10-144 DEPARTMENT OF HUMAN SERVICES

Maine Center for Disease Control and Prevention

Chapter 252: RULES GOVERNING THE IMPLEMENTATION OF HYPODERMIC APPARATUS EXCHANGE PROGRAMS

Pursuant to its statutory authority (22 M.R.S.A. §1341), the Department of Health and Human Services, Maine Center for Disease Control and Prevention (hereinafter “Maine CDC”) adopts the following rules governing the establishment of hypodermic apparatus exchange programs (hereinafter “Needle Exchange Programs”) in order to prevent the transmission of the HIV virus and other blood borne pathogens.

SECTION I. General Definitions

The following terms used in these regulations shall have the meanings specified.

A. Applicant: means each individual who signs the application for certification of a Needle Exchange Program. The applicant must be the individual who has the ultimate responsibility for ensuring that a Program operates in compliance with these regulations.

B. Administrator: is a person having the authority and responsibility for the operation of the Needle Exchange Program and for staff performance.

C. Certification Review Team: may consist of representatives from the following groups, or their appointees: the HIV/STD program and/or the Epidemiology Program of the Maine CDC; the Office of Substance Abuse; the Maine Association of Chiefs of Police; the Maine Department of Public Safety; the Bureau of Labor Standards; the Maine Drug Enforcement Agency; HIV Prevention Service Providers and Consumer representatives. The Director of the Maine CDC or his/her designee will appoint appropriate members of the Certification Review Team for the purpose of reviewing applications for certification of Needle Exchange Programs.

D. Consumer: is a person eighteen (18) years of age or older who receives Needle Exchange services.

E. Consumer Education and Referral Plan: means a written plan for the education of consumers on: the prevention and treatment of HIV, Viral Hepatitis and other blood borne pathogens, substance abuse treatment and a written plan for how referrals to appropriate services will be made. The plan will include a list of referrals to substance abuse treatment providers, social service providers, and HIV and Viral Hepatitis service and

treatment providers available in the area the Needle Exchange Program serves.

F. Consumer Confidentiality Protocol: a written protocol, which strictly limits the disclosure of consumer identification information and consumer HIV status.

G. Commissioner: means the person who heads the Department of Health and Human Services.

H. Department: means the Maine Department of Health and Human Services.

I. Documented: means written, signed and dated.

J. Hypodermic Apparatus: a syringe used with a hollow needle for the injection of material beneath the skin.

K. Needle Disposal Plan: means a written plan which describes a coordinated program for the terminal disposal and incineration of used syringes in compliance with the Occupational Safety and Health Administration's guidelines regarding Occupational Exposure to Blood borne Pathogens and the Safe Discarding and Containment of Contaminated Sharps pursuant to 29 C.F.R.§1910.1030, 56 FR 64175, 57 FR 12717, 57 FR 29206, 66 FR 5318, 5325, 71 FR 16669, 16672-73, and 73 FR 75568, 75586. A copy of these guidelines is available from the U.S. Department of Labor, Occupational Health and Safety Administration.

L. New Enrollee: is considered a person eighteen (18) years of age or older who enrolls into a Needle Exchange Program for the first time. If a consumer exits or is disenrolled from a needle exchange program and re-enrolls at a later time he/she will be considered a "New Enrollee."

M. Occupational Safety and Health Administration: means (OSHA).

N. Policies: are written standards that govern the provisions of Needle Exchange services.

O. Policy and Procedures Manual: is a written manual detailing the program's confidentiality safeguards, safety procedures, blood borne pathogen exposure protocols, referral services for consumers, complaint procedures, consumer enrollment and termination guidelines, procedures for implementing all program operating requirements listed in Section II, E, Operating Requirements and all other policies and procedures necessary for the safe and lawful operation of a Needle Exchange Program.

P. Procedures: are specific, written directions to accomplish policies.

Q. Program: A Certified Needle Exchange Program including all staff.

R. Program Data Collection Protocols: means written data collection instruments for recording the following information: demographic information of all consumers including age, race, ethnicity, sex and gender; the number of syringes collected, distributed and disposed of at each site; the number of consumers exchanging syringes; the number of referrals made to HIV service and treatment providers; the number of consumers who received an HIV test through the Administrator; the number of referrals made to substance abuse treatment providers; the number of new enrollees receiving clean syringes without exchange at enrollment, the number of syringes distributed to new enrollees without exchange at enrollment. This data shall be provided to the Maine CDC annually, or as often as the Maine CDC may deem necessary.

S. Protocols: are written guidelines that define the limits and extent of practice of the staff of a Needle Exchange Program.

T. Proprietary Agency: means a private profit-making agency licensed by the state to conduct business in Maine.

U. Public Notice: means written notice to law enforcement, substance abuse treatment providers, HIV prevention service providers, and local governing bodies of a Program’s intent to establish and maintain an HIV prevention syringe exchange program in a community. Part of the notice shall include an explanation of the HIV prevention goals of the program, and an invitation to participate in the implementation of the local Program.

V. Signature: means at least the first initial and full surname and title (for example, S. Jones, R.N.) of a person, legibly written, generated by computer with authorization safeguards, or communicated by a facsimile communications system (FAX) followed by the original.

W. Site: means the location (s) or venue(s) where Needle Exchange services are offered to consumers.

X. Staff: means anyone involved in providing Needle Exchange services on behalf of a Program.

Y. Staff Training Plan: means a written plan in compliance with the Occupational Safety and Health Administration's guidelines regarding Occupational Exposure to Blood borne Pathogens and the Safe Discarding and Containment of Contaminated Sharps pursuant to 29 C.F.R.§1910.1030, 56 FR 64175, 57 FR 12717, 57 FR 29206, 66 FR 5318, 5325, 71 FR 16669, 16672-73, and 73 FR 75568, 75586, and the Maine CDC Privacy Policy dated July 1, 2006. A copy of the Maine CDC Privacy Policy is available through the Maine CDC. Staff training will consist of education in confidentiality protocols and blood borne pathogen infection control including post-exposure protocols. Staff training will also include HIV prevention education, substance abuse treatment education, and any and all training necessary to the safe and lawful operation of a Needle Exchange Program.

Z. Staff List: means an up-to-date written list of the names, addresses, date of birth, and social security numbers of all staff involved in a Needle Exchange Program which shall be maintained at the Administrator's office.

SECTION II. Certification Application Procedures

A. Filing of Application

Any person or other entity desiring certification to engage in a Needle Exchange Program shall, prior to the commencement of such operation, file an application for certification with the Department. Applications submitted on behalf of a corporation or association shall be made by any two officers thereof or by the administrator of the Program. Applicants must submit five copies of the full application. All applicants shall comply with the rules and regulations adopted pursuant to Title 22 M.R.S.A. §2141 et seq.

The Certification Review Team will review the application and within thirty (30) working days thereof forward their advisory recommendations to the Director of the Maine CDC. The Director will issue a final decision regarding certification within ten (10) working days of receipt of the Review Team's recommendations. The Director shall send notice of program certification to the Maine Department of Public Safety, the Maine Drug Enforcement Agency and to appropriate law enforcement agencies, within ten (10) working days of certification or change in certification.

B. Contents of Application

Each application shall contain:

1. The name by which the Program is to be legally known and the name under which it shall be doing business.

2. For proprietary corporations: the full name and address of each person, firm or corporation having (directly or indirectly) an ownership interest of 5% or more in the Program.

3. For business entities with one owner or business partnerships: the full name and address of each partner.

4. For not-for-profit organizations: the full name and address of the President of the Board of Directors or appropriate municipal government representative.

5. The name, home address, home telephone number and office telephone number of the individual designated by the applicant as the administrator of the Program.

6. A description of all facilities utilized by the Program including all locales and venue(s) for mobile service. This will include the address (es), telephone number(s), and name of the owner(s) of all buildings utilized by the Program. All branches and sub units must be identified by address (es), telephone number(s), and identifying names.

7. The names, addresses, and dates of birth of all staff of a Needle Exchange Program.

8. The hours of operation for all branches, subunits and locales, including mobile service units.

C. Additional Application Information:

Each application must also include:

1. A copy of a Program’s Consumer Confidentiality Protocol.

2. A copy of a Program’s Consumer Education and Referral Plan.

3. A copy of a Program’s Needle Disposal Plan.

4. A copy of a Program’s Staff Training Plan.

5. A copy of a Program’s Data Collection Protocols.

6. Proof of Public Notice.

7. A copy of the Program's Policy and Procedures Manual.

D. Suitability of Applicant

In acting upon any application for certification or recertification, the Department shall determine the suitability of the applicant to run a Needle Exchange Program.

1. A determination of suitability shall require the applicant to demonstrate willingness and ability to operate and manage the Program in compliance with these regulations and all relevant laws. In making this determination, the Department shall consider each of the following factors:

   a. Record and reputation for lawful conduct in business and personal affairs of the corporation, the program administrator and the management staff over the previous five (5) years (including, but not limited to, a criminal conviction).

   b. Information which relates to the ability to comply with all applicable laws and regulations.

   c. Any information reasonably related to the ability to provide safe services to the public.

   d. Management and oversight experience, including the capacity to manage the general operations and staff of the Program for which the Certification is sought.

   e. Experience in the field of health care, public health, social services or areas related to the provision of HIV or substance abuse prevention and treatment.

   f. Conduct which demonstrates an understanding of, and compliance with consumers' rights and confidentiality.

E. Operating Requirements

In operating a Needle Exchange Program:

1. Programs must adhere to a strict one-for-one syringe exchange distribution policy and shall not distribute syringes without receiving a used syringe in return. An exceptions must be made for a new enrollee who has no needles for the initial exchange.

2. Consumers must enroll in the needle exchange program to receive needle exchange services.

3. Programs shall not knowingly distribute syringes to persons less than 18 years of age.

4. Programs shall comply with all applicable Maine Statutes, rules, regulations

5. Programs may furnish clean syringes to a new enrollee upon the condition the enrollee exchanges those needles, once used, for new needles or disposal.

6. Programs shall not accept remuneration from consumers for delivering Needle Exchange services.

7. Program staff and their representatives shall carry identification and a copy of their program's certification document while conducting program business All persons operating a mobile unit must carry a copy of the Program's certification while conducting program business.

8. The Administrator shall assure that consumer enrollment guidelines, which describe the laws and rules applicable to Needle Exchange Services, be readily available to all consumers.

9. Upon request by a consumer, Programs must offer a means of confidential enrollment identification in order to avoid detention for the transport of used syringes which contain trace elements of controlled substances or scheduled drugs.

F. Notification Obligation of Program

1. Each Program will notify the Maine CDC in writing of any changes in:

   a. Ownership.

b. Relocation or change of the Program address and telephone number.

c. Administrator, management or staff of the program.

d. Change in operating hours.

2. Each program will notify the Maine CDC of all data gathered for the prior year using the Program Data Collection Protocol. The Maine CDC must receive this data by November 1 of each and every year of the Program's operation.

3. Upon written request by local law enforcement each program will provide a staff list within five (5) days.

G. Posting of Certification

The Certification granted by the Department shall be conspicuously posted in the offices of the Administrator of a Program.

H. Refusal to Certify

The Department shall refuse certification of an applicant if it finds that any or all of the following conditions exist:

1. The Department finds that the information submitted in the Program's application is incorrect or incomplete;

2. The applicant does not meet all the requirements of applicable laws and regulations;

3. The applicant or its staff has violated applicable laws, rules, and regulations in the five (5) years preceding date of application.

I. Suspension or Revocation of Certification

1. The Department may suspend or revoke any certification issued pursuant to Title 22 M.R.S.A. ch. 252-A, §1341 for:

a. Violation of applicable laws, regulation and rules; or

b. Conduct committing, permitting, aiding or abetting any illegal practices in the operation of a Needle Exchange Program; or

c. Conduct detrimental to the welfare of the consumers of the Needle Exchange services

2. Written notice of the Department's decision shall be mailed to the program's last known address.

3. Upon suspension or revocation of a certification, the certification shall be immediately surrendered to the Department and all operations shall cease.

4. The Maine CDC shall inform law enforcement agencies and representatives of the Certification Review Team of the revocations of, or changes in, Program certification within ten days.

J. Right of Inspection

Any duly designated employee of the Department shall have the right to enter upon and into the premises of any certified Needle Exchange Program. These employees can inspect relevant program documents to determine whether the Program is in compliance with these rules and regulations. Inspections may be announced or unannounced at the sole discretion of the certifying authority.

K. Length of Certification

A Certification shall be considered valid until suspended or revoked by the Maine CDC.

l. Appeals Procedure

Any person aggrieved by the Department's decision to deny, suspend or revoke certification to a program may request a hearing as provided by the Maine Administrative Procedures Act, Title 5 M.R.S.A. § 9051, et seq. A request for a hearing must be made in writing within thirty (30) days of the date that the Department's decision was issued. The request for hearing must be made in writing to the Director of the Maine CDC and must state clearly the reasons for the request. Hearings will be conducted pursuant to the rules of the Office of Administrative Hearings, as set forth in the Administrative Hearing Manual and in conformity with the Administrative Procedures Act, Title 5 M.R.S.A. § 8001 et seq. Any person or party dissatisfied with the Administrative Hearings Officer's decision has the right of Judicial Review under Title 5 M.R.S.A. § 11001 et seq. and Rule 80C of the Maine Rules of Civil Procedure.

M. Records and Review

The Department shall be afforded full access to, and the right to examine and copy, either manually or by photocopy, all records, documents and reports required to be kept by a program under these regulations, at no expense to the Department.

N. Compliance with All State and Federal Regulations

The Needle Exchange Program and its staff must operate and furnish services in compliance with all applicable federal and state regulations.

O. Change in Ownership of the Needle Exchange Program

No certification shall be assigned or transferred.

The statutory authority of the Department to adopt these rules is P.L. 2007, c. 346, Sec. A-1, codified at 22 M.R.S.A. §1341(Supp.2008).