

New York Codes, Rules and Regulations, tit.10, sec. 80.135

Effective Date: 10/13/93

Title: Section 80.135 - Authorization to conduct hypodermic syringe and needle exchange programs

80.135 Authorization to conduct hypodermic syringe and needle exchange programs.

(a) Employees or trained volunteers of community-based not-for-profit organizations and government entities engaged in clean hypodermic syringe and needle exchange programs designed to reduce the transmission of human immunodeficiency virus may obtain, possess and furnish hypodermic syringes and hypodermic needles, without prescription, when authorized by the Commissioner in connection with the distribution or collection of hypodermic syringes and hypodermic needles for the purpose of preventing the transmission of human immunodeficiency virus in users of injectable drugs. This authorization will be granted only in accordance with a plan submitted by the not-for-profit corporation or government entity to and approved by the Commissioner, using the standards contained in this section. This authorization will be based upon the plan meeting the requirements of the regulation.

(b) The Department will review the plan submitted by the not-for-profit corporation or government entity using the following standards:

(1) The plan demonstrates the need for a hypodermic syringe and needle exchange program within the targeted community(ies);

(2) The plan demonstrates organizational capability and commitment necessary to conduct a hypodermic syringe and needle exchange program, to interact effectively with the community(ies) where a hypodermic syringe and needle exchange program is planned, and to enlist support for and to further integration of hypodermic and needle exchange services within the community(ies);

(3) The plan demonstrates an adequacy of the design and protocol for the conduct of a hypodermic syringe and needle exchange program;

(4) The plan demonstrates organizational capability to provide comprehensive harm reduction services, including HIV prevention education and counseling and direct provision of or referral to health and human services, including drug treatment;

(c) This authorization extends only to those hypodermic needles and hypodermic syringes distributed or collected pursuant to the approved plan and only as long as such employees or trained volunteers of the not-for-profit organizations or government entities are assigned to the program. The organization or entity must develop and maintain a list of employees and trained volunteers who are authorized to obtain, possess and furnish hypodermic syringes and hypodermic needles, and furnish this list to the Department. All personnel changes to this list shall be reported immediately to the Department.

(d) An approval obtained pursuant to subdivision (a) of this section shall continue until two years from the date of notification by the Commissioner of approval of the plan submitted by the not-for-profit organization or government entity or until receipt by the organization or entity of a written notice of termination of the program from the Commissioner, whichever shall first occur. The Commissioner may approve extensions of the plan for additional two year periods if the not-for-profit corporation or government entity complied with the

requirements of this section during the prior two year period.

(e) Individuals participating in the approved plan may obtain and possess hypodermic syringes and hypodermic needles without prescription from individuals authorized pursuant to subdivision (a) of this section provided that:

(1) this authorization extends only to obtaining or possessing those hypodermic syringes and hypodermic needles which have been distributed or collected pursuant to the approved plan; and

(2) this authorization is effective only so long as the person is an active participant in the approved plan; and

(3) this authorization shall be automatically void with respect to any hypodermic syringe or hypodermic needle which is sold or furnished or attempted to be sold or furnished by a participant in violation of state or federal law.

(f) An approval pursuant to subdivision (a) of this section shall allow a not-for-profit organization or government entity to purchase hypodermic syringes or hypodermic needles as part of a needle exchange plan approved by the Commissioner, and designed to reduce the transmission of human immunodeficiency virus.

(g) An organization or entity authorized by the Commissioner to conduct a hypodermic syringe and needle exchange program must adhere to policies and procedures approved by the Department in connection with the conduct of a hypodermic syringe and needle exchange, which will include, but not be limited to:

(1) requirements for training for staff and volunteers;

(2) procedures to ensure staff security;

(3) policies and procedures for enlisting community support for the program, including development of a community advisory board reflective of the community in which the hypodermic syringe and needle exchange program is located; (4) procedures and reporting requirements involving community concerns regarding the conduct of a hypodermic syringe and needle exchange program, including those involving law enforcement agencies;

(5) policies and procedures for determining eligibility of individuals for participation in a hypodermic syringe and needle exchange program;

(6) policies and procedures to ensure comprehensive assessment and service referral for injectable drug users under the age of 18;

(7) procedures for enrollment of participants in a hypodermic syringe and needle exchange program and issuance of participant identification cards;

(8) procedures for obtaining and recording participant information;

(9) policies and procedures for identifying program hypodermic syringes and needles;

(10) policies and procedures for distribution and collection of hypodermic syringes and needles, including the number of needles that can be provided to a plan participant in a single transaction;

(11) procedures to ensure that hypodermic syringes and needles are secured properly and that the handling and disposal of hypodermic syringes and needles is safeguarded and in accordance with State and federal law and regulations;

(12) policies and procedures to terminate program participants;

(13) procedures for developing new sites or expanding or changing existing sites for hypodermic syringe and needle exchange programs;

(14) policies and procedures relating to the provision of HIV prevention education and counseling for program participants;

(15) policies and procedures for referring program participants to services, including developing and formalizing referral linkages;

(16) procedures for data collection and program reporting; and

(17) policies and procedures for evaluation of hypodermic syringe and needle exchange programs.

(h) The following records of hypodermic syringes, hypodermic needles, participants and transactions shall be maintained by the organization or entity engaged in exchanging hypodermic syringes and hypodermic needles:

(1) An inventory of hypodermic syringes and hypodermic needles, including the number purchased and distributed, and the balance on hand;

(2) A record of the number of hypodermic syringes and hypodermic needles distributed to each participant in each transaction;

(3) A record of the number of used hypodermic syringes and hypodermic needles returned by each participant in each transaction;

(4) The number and manner of disposal of hypodermic syringes and hypodermic needles collected by the program;

(5) A record of the number of participants provided HIV prevention education and counseling; the number and types of services directly provided or provided by referral to participants, including referral to HIV antibody testing services, health care services, including evaluation and treatment for HIV infection, sexually transmitted diseases and tuberculosis, family planning, prenatal and obstetrical care, social services and drug abuse treatment services.

(i) An organization or entity functioning under a needle exchange plan approved under subdivision (a) of this section must ensure that hypodermic syringes and needles are secured properly and must safeguard the handling and disposal of hypodermic syringes and needles in accordance with State and federal law and regulations.

(j) An organization or entity functioning under a needle exchange plan approved under subdivision (a) of this section must provide a quarterly report of activities to the Commissioner in a format provided by the Department which shall include, but not be limited to:

(1) the number of program participants;

(2) aggregate information regarding the characteristics of program participants;

(3) the total number of hypodermic syringes and hypodermic needles distributed during the quarter, and the average number distributed per participant per transaction during the quarter;

(4) the total number of hypodermic syringes and hypodermic needles collected during the quarter, and the average number collected per participant transaction during the quarter;

(5) the number of participants provided HIV prevention education and counseling;

(6) the number and types of services directly provided or provided by referral to participants, including referral to HIV counseling and testing, health care services, including evaluation and treatment for HIV infection, sexually transmitted diseases and tuberculosis, family planning, obstetrical and prenatal care, social services and drug abuse treatment services;

(7) significant problems encountered and program milestones achieved; and

(8) other information deemed necessary by the Department to ensure that the conduct of a hypodermic syringe and needle exchange program adheres to the requirements of this regulation. The quarterly report must be submitted to the Commissioner no later than 30 days after the end of each quarter after the plan is approved.

(k) The organization or entity functioning under an approved needle exchange plan shall provide an annual report of plan activities to the Commissioner, summarizing the information provided on a quarterly basis as contained in subdivision (j) of this section in a format provided by the Department. In addition, the report shall contain an evaluation of the organization's progress in attaining the plan's goals. The annual report must be submitted to the Commissioner no later than 60 days after the program has been approved for a period of one year and at the same time annually thereafter.

(l) An organization or entity functioning under a needle exchange plan approved under subdivision (a) of this section may be inspected by authorized representatives of the State Commissioner of Health as necessary to ensure compliance with the requirements of this section. An organization or entity found to be in violation of these regulations will receive written notification of the violation from the Commissioner and a time period, not to exceed 30 days from the date of written notification, to correct the violation. If the organization or entity continues to be in violation of these regulations after the date required for correction, the Commissioner may terminate approval of the plan. The Commissioner may also terminate the plan immediately if s/he determines that approval of the plan is no longer in the public interest.

(m) Any not-for-profit organization or government entity seeking to obtain, possess and furnish hypodermic syringes and hypodermic needles, without prescription, must submit a plan to the Commissioner for approval, which must be in a format specified by the Department, and will include, but not be limited to:

(1) the name and address of the not-for-profit organization or government entity;

(2) the name and title of the individual authorized to represent the program in

seeking approval;

(3) information regarding organizational capability and commitment relating to the conduct of a hypodermic syringe and needle exchange program;

(4) an assessment of the need for a hypodermic syringe and needle exchange program within the targeted community(ies);

(5) a description of the applicant's previous and planned activities to interact with a community(ies) where a hypodermic syringe and needle exchange program is planned, to enlist support for and to further integration of the hypodermic syringe and needle exchange program within the community(ies);

(6) a description of staffing for the proposed program, including employees or trained volunteers;

(7) a description of training planned for employees and volunteers staffing the proposed program;

(8) a list of employees and trained volunteers staffing the proposed program;

(9) the design and protocols of the project, including the geographic area and the method of program operation; including procedures for determining eligibility of individuals for participation in the program; procedures to ensure comprehensive assessment and service referral to injecting drug users under the age of 18; procedures for enrollment of participants in the program, including issuance of participant identification cards; procedures for obtaining and recording participant information; procedures for identifying program hypodermic syringes and needles; procedures to ensure staff security; procedures for distribution and collection of hypodermic syringes and needles, including the number of needles that can be provided to a plan participant in a single transaction.

(10) the proposed plans for the proper safeguarding and handling and disposal of hypodermic syringes and needles, including inventory control, and securing injection equipment from theft, adherence to appropriate infection control practices and appropriate disposal of used hypodermic syringes and needles;

(11) the proposed plan to provide program participants with HIV prevention education and counseling regarding drug and sexual risk behaviors and risk reduction practices, including cleaning of injection equipment, use of condoms, and distribution of bleach kits and condoms, and referral for ongoing HIV prevention education and psychosocial support.

(12) the proposed plan for direct provision or referral to HIV antibody testing services, health services, including evaluation and treatment services for HIV infection, sexually transmitted diseases and tuberculosis, family planning, prenatal and obstetrical care, social services and drug abuse treatment services, including the plan to work with service providers and community-based organizations to establish service linkages;

(13) the proposed plan for evaluating program services and goals.