**STATE OF MAINE**

**SYRINGE SERVICES PROGRAMS RULE**



**10-144 Code of Maine Rules**

**Chapter 252**

**Department of Health and Human Services**

**Effective Date: November 30, 2022**

**10-144 DEPARTMENT OF HEALTH AND HUMAN SERVICES**

 **MAINE CENTER FOR DISEASE CONTROL AND PREVENTION**

**Chapter 252: SYRINGE SERVICES PROGRAMS RULE**

**Summary**: Pursuant to the authority granted by 22 MRS ch. 252-A §1341, the Maine Center for Disease Control and Prevention (Maine CDC) establishes hypodermic apparatus exchange programs (herein known as Syringe Services Programs) to ensure greater protection of health and safety of Consumers who inject drugs, by governing programs that will offer new syringes, education on disposal of used syringes, resources for treatment, and help prevent human immunodeficiency virus (HIV) and other blood borne pathogens caused by syringe re-use.

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**SECTION 1. GENERAL DEFINITIONS**

A. **Definitions**. As used in this rule, the following terms have the following meanings:

 1. **Applicant** means each individual who signs the application for certification of a Syringe Services Program (SSP or Program). The applicant must be the individual who has the ultimate responsibility for ensuring that a Program operates in compliance with this rule.

 2. **Administrator** means a person having the authority and responsibility for the operation of the Syringe Services Program and for staff performance.

 3. **Certification Review Team** means the stakeholder group charged with reviewing SSP applications that may consist of representatives from the following groups, or their appointees: the HIV/STD program and/or the Epidemiology Program of the Department of Health and Human Services Maine Center for Disease Control and Prevention (Maine CDC); the Department of Health and Human Services Office of Behavioral Health; the Maine Association of Chiefs of Police; the Maine Department of Public Safety; the Maine Department of Labor 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 Syringe Services Programs.

 4. **Consumer** means a person eighteen (18) years of age or older who receives Syringe Services.

 5. **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 use disorder treatment and a written plan for how referrals to appropriate services will be made. The plan will include a list of referrals to substance use disorder treatment providers, social service providers, and HIV and Viral Hepatitis service and treatment providers available in the area the Syringe Services Program serves.

 6. **Consumer Confidentiality Protocol** means a written protocol which strictly limits the disclosure of Consumer identification information and Consumer HIV status.

 7. **Commissioner** means the person who heads the Department of Health and Human Services.

 8. **Department** means the Maine Department of Health and Human Services Maine Center for Disease Control and Prevention (Maine CDC).

 9. **Documented** means written, signed and dated.

 10. **Exchange Event** means the Consumer’s visit to a Syringe Services Program to exchange one or more used syringes for new syringes or to receive any other Syringe Services.

 11. **Hypodermic Apparatus** means a syringe used with a hollow needle for the injection of material beneath the skin.

 12. **Needle or Syringe 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 under 29 CFR §1910.1030.

 13. **New Enrollee** means a person eighteen (18) years of age or older who enrolls into a Syringe Services Program for the first time. If a Consumer exits or is disenrolled from a Syringe Services Program and re-enrolls at a later time he/she will be considered a “New Enrollee.”

 14. **Occupational Safety and Health Administration** means (OSHA).

 15. **Policies** means written standards that govern the provisions of Syringe Services.

 16. **Policy and Procedures Manual** means the 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 2, E, (Operating Requirements) and all other policies and procedures necessary for the safe and lawful operation of a Syringe Services Program.

 17. **Procedures** means the specific, written directions to accomplish policies.

 18. **Program** means a Certified Syringe Services Program including all staff.

 19. **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 receiving syringe services; 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 use disorder treatment providers; the number of new enrollees receiving new syringes without exchange at enrollment; and the number of syringes distributed to new enrollees without exchange at enrollment. This data must be provided to the Maine CDC annually, or as often as the Maine CDC may deem necessary.

 20. **Protocols** means the written guidelines that define the limits and extent of practice of the staff of a Syringe Services Program.

 21. **Public Notice** means written notice to law enforcement, substance use disorder treatment providers, HIV prevention service providers, and local governing bodies of a Program’s intent to establish and maintain an HIV prevention Syringe Services Program in a community, including an explanation of the HIV prevention goals of the Program and an invitation to participate in the implementation of the local Program.

 22. **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.

 23. **Site** means the location (s) or venue(s) where Syringe Services are offered to consumers.

 24. **Staff** means anyone involved in providing Syringe Services on behalf of a Program.

 25. **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 under 29 C.F.R. §1910.1030 and the Maine CDC Privacy Policy..

 26. **Staff List** means an up-to-date written list of the names, addresses, and dates of birth of all staff involved in a Syringe Services Program which must be maintained at the Administrator’s office.

 27. **Syringe** means the same as “hypodermic apparatus” as that term is used in 22 MRS §1341 and is defined at Section 1(11)) of this rule.

 28. **Syringe** **Services** means “hypodermic apparatus exchange” as defined in 22 MRS §1341 and may include, but is not limited to, receiving new syringes, referrals, and educational materials about prevention, treatment, and proper disposal of syringes.

**SECTION 2. Certification Application Procedures**

 A. **Filing of Application**

 Any person or other entity desiring certification to operate a Syringe Services Program must, prior to the commencement of such operation, file an application for certification with the Department. Applications submitted on behalf of a corporation or association must be made by any two officers thereof or by the Administrator of the Program. Applicants must submit one copy of the full application. Previously certified applicants who relocate to a new site within their current geographic area of certification must submit all information related to Section 2(B), to the Department, in lieu of a full application.

 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 or designee must send notice of program certification to the Maine Department of Public Safety, the Maine Drug Enforcement Agency and appropriate law enforcement agencies, within ten (10) working days of certification or change in certification.

 B. **Contents of Application**

 Each application must contain:

 1. The name by which the Program is to be legally known and the name under which it will 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 description must include the address (es), telephone number(s), and name of the owner(s) of all buildings utilized by the Program. All branches and subunits must be identified by address (es), telephone number(s), and identifying names.

1. The names, addresses, and dates of birth of all staff of a Syringe Services Program.
2. The hours of operation for all branches, subunits and locales if mobile service.
3. An approved letter of registration with a valid biomedical waste generator number from the Maine Department of Environmental Protection, to demonstrate compliance with 38 MRS §1319-O(3) and any applicable rules for the handling and disposal of biomedical waste.

 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 or Syringe 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 SSP certification or recertification, the Department will determine the suitability of the applicant to operate a Syringe Services Program.

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

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

 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 use disorder prevention and treatment.

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

 E. **Operating Requirements**

 In operating a Syringe Services Program:

 1. Programs must adhere to a distribution policy that allows the one-for-one exchange of a used syringe for each new syringe provided to the Consumer. In instances where the Consumer cannot offer a used syringe to be exchanged, a Program may provide a Consumer with new syringes as needed, but may not exceed 100 syringes per Consumer per encounter.

 2. The Program may further limit the number of syringes provided to each Consumer based on its Policy and Procedures Manual, defined in Section 1(A)(16) and referenced in Section 2(C) of this rule.

 3. Consumers must enroll in the Syringe Services Program to receive Syringe Services.

 4. Enrolled Consumers may receive Syringe Services from any certified Program via mobile site or fixed site, regardless of where the Consumer resides.

 5. Programs may not knowingly distribute syringes to persons less than 18 years of age.

 6. Programs must comply with all applicable Maine Statutes, rules, and regulations.

 7. Programs may furnish new syringes to a new enrollee when the enrollee exchanges used syringes for new syringes or disposal. However, a syringe exchange is not required by this rule.

 8. Programs may not accept remuneration from Consumers for delivering Syringe Services.

 9. Program staff and their representatives must carry identification and a copy of their program’s certification document while conducting program business. All mobile units must carry a copy of the Certification while conducting Program business.

 10. Program Consumer enrollment guidelines must require notifying all Consumers regarding rules and laws applicable to Syringe Services.

 11. Staff hired at the Syringe Services Program must be trained in confidentiality protocols and blood borne pathogen infection control including post-exposure protocols. Staff training must also include HIV prevention education, substance use disorder treatment education, and any and all training necessary for the safe and lawful operation of a Syringe Services Program.

 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. Operating hours; and

 e. Policy and Procedures Manual.

 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 15 of each and every year of the Program’s operation.

 G. **Posting of Certification**

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

 H. **Refusal to Certify**

 The Department will 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 laws, rules, and regulations pertaining to or in connection with the operation of a Syringe Services Program 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 22 MRS 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 Syringe Services Program; or

 c. Conduct detrimental to the welfare of the Consumers of the Syringe Services

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

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

 4. The Maine CDC will 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 must be permitted to enter upon and into the premises of any certified Syringe Services Program. These employees may 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 Department.

 K. **Length of Certification**

 The Department will certify Programs for a period of up to five (5) years, pursuant to 22 MRS §1341(2)(H). The Department will renew Program certification every five years, provided it determines continued compliance, upon the Program’s application for renewal. A Certification will be considered valid until it expires or is 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 or SSP applicant may request a hearing as provided by the *Maine Administrative Procedure Act*, 5 MRS §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 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 Procedure Act*, 5 MRS §8001 *et seq*. Any person or party dissatisfied with the Administrative Hearings Officer’s decision has the right of Judicial Review under 5 MRS §11001 *et seq*. and Rule 80C of the *Maine Rules of Civil Procedure*.

 M. **Records and Review**

 The Department must be afforded full access to, and the right to examine and copy, all records, documents and reports required to be kept by a Program under this rule, at no expense to the Department.

 N. **Compliance with All State and Federal Regulations**

 The Syringe Services Program and its staff must operate and furnish services in compliance with all applicable federal and State regulations.

 O. **Change in Ownership of the Syringe Services Program**

 No certification may be assigned or transferred.

STATUTORY AUTHORITY:

 22 MRS ch. 252-A §1341; PL 2021 ch. 434 and 545

EFFECTIVE DATE:

 Forms specify July 15, 1998; filing received June 26, 1998 – as “Rules Governing the Implementation of Hypodermic Apparatus Exchange Programs”

AMENDED:

 July 1, 2009 – filing 2009-241

 September 1, 2022 – filing 2022-168 (EMERGENCY) – as “Syringe Services Programs Rule”

 November 30, 2022 - filing 2022-229