

**New York State Department of Health
AIDS Institute**

**Guidelines for Development and Submission of
Syringe Exchange Program Waiver Applications**

Agencies requesting authorization to conduct a syringe exchange program under Part 80.135 of Title 10 of the Official Compilation of Codes, Rules and Regulations of the State of New York must submit a plan for providing these services to the New York State Department of Health in a format specified by the Department. The plan must be approved by the Commissioner of the New York State Department of Health prior to the agency engaging in syringe exchange services. The authorization from the Commissioner will be based upon the plan being in compliance with the requirements of the regulation. The plan must minimally include the following elements to be considered for approval.

Agency Information:

1. The name and address of the community-based not-for-profit organization or government entity that proposes to engage in syringe exchange;
2. The name, title and telephone number of the individual authorized to represent the program. Provide the name, title and telephone number of the project director if different.
3. Evidence of organizational status, such as a copy of 501(c)(3) approval;
4. A description of the agency's experience in providing services that relate to syringe exchange including HIV and hepatitis C (HCV) services and services to injection drug uses;

This description should include information regarding organizational capability and commitment relating to the conduct of a hypodermic syringe and needle exchange program including a letter from the Board of directors supporting the proposed project. The information should include a description of the administrative structure for oversight and support of the project.
5. A description of how the project will be funded including other resources such as in-kind contributions of space and utilities, staffing and use of volunteers;

Community Need and Support

1. An assessment of the need for a syringe exchange program within the targeted communities and populations. The number and rate of hepatitis C cases in the area may serve as an indicator of injection drug use.
2. A description of the applicant's previous and planned activities to interact with communities and populations where a syringe exchange program is planned, to enlist support for and to further integration of the hypodermic syringe and needle exchange program within the communities and populations;

Examples of these activities include the development of a community advisory board reflective of the community and meetings with local law enforcement agencies to discuss procedures and reporting requirements.

Project Staff

1. A description of the staffing for the proposed program, including employees or trained volunteers, and, when available, the credentials of key project staff;
2. A description of the training that will be provided to employees and trained volunteers staffing the proposed program, including specific training and written protocols regarding New York State regulations for approved syringe exchange programs;
3. A list of employees and trained volunteers staffing the proposed program, if available;
When there are changes to this list, the Department of Health must be informed of any changes to this list.

Program Services and Operations

1. A summary of the goals and objectives of the program;
2. A description of the design and protocols of the program in details and the method of program operation including:
 - a. Geographic area where services will be provided. If there is overlap with previously approved syringe exchange programs, explain how activities will be coordinated;
 - b. Policies and procedures for determining eligibility for participation in the program;
 - c. Procedures to provide assessment and service referral to injecting drug users under the age of 18;
 - d. Procedures to obtain and record information regarding participant characteristics. Minimal information that must be obtained includes sex, race/ethnicity and age of participants;
 - e. Procedures for enrollment of participants in the program, including issuance of participant identification cards;
 - f. Procedures to ensure staff security;
 - g. Procedures and protocols for distribution and collection of hypodermic syringes and needles, specifying:
 - i. Type of sites (fixed or mobile);
 - ii. Location of operation;
 - iii. Hours and days of operation;
 - iv. Method of operation, including the number of syringes that can be provided to a plan participant in a single transaction;
 - v. Circumstances under which a participant will be terminated from the program.
3. A description of how HIV and HCV prevention and treatment education and other appropriate interventions will be provided to program participants including:
 - a. Distributing written prevention materials;
 - b. Providing face-to-face prevention education either by syringe exchange staff or by other appropriate individuals working with the program. Information regarding risk behavior and risk reduction related to both sexual and drug-using behaviors must be provided. HIV and HCV education should include:
 - i. Information regarding transmission related to sexual and drug-using behaviors;
 - ii. Risk reduction practices related to sexual and drug-using behaviors;
 - iii. Distribution and demonstration of condoms and dental dams; and

- iv. Distribution and demonstration of bleach kits for cleaning of injection equipment and other safer injection techniques.
 - c. Referral for ongoing HIV and HCV prevention, treatment and psychological support.
- 4. A description of how appropriate waste disposal practices will be followed, including disposal of syringes in appropriate sharps containers and disposal of infectious waste as determined by the New York State and local regulations;
- 5. A description of the agency's plan to provide services directly or by referral to participants of syringe exchange programs, including:
 - a. HIV antibody testing and counseling services;
 - b. HCV antibody screening;
 - c. Health care services, including evaluation and treatment for HIV infection, HCV, sexually transmitted diseases and tuberculosis;
 - d. Family planning;
 - e. Prenatal and obstetrical care;
 - f. Social services; and
 - g. Opioid use disorder treatment, including the plan to work with service providers and community-based organizations to establish service linkages.

Evidence of referral relationships, such as signed linkage or referral agreements, should be provided. Formal referral agreements are not required for approval but must be obtained as soon as possible. Indicate current participation in service consortia (such as Opioid Task Force) and indicate a willingness to participate in such consortia as appropriate in the future.

- 6. With respect to record keeping and reporting,
 - a. Indicate that the agency will maintain an inventory control system, which includes the number of syringes received and/or purchased, number of syringes distributed and the balance on hand. Describe how injection equipment will be secured from theft;
 - b. Indicate that the agency will maintain records of the number of syringes distributed to and collected from each participant in each transaction;
 - c. Describe how appropriate infection control practices will be followed, i.e. participants will place used injection equipment in sharps containers without handling by syringe exchange staff. Indicate that the agency will maintain records of the number and manner of disposal of syringes collected by the program;
 - d. Indicate that the agency will maintain records of the number of participants provided HIV/HCV prevention and treatment education and other appropriate interventions; the number and types of services directly provided or provided by referral to participants, including services indicated in 5 above;
 - e. Indicate that the agency will submit a monthly report of activities to the Commissioner in a format provided by the Department which shall include the number of program participants, aggregate information regarding the characteristics of program participants, the total number of syringes distributed during the month and the average number distributed per participant per transaction during the month,

- the total number of syringes collected during the month and the average number collected per participant transaction during the month, the number of participants provided HIV and HCV prevention education and other appropriate interventions, the number and types of services directly provided or provided by referral to participants, significant problems encountered and milestones achieved and other information deemed necessary by the Department to ensure that the conduct of a syringe exchange program adheres to the requirement of the regulations. The monthly report is due no later than 15 days after the end of the prior month (e.g. September report is due by October 15).
- f. Indicate that the agency will submit an annual report summarizing the information obtained above, including an evaluation of the organization's progress in attaining the plan's goals. The annual report is due no later than 60 days after the program has been approved for one year and at the same time annually thereafter.
7. A description of the proposed plan for evaluating program services and goals, including the following:
 - a. Goals and objectives for the project must be clearly defined for the purpose of evaluation, including projected number of participants, projected number of syringes distributed and returned, participant retention rate, etc.
 - b. Evaluation design should include both process and outcome measures.
 8. Describe procedures for developing new sites or expanding or changing existing sites for syringe exchange operations.

Completed waiver applications should be submitted to:

Allan Clear, Director
Office of Drug User Health
AIDS Institute
New York State Department of Health
90 Church Street, 13th Floor
New York, NY 10007