OF APPROVAL OF REGULATORY  
ACTION**

**Regulatory Action:**

**Government Code Section 11349.3**

**Title 17, California Code of Regulations**

**OAL File No. 2013-0605-01 S**

**Adopt sections:** 7000, 7002, 7004, 7006,  
7008, 7010, 7012, 7014,  
7016

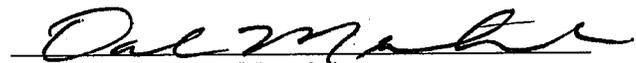
**Amend sections:**  
**Repeal sections:**

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This rulemaking action establishes a process through which qualified entities may apply to the California Department of Public Health for certification to provide syringe exchanges to intravenous drug users in areas where conditions exist for the rapid spread of HIV, viral hepatitis, or other bloodborne pathogens. The rulemaking includes, among other things, the application and certification processes, standards for denials, the renewal process, standards for denial of renewals and for revocations, and operating and reporting requirements for certified syringe exchange programs.

OAL approves this regulatory action pursuant to section 11349.3 of the Government Code. This regulatory action becomes effective on 10/1/2013.

Date: 7/16/2013



Dale P. Mentink  
Senior Staff Counsel

For: DEBRA M. CORNEZ  
Director

Original: Dr. Ron Chapman, MD, MPH  
Copy: Laurel Prior

**NOTICE PUBLICATION/REGULATORY SUBMISSION**

**REGULAR** See instructions on reverse

For use by Secretary of State only

STD. 400 (REV. 01-2013)

<b>OAL FILE NUMBERS</b>	NOTICE FILE NUMBER <b>Z-2013-0122-04</b>	REGULATORY ACTION NUMBER <b>2013-0605-015</b>	EMERGENCY NUMBER
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ENDORSED FILED  
IN THE OFFICE OF  
  
2013 JUL 16 PM 3:43

*Debra Bowen*  
DEBRA BOWEN  
SECRETARY OF STATE

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2013 JUN -5 A 11:51

OFFICE OF  
ADMINISTRATIVE LAW

NOTICE	REGULATIONS
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AGENCY WITH RULEMAKING AUTHORITY California Department of Public Health	AGENCY FILE NUMBER (if any) DPH-11-021
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**A. PUBLICATION OF NOTICE (Complete for publication in Notice Register)**

1. SUBJECT OF NOTICE Syringe Exchange Program (SEP) Certification	TITLE(S) 17	FIRST SECTION AFFECTED 7000	2. REQUESTED PUBLICATION DATE February 1, 2013
3. NOTICE TYPE <input checked="" type="checkbox"/> Notice re Proposed Regulatory Action <input type="checkbox"/> Other	4. AGENCY CONTACT PERSON Laurel Prior	TELEPHONE NUMBER (916) 440-7673	FAX NUMBER (Optional) (916) 440-5747
<b>OAL USE ONLY</b> <input type="checkbox"/> Approved as Submitted <input type="checkbox"/> Approved as Modified <input type="checkbox"/> Disapproved/Withdrawn	NOTICE REGISTER NUMBER <b>2013, 5-2</b>	PUBLICATION DATE <b>2/1/2013</b>	

**B. SUBMISSION OF REGULATIONS (Complete when submitting regulations)**

1a. SUBJECT OF REGULATION(S) Syringe Exchange Program (SEP) Certification	1b. ALL PREVIOUS RELATED OAL REGULATORY ACTION NUMBER(S)
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2. SPECIFY CALIFORNIA CODE OF REGULATIONS TITLE(S) AND SECTION(S) (Including title 26, if toxics related)	ADOPT 7000, 7002, 7004, 7006, 7008, 7010, 7012, 7014, 7016
	AMEND
	REPEAL
TITLE(S) 17	

3. TYPE OF FILING

<input checked="" type="checkbox"/> Regular Rulemaking (Gov. Code §11346)	<input type="checkbox"/> Certificate of Compliance: The agency officer named below certifies that this agency complied with the provisions of Gov. Code §§11346.2-11347.3 either before the emergency regulation was adopted or within the time period required by statute.	<input type="checkbox"/> Emergency Readopt (Gov. Code, §11346.1(h))	<input type="checkbox"/> Changes Without Regulatory Effect (Cal. Code Regs., title 1, §100)
<input type="checkbox"/> Resubmittal of disapproved or withdrawn nonemergency filing (Gov. Code §§11349.3, 11349.4)	<input type="checkbox"/> Resubmittal of disapproved or withdrawn emergency filing (Gov. Code, §11346.1)	<input type="checkbox"/> File & Print	<input type="checkbox"/> Print Only
<input type="checkbox"/> Emergency (Gov. Code, §11346.1(b))		<input type="checkbox"/> Other (Specify) _____	

4. ALL BEGINNING AND ENDING DATES OF AVAILABILITY OF MODIFIED REGULATIONS AND/OR MATERIAL ADDED TO THE RULEMAKING FILE (Cal. Code Regs. title 1, §44 and Gov. Code §11347.1)

5. EFFECTIVE DATE OF CHANGES (Gov. Code, §§ 11343.4, 11346.1(d); Cal. Code Regs., title 1, §100)

<input checked="" type="checkbox"/> Effective January 1, April 1, July 1, or October 1 (Gov. Code §11343.4(a))	<input type="checkbox"/> Effective on filing with Secretary of State	<input type="checkbox"/> §100 Changes Without Regulatory Effect	<input type="checkbox"/> Effective other (Specify) _____
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6. CHECK IF THESE REGULATIONS REQUIRE NOTICE TO, OR REVIEW, CONSULTATION, APPROVAL OR CONCURRENCE BY, ANOTHER AGENCY OR ENTITY

<input checked="" type="checkbox"/> Department of Finance (Form STD. 399) (SAM §6660)	<input type="checkbox"/> Fair Political Practices Commission	<input type="checkbox"/> State Fire Marshal
<input type="checkbox"/> Other (Specify) _____		

7. CONTACT PERSON Laurel Prior	TELEPHONE NUMBER (916) 440-7673	FAX NUMBER (Optional) (916) 440-5747	E-MAIL ADDRESS (Optional) lprior@cdph.ca.gov
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8. I certify that the attached copy of the regulation(s) is a true and correct copy of the regulation(s) identified on this form, that the information specified on this form is true and correct, and that I am the head of the agency taking this action, or a designee of the head of the agency, and am authorized to make this certification.

SIGNATURE OF AGENCY HEAD OR DESIGNEE <i>Belinda B. Whitsett</i>	DATE 5/23/2013
TYPED NAME AND TITLE OF SIGNATORY Belinda Whitsett, Acting Deputy Director and Chief Counsel, Office of Legal Services/CDPH	

For use by Office of Administrative Law (OAL) only

ENDORSED APPROVED

JUL 16 2013

Office of Administrative Law

**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 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, 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, Health and Safety Code; and 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 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 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 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 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 HIV Prevention Bulletin: Medical Advice for Persons Who Inject Illicit Drugs, May 9, 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 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 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.

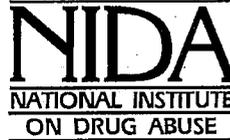
SEPs certified by the department must return a report to the department, postmarked or delivered by email by the anniversary date of certification each and every year of the program's operation under the department's certification. The report shall include:

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



May 9, 1997

## HIV PREVENTION BULLETIN: MEDICAL ADVICE FOR PERSONS WHO INJECT ILLICIT DRUGS

Dear Colleague:

Preventing drug use and providing substance abuse treatment for persons who inject illicit drugs are crucial to preventing many blood-borne infections, including human immunodeficiency virus (HIV). However, many drug users are not currently in substance abuse treatment programs because of multiple factors including the limited availability of these programs and the lack of readiness or willingness of some drug users to enter substance abuse treatment. Consequently, substantial numbers of drug users continue to inject drugs.

This bulletin summarizes new information on preventing transmission of HIV and other blood-borne infections among persons who inject drugs and updates prevention recommendations published in April 1993. <sup>\*1</sup> The findings of a 1995 workshop on the use of sterile syringes by persons who inject drugs and several recent publications <sup>2,3,4,5,6</sup> indicate that persons who inject drugs should use sterile syringes\*\* to prevent the transmission of HIV and other blood-borne infectious diseases. These conclusions should be considered by clinicians providing health care to persons who use or inject drugs and by public health professionals planning and carrying out HIV prevention programs for injection drug users (IDUs). Health professionals should inform IDUs that using sterile syringes is safer than reusing syringes, including syringes that have been disinfected with bleach. The information in this bulletin has been prepared for health professionals involved in programs serving persons who inject drugs. Separate educational materials will be prepared to inform drug injectors of these findings.

\* Issued jointly by the Centers for Disease Control and Prevention, the National Institute on Drug Abuse of the National Institutes of Health, and the Center for Substance Abuse Treatment of the Substance Abuse and Mental Health Services Administration.

\*\* The term "syringes" is used throughout this bulletin to refer to both syringes and needles.



## INJECTION DRUG USE AND THE TRANSMISSION OF HIV AND OTHER BLOOD-BORNE INFECTIONS

The reuse and "sharing" of blood-contaminated injection equipment and blood-contaminated dissolved drugs play substantial roles in the transmission of HIV,<sup>2</sup> hepatitis B virus (HBV), hepatitis C virus (HCV),<sup>7</sup> and other blood-borne infections. These infections cause illness and death among drug users, their sex partners, and, through mother-to-infant transmission, their children. More than one third (35%) of all AIDS cases reported in the United States in 1995 were directly or indirectly associated with injection drug use.<sup>8</sup>

Blood is introduced into needles and syringes at the start of every intravenous injection. The reuse of a blood-contaminated syringe by another drug injector (sometimes called "direct syringe sharing") carries a substantial risk of transmission of blood-borne infections, including HIV, HBV, and HCV. In addition, blood and blood-borne infections can be introduced into drug solutions by the use of blood-contaminated syringes to prepare drugs; the reuse of water; the reuse of bottle caps, spoons, or other containers ("spoons" and "cookers") used to dissolve drugs in water and to heat drug solutions; and the reuse of small pieces of cotton or cigarette filters ("cottons") used to filter out particles that could block the needle.<sup>9,10</sup> Multiperson use of contaminated water, dissolved drugs, and drug preparation equipment is sometimes called "indirect sharing."<sup>11</sup>

Because some "street" sellers of syringes repackage used syringes and sell them as sterile syringes,<sup>12</sup> persons who continue to inject drugs should obtain syringes from reliable sources of sterile syringes, such as pharmacies.

In addition to HIV, HBV, HCV and other blood-borne infections, persons who inject drugs are at risk of other serious infections.<sup>13</sup> Use of alcohol swabs to clean the injection site prior to injection has been shown to reduce the occurrence of cellulitis, injection site abscesses, and, possibly, endocarditis among persons who inject drugs.<sup>13,14</sup>

## CRITICAL IMPORTANCE OF PREVENTION AND TREATMENT OF DRUG DEPENDENCE

The risks of transmission of blood-borne illnesses are compelling reasons for strengthening public health and community efforts to help persons avoid starting drug injection and to help IDUs stop using drugs. Addiction is a major factor in the use of drugs such as heroin, cocaine, and amphetamines. While the recommendations in this bulletin will help reduce the individual and public health risks associated with injection drug use, the ultimate goals are to prevent at-risk individuals from initiating injection drug use and to help drug injectors stop drug injection through substance abuse treatment and recovery from addiction. For most persons who are addicted to drugs, admission to drug and alcohol treatment programs is a key step in reducing and/or stopping their drug use.

## A 1995 WORKSHOP AND RECENTLY PUBLISHED STUDIES AND RECOMMENDATIONS

On February 15-16, 1995, a workshop on the role of sterile syringes in the prevention of HIV transmission among drug users who continue to inject was held at Johns Hopkins University in Baltimore, Maryland. The workshop was sponsored by the Centers for Disease Control and Prevention (CDC), the Center for Substance Abuse Treatment (CSAT) of the Substance Abuse and Mental Health Services Administration (SAMHSA), the National Institute on Drug Abuse (NIDA) of the National Institutes of Health (NIH), and the Johns Hopkins University School of Hygiene and Public Health.

In September 1995, the findings and conclusions of a two-year National Academy of Sciences (NAS) study were published in a report entitled "Preventing HIV Transmission: The Role of Sterile Needles and Bleach."<sup>2</sup> Also in September 1995, the *Journal of Acquired Immune Deficiency Syndrome and Human Retrovirology* published reports of the evaluation of laws enacted in Connecticut in 1992 that allowed the purchase without a prescription and the legal possession of as many as 10 syringes.<sup>3,4</sup>

In 1996, the U.S. Preventive Services Task Force published guidelines recommending that drug users who continue to inject be advised to use sterile syringes and take other steps to prevent health problems associated with injecting drugs.<sup>5</sup> Also in 1996, the American Medical Association published a physician guide to HIV prevention that stated that primary care physicians can help their patients reduce HIV risk from injecting drugs by encouraging them to "Use a new needle and syringe each time drugs are injected."<sup>6</sup>

Based on discussions during the 1995 Johns Hopkins workshop and the findings from these studies, the new recommendations for drug users who continue to inject drugs include: (1) substance abuse treatment to reduce or eliminate drug injection; (2) the use of sterile syringes to reduce the spread of blood-borne infections; (3) the use of new, ideally, sterile water and equipment to prepare drugs; and (4) adequate disinfection of the injection site by drug users to prevent local infection and endocarditis.

## IMPLICATIONS OF NEW INFORMATION ON HIV RISKS ASSOCIATED WITH DRUG INJECTION

To minimize the risk of disease transmission, persons who continue to inject drugs should be advised to always use sterile injection equipment; warned never to reuse needles, syringes, and other injection equipment; and told that using syringes that have been cleaned with bleach or other disinfectant is not as safe as using new, sterile syringes. The NAS report stated: "For injection drug users who cannot or will not stop injecting drugs, the once-only use of sterile needles and syringes remains the safest, most effective approach for limiting HIV transmission."<sup>2</sup> CDC recommends that all syringes used for parenteral injections be sterile.<sup>15</sup> Drug preparation equipment, such as "cottons," "cookers," water, and syringes should not be reused because they are usually

contaminated with blood. Most syringes and needles used by drug injectors were not designed for reuse. Boiling needles and syringes for 15 minutes between uses can disinfect the equipment. However, boiling may alter the shape and functioning of the plastic syringes widely used by drug injectors in the United States. Disinfecting previously used needles and syringes with bleach (or other chemicals) can reduce the risk of HIV transmission, but using disinfected syringes is not as safe as using a new, sterile needle and syringe.<sup>16</sup> The NAS report found that bleach disinfection (using the procedures described in the April 1993 NIDA, CSAT, CDC bulletin on bleach) is likely to be effective but ". . . is clearly an intervention to be used when injection drug users have no safer alternatives."<sup>2</sup>

## PROVISIONAL RECOMMENDATIONS TO DRUG USERS WHO CONTINUE TO INJECT

Health care workers involved in programs that serve drug users should communicate the following recommendations to drug users who continue to inject. Adhering to these drug preparation and injection procedures will reduce the public health and individual health risks associated with drug injection for both drug users and other persons in their communities.

Persons who inject drugs should be regularly counseled to:

- I. Stop using and injecting drugs.
- II. Enter and complete substance abuse treatment, including relapse prevention.
- III. Take the following steps to reduce personal and public health risks, if they continue to inject drugs:
  - Never reuse or "share" syringes, water, or drug preparation equipment.
  - Use only syringes obtained from a reliable source (e.g., pharmacies).
  - Use a new, sterile syringe to prepare and inject drugs.
  - If possible, use sterile water to prepare drugs; otherwise use clean water from a reliable source (such as fresh tap water).
  - Use a new or disinfected container ("cooker") and a new filter ("cotton") to prepare drugs.
  - Clean the injection site prior to injection with a new alcohol swab.
  - Safely dispose of syringes after one use.

The availability of new, sterile syringes varies, depending on state and local regulations regarding the sale and possession of syringes and on other factors, such as the existence of syringe exchange programs sponsored by local HIV prevention organizations.<sup>17</sup> If new, sterile syringes and other drug preparation and injection equipment are not available, then previously used equipment should be boiled or

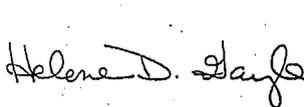
disinfected with bleach using the methods recommended in the April 1993 bulletin.<sup>1</sup>

In addition, drug users should be provided information on how to prevent HIV transmission through sexual contact and, for women, information on reducing the risk of mother-to-infant HIV transmission.

## FOR MORE INFORMATION

For more information or to comment on this bulletin, please contact the following staff members of the organizations releasing this bulletin: CDC - Dr. T. Stephen Jones at 404-639-5200 (fax 404-639-5260); HRSA - Dr. A. Russell Gerber at 301-443-4588 (fax 301-443-1551); NIDA - Dr. Steven W. Gust at 301-443-6480 (fax 301-443-9582); and SAMHSA - Mr. Adolfo Mata at 301-443-5305 (fax 301-443-3817).

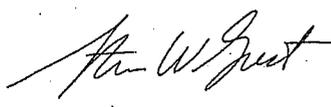
Sincerely yours,



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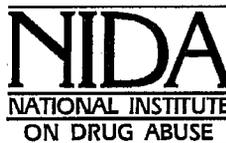


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Single copies of the publications marked with \*\* and the executive summary of the National Academy of Sciences report are available at no cost from the CDC National AIDS Clearinghouse (1-800-458-5231).

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