Syringe Service Programs Application Guidance

Maine Center for Disease Prevention and Control
Infectious Disease Prevention Program

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Introduction

In order to operate a syringe service program (SSP) in the State of Maine, the person or other entity wishing to operate the program must be certified by the Maine Center for Disease Control and Prevention (Maine CDC). Maine CDC may certify syringe service programs that meet the requirements established by state law Title 22 M.R.S.A. ch 252 –A, &1341. Pursuant to 22 M.R.S.A. ch 252 –A, &1341, Maine CDC may not limit the number of hypodermic apparatuses (syringes) provided by the programs to participants. The Maine CDC may not limit the number of hypodermic apparatuses (syringes) that participants served by the programs may legally possess, transport or exchange. According to these rules, any person or other entity desiring certification to engage in a syringe service program shall, prior to the commencement of such operation, file an application for certification with the Maine CDC. To assist with the application process, the Maine CDC has issued the following guidance on how to become a certified syringe service program. Please include in your application, all information outlined in this guidance. For more information, please contact the Maine CDC at 800-821-5821 and ask to speak with someone in the Infectious Disease Prevention Program regarding Syringe Service Programs.

Section I: Certification Application Procedures

A. Filing an Application

To apply for certification, an application must be filed with the Maine CDC, Infectious Disease Prevention Program. Applications submitted on behalf of a corporation or association shall be made by any two officers or by the administrator of the program. Please submit applications via email to Jeff Caulfield, the Viral Hepatitis Prevention Coordinator at jeff.caulfield@maine.gov. All applicants must comply with the rules and regulations adopted pursuant to Title 22 M.R.S.A. § 1341.

The Certification Review Team, a team consisting of representatives from various groups or their appointees, grants certification. Such groups may include, but are not limited to, the Infectious Disease Prevention Program and/or the Infectious Disease 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 to review applications for certification of Syringe Service Programs.

The Certification Review Team will grant certification to organizations based on a formal review process. The Team will use the "Rules Governing the Implementation of Hypodermic Apparatus Exchange Programs" as well as an internal checklist to review the applications. The Team will review the applications within thirty (30) working days and 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 Team's recommendations. The Director will send notice of program certification to the Maine Department of Public Safety, the Maine Drug Enforcement Agency and to appropriate law enforcement and political agencies, within ten (10) working days of certification or change in certification.

It is the job of the Certification Review Team to ensure that applications for certification are complete and thorough. The Team has the right to approve the application, not approve the application, ask for more information and/or make recommendations for change(s). Inclusion of all the information requested in this guidance does not ensure certification; however, this information is required of a complete application.

At the end of this document, Section II: Definitions, explains some of the key terms used in this document. In addition, to help ensure that applicants have included all necessary information, please refer to the Application Checklist (see Appendix A). This checklist is a quick and easy way to be sure that all of the necessary information has been included in the application.

B. Contents of Application

Each application shall contain:

Name of the Syringe Service Program
Include the name by which the Program is to be legally known and the name under which it will be doing business.

Organization Identification
Identify the organization type and include the additional information requested below. Please note that you must identify only ONE type of organization and provide information for that type only.

> *Proprietary corporation*: include 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.
> *Business entity:* include the full name and address of each partner.
> *Not-for-profit:* include the full name and address of the President of the Board of Directors or appropriate municipal government representative.

Administrator of the Program
Each Program must designate an Administrator. The Administrator is the person having the authority and responsibility for the operation of the Syringe Service Program and for staff performance. Include the name, home address, home telephone number and office telephone number of the person designated by the applicant as the Administrator.

Description of Facilities
Include a description of all facilities used by the Program including, all locales and venues for mobile service. Please include all 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 name(s). Additionally, include a brief description of the facility or location. Include hours of operation for all branches, subunits and locales if mobile service. Some questions to consider answering might be: Where will consumers park? What does the location look like (layout of office space or location)? Where is the physical location of the Syringe Service Program within the agency? Will consumers be required to check-in with a receptionist upon entering the building? How is privacy provided for participants? Where will participants and Program staff meet?

Organizational Structure
Provide an organizational chart to include syringe service program positions and other key organizational positions relevant to the operation of the SSP e.g. Executive Director, Director of Finance. You do not need to provide staff names.

C. Additional Application Information

Each application must also contain:

Consumer Confidentiality Protocol

A copy of the consumer confidentiality protocol must be included in the application. The protocol must be a written document that clearly limits the disclosure of confidential information, including, but not limited to, client information, family information, HIV or hepatitis status, medical diagnosis, or other characteristics of the case. This section should specify what information is to be kept confidential, how confidentiality will be maintained and a description of specific situations, if any, when confidentiality cannot be maintained. Finally, this section should include a description of the policy should a breach of confidentiality occur.

Consumer Education and Referral Plan

A copy of the Program's Consumer Education and Referral Plan must be included in the application. This plan should describe the education provided to consumers on the prevention and treatment of HIV, hepatitis and other blood borne pathogens, as well as on substance abuse treatment centers. Describe how and when this education will occur. Additionally, a referral plan must be submitted, including a list of substance use disorder treatment providers, HIV and hepatitis testing and treatment providers, and other social service providers. The plan should detail how a referral would be implemented and documented.

Syringe Disposal Plan

A copy of the Program's Syringe Disposal Plan must be included in the application. The plan must detail how syringes, both used and unused, will be stored, transported for exchange, collected, disposed of and shipped. Be sure that the Program's guideline for handling syringes is compliant with Occupational Safety and Health Administration (OSHA) guidelines regarding Occupational Exposure to Blood borne Pathogens and the Safe Discarding and Containment of Contaminated Sharps under 29 C.F.R. § 1910.1030. Information on these guidelines can be found at www.osha.gov. Additionally, staff at the Maine CDC can connect agencies with an OSHA representative. This representative may be able to provide technical assistance to agencies trying to interpret OSHA guidelines.

Staff Training Plan

A copy of the Program's Staff Training Plan must be included in the application. When applicable, this written plan must meet all OSHA guidelines regarding Occupational Exposure to Blood Borne Pathogens and the Safe Discarding and Containment of Contaminated Sharps under 29 C.F.R. § 1910.1030. The plan should be as specific as possible and, minimally, include training on confidentiality protocols, blood borne pathogen infection control including detailed post-exposure protocols, HIV and hepatitis B & C prevention, substance use disorder treatment, the referral process and any and all training necessary for the safe and lawful operation of the Program. Include a timeline for training any new staff. Protocols for ensuring adequate staff knowledge (i.e. pre/post-test) and means of verifying training must be included.

Data Collection Protocols

A copy of the Program's Data Collection Protocols must be included in the application. The protocols must describe how information will be collected and recorded regarding the number of syringes collected, distributed and disposed of at each site, the number of consumers exchanging syringes, the number of referrals made to support services (such as HIV & hepatitis testing, treatment, substance use disorder treatment, financial assistance, food and housing support). Include who will be responsible for collecting the information, how it will be collected and who will be responsible for making sure it is collected correctly.

Data on the number of syringes collected, distributed and disposed of at each site, the number of consumers enrolled in the Program and the number of referrals and type of referral made must be provided annually to the Maine CDC, or as often as the Maine CDC deems necessary.

Proof of Public Notice

Any person(s) wishing to start a Syringe Service Program must provide community stakeholders with written, public notice of the intent to establish and maintain a Syringe Service Program in a given area. Written, public notice must be given to law enforcement, substance use disorder treatment providers, HIV & hepatitis prevention service providers, and local governing bodies, of a Program's intent to establish and maintain a Syringe Service Program in a community. The letter must include an explanation of the program's goals and an invitation for community stakeholders to participate in the implementation of the Program. Include a copy of the public notice letter in the application. A certified letter must be sent to all towns within the Program's service area with populations exceeding 3,000. All towns within the Program's service area with populations of less than 3,000 must also be notified; however, these towns may be sent a letter via regular mail. A copy of the receipt of delivery on all certified letters must be included with the application for certification.

Policy and Procedures Manual

A copy of the Syringe Service Program's Policy and Procedures Manual must be included in the application. A policy and procedures Manual is a written manual detailing the Program's operations. This document should provide the reader with a comprehensive understanding of the entire Syringe Service Program. In order to provide the reader with this comprehensive understanding, it may be necessary to include copies of documents developed to meet previous requirements in this guidance, such as the Syringe Disposal Plan. Remember the Policy and Procedures Manual will be the document used at your agency to operate the Syringe Service Program; therefore, it must include **ALL** information relevant to Program operation.

This written manual must detail the Program's:

- Confidentiality safeguards – Explain how the confidentiality of Program participants will be safeguarded and under what circumstances, if any, confidentiality will not/cannot be maintained.

  Note: It is possible that this section of the manual will closely mirror the Consumer Confidentiality Protocol.

- Safety procedures – Describe what measures will be taken to ensure the safety

of both staff and clients. Provide separate strategies for each group. Safety procedures, in this sense, do not refer to blood borne pathogen safety strategies, but rather, personal safety.

- Blood borne pathogen exposure protocols – Describe the agency specific process that would occur should a staff member be exposed to blood borne pathogens. Specific protocols should be developed that detail where health services will be accessed, what health services will be offered and a timeline of how this process will occur.

- Referral services for consumers – Describe how the need for a referral will be assessed and the process by which the referral would be implemented and documented.
  Note: It is possible that this section of the manual will closely mirror the Consumer Education and Referral Plan..

- Complaint procedures – Describe the process by which complaints and suggestions from clients, staff and the community will be processed and addressed. Explain the Program's grievance policy and protocols.

- Consumer enrollment and termination guidelines – Describe the process by which a client becomes enrolled in the program. Include information on how the client will be identified and tracked while still maintaining confidentiality, what information clients will receive when they enroll and how they will be made aware of the policies governing the Program. This section should include information on the circumstances under which a person would be terminated from syringe services and how such incidences will be documented.

- Procedures for implementing all program operating requirements – The policy and procedure manual must address all the Operating Requirements (see section E). If these requirements have been addressed in other sections of the document, state the requirement and reference it's place in document. If one or more of these requirements have not been addressed in other sections of the document, state the requirement(s) and explain how the requirement(s) will be operationalized.

D. Suitability of Applicant

In acting upon any application for certification or re-certification, the Department shall determine the suitability of the applicant to run a Syringe Service Program. A history of criminal conviction, either by staff or of the organization, does not necessarily disqualify certification.

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, hepatitis 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 Syringe Service Program:

1. Programs must adhere to a strict one-for-one syringe exchange distribution policy, meaning the program must receive one used syringe for every new syringe it distributes to program participants. However, participants can receive a "starter" amount of syringes without submitting any used syringes upon enrollment with a syringe service program.

2. Consumers must enroll in the Syringe Service Program to receive 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 and regulations.

5. Programs shall not accept remuneration from consumers for delivering Syringe Service Program services.

6. Program staff and their representatives shall 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.

7. Programs shall provide consumer enrollment guidelines that include notifying all consumers regarding rules and laws applicable to Syringe Service Programs.

8. If consumers request a means of confidential enrollment identification to avoid detention for transporting used syringes containing trace elements of substances Programs must offer this.

F. Notification Obligation of Program

1. Each Program will notify the Maine CDC in writing on any changes in:
   a. Ownership;

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

   c. Administrator or management of the Program.

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 year 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 Syringe Service Program; or

c. Conduct detrimental to the welfare of the consumers of the Syringe Service Program.

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 designated employee of the Department shall have the right to enter upon and into the premises of any certified Syringe Service 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. § 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 Syringe Service 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 Service Program

No certification shall be assigned or transferred.

Section II: Definitions

The following terms used in this guidance come directly from Title 22 M.R.S.A. ch. 252-A, §1341; Rules Governing the Implementation of Hypodermic Apparatus Exchange Programs (Syringe Service Programs).

a. Applicant: means each individual who signed the application for certification of a Syringe Service 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 for the Syringe Service Program and for staff performance.

c. Certification Review Team: may consist of representatives from the following groups, or their appointees: the Infectious Disease Prevention Program and/or the Infectious Disease 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 and his/her designee will appoint appropriate members of the Certification Review Team for the purpose of reviewing applications for certification of Syringe Service Program.

d. Consumer: is a person eighteen (18) years of age or older who receives Syringe Service Program services.

e. Consumer Education Referral Plan: means a written plan for education of consumers on the prevention and treatment of HIV, hepatitis and other blood borne pathogens, and on substance abuse treatment. The plan will include a list of referrals to substance abuse treatment providers, social service providers, and HIV & hepatitis service and treatment providers.

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

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

h. Department: means the 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. New Enrollee: is considered a person eighteen (18) years of age or older who enrolls into a Syringe Service Program for the first time. If a consumer exits or is disenrolled from a

Syringe Service Program and re-enrolls at a later time he/she will be considered a "New Enrollee."

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

m. Policies: are written standards that govern the provisions of Syringe Service Programs.

n. Policy and Procedures Manual; is a written manual detailing the Program's confidentiality safeguards, safety procedures, blood borne pathogens exposure protocols, referral services for consumers, complaint procedures, consumer enrollment and termination guidelines, procedures for implementing all program operating requirements (see Operating Requirements, pp 8-9) and all other policies and procedures necessary for the safe and lawful operation of a Syringe Service Program.

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

p. Program: a Certified Syringe Service Program including all staff.

q. Program Data Collection Protocols: means written data collection instruments for recording the following information: the number of syringes collected, distributed and disposed of at each site, the number of referrals made to HIV & hepatitis service and treatment providers; and the number of referrals made to substance abuse treatment providers. This data shall be provided to the Maine CDC annually, or as often as the Maine CDC may deem necessary.

r. Protocols: are written guidelines that define the limits and extent of practice of the staff of a Syringe Service Program.

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

t. Public Notice: means written notice to law enforcement, substance abuse treatment providers, HIV & hepatitis prevention service providers, and local governing bodies of a Program's intent to establish and maintain an HIV & hepatitis prevention syringe service program in a community. Part of the notice shall include explanation of HIV & hepatitis prevention goals of the Program, and an invitation to participate in the implementation of the Program.

u. 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.

v. Site: means the location(s) where Syringe Service Program services are offered to consumers.

w. Staff: means anyone involved in providing Syringe Service Program services on behalf of a Program.

x. 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. Staff training will also include HIV & hepatitis prevention education, substance abuse treatment education, and any and all training necessary to the safe and lawful operation of a Syringe Service Program.

y. 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 Syringe Service Program which shall be maintained at the Administrator's office.

z. Syringe Disposal Plan: means a written plan which describes a coordinated program for the terminal disposal and incineration of used syringes in compliance with Occupational Safety and Health Administration's guidelines regarding Occupational Exposure to Blood borne Pathogens and the Safe Discarding and Containment of Contaminated Sharps under 29C.F.R. § 1910.1030

APPENDIX A
SYRINGE SERVICE PROGRAM (SSP)
APPLICATION CHECKLIST

REQUIREMENT	**INCLUDED IN DOCUMENT**	
1. Name of SSP	Y	N
2. Organization identification (Check only one) ___ a. Proprietary corporation – full name and address of each person, firm or corporation having an ownership interest of 5% or more in the SSP. ___ b. Business entity - full name and address of owner or each partner. ___ c. Not-for-profit - full name and address of the President of the Board of Directors or municipal	Y	N
3. Administrator of SSP – name, home address, home telephone number and office telephone number of administrator of SSP	Y	N
4. Description of facilities used by SSP – address(es), telephone number(s), and name(s) of owner(s) of all building used by the SSP; all branches and sub units identified by address(es), telephone number(s), and identifying name(s); description of facility	Y	N
5. Organizational Chart		
6. Copy of SSP's Consumer Confidentiality Protocol – a written protocol, which specifies what client information is to remain confidential, how confidentiality will be maintained and specific circumstances , if any, when confidentiality cannot be maintained.	Y	N
7. Copy of SSP's Consumer Education and Referral Plan – a written plan, which must include the following components: a. Education of consumers on the prevention and treatment of HIV, hepatitis and other blood borne pathogens b. Education of consumers on substance abuse treatment c. Protocols detailing how a referral would be implemented and documented. d. List of referrals to substance abuse treatment providers, social service providers, and HIV & hepatitis service and treatment providers	Y	N
8. Copy of SSP's Syringe Disposal Plan – a written plan which	Y	N

describes a coordinated program for the storage, transportation, collection, terminal disposal and shipping 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 C.F.R.§1910.1030

9. Copy of SSP's Staff Training Plan – 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; plan must include education of staff in the following: Y N
    a. Confidentiality protocols
    b. Blood borne pathogen infection control including post-exposure protocols
    c. HIV and Hepatitis B & C prevention
    d. Substance abuse treatment
    e. The referral process
    f. Any and all training necessary to the safe and lawful operation of the SSP

10. Copy of SSP's Data Collection Protocols – written data collection instruments for recording the following information: Y N
    a. Number of syringes collected, distributed and disposed at each site
    b. Number of consumers exchanging syringes
    c. Number of referrals made to HIV & hepatitis service and treatment providers
    d. Number of referrals made to HIV & hepatitis services and various other substance abuse treatment providers

    Include who is responsible for collecting the information and how it will be collected.

11. Proof of Public Notice –written notice of the SSP's intent to establish and maintain a SSP in the community given to: Y N
    a. Law enforcement
    b. Substance abuse treatment providers
    c. HIV & hepatitis prevention service providers
    d. Local governing bodies

    The notice must include:
    a. An explanation of the HIV & hepatitis prevention goals of the SSP
    b. An invitation to participate in the implementation of the SSP

    Proof of Public Notice must be included for towns with populations over 3,000.

12. Copy of SSP's Policy and Procedures Manual – a written Y N

manual detailing the following:

a. Confidentiality safeguards
b. Safety procedures
c. Blood borne pathogen exposure protocols
d. Referral services for consumers
e. Complaint procedures
f. Consumer enrollment and termination guidelines
g. Procedures for implementing the following SSP operating requirements:
    (1) Strict one-for-one syringe exchange, with exception for new enrollees.
    (2) Shall not knowingly distribute syringes to persons less than 18 years of age
    (3) Compliance with all Maine Statutes, rules and regulations
    (4) Shall not accept remuneration from consumers for SSP services
    (5) SSP staff and representatives carry identification and a copy of their SSP's certification document while conducting SSP business