

Pursuant to the authority vested in the Commissioner of Health by Sections 3308 and 3381 of the Public Health Law (PHL), Sections 80.135 and 80.137 of Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York (NYCRR) are hereby amended to be effective upon publication of a Notice of Adoption in the New York State Register, to read as follows:

Paragraphs (12) and (13) of subdivision (m) of section 80.135 is amended, a new paragraph (14) of subdivision (m) is added, and a new subdivision (n) is added to read as follows:

- (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, viral hepatitis and drug [abuse] treatment services, including the plan to work with service providers and community-based organizations to establish service linkages; [and]
- (13) the proposed plan for evaluating program services and goals[.]; and
- (14) overdose prevention education that specifically includes information about methods participants should use to prevent any adverse reactions from:
 - (i) injecting fentanyl; and
 - (ii) lack of knowledge of the kinds and amounts of substances users are injecting.
- (n) The Commissioner may approve programs with plans that do not include all of the elements specified in subdivision (m) of this section, provided that:

- (1) the not-for-profit organization or government entity does not receive funding to operate such hypodermic syringe or needle exchange program from the Department;
- (2) the not-for-profit organization or government entity provides other services to individuals at heightened risk for adverse outcomes;
- (3) the plan includes at least the following elements:
 - (i) a description of staffing and training planned for employees and volunteers working for the proposed program.
 - (ii) if the plan does not have procedures for enrollment of participants in the program or issuance of participant identification cards, procedures to make it possible for clients to demonstrate that they received syringes from a legally authorized program.
 - (iii) policies and procedures for the proper safeguarding, handling and disposal of hypodermic syringes and needles, including inventory control, securing injection equipment from theft, adherence to appropriate infection control practices, and appropriate disposal of used hypodermic syringes and needles.
 - (iv) policies and procedures for enlisting community support for the program, including responding to concerns from the community and law enforcement agencies.
 - (v) submission of quarterly reports to the Department, in a format determined by the Department; and

(4) the program is approved by any other state agency that licenses or certifies the operations of the not-for-profit organization or government entity.

Subparagraph (i) of paragraph (2) of subdivision (d) of section 80.137 is amended to read as follows:

- (i) shall not advertise to the public the availability for retail or furnishing of hypodermic syringes and needles without a prescription; provided, however, that in-store signage indicating that hypodermic syringes and needles may be purchased without a prescription, and which is consistent with guidance issued by the Department, shall not be considered advertising to the public; and

REGULATORY IMPACT STATEMENT

Statutory Authority:

Under New York State Public Health Law (PHL) Section 3308(2), the New York State Department of Health (NYSDOH) Commissioner is authorized to make any rules, regulations and determinations which may be necessary or proper to supplement the provisions of PHL Article 33 (Controlled Substances). The statutory authority for New York State's syringe exchange programs (SEPs) exists under PHL Section 3381(1)(b), which grants the NYSDOH Commissioner the power to authorize persons to legally obtain and possess hypodermic syringes and hypodermic needles. PHL Section 3381(4) and PHL Section 3381(5)(f) set forth the statutory authority for the expanded syringe access program (ESAP) and the manner in which pharmacies, health care facilities and health care practitioners furnish syringes without a prescription.

Legislative Objectives:

The goal of both SEP and ESAP is to reduce the spread of blood-borne pathogens, reduce or eliminate other harms associated with contaminated syringes, and improve the health of individuals who inject drugs, and their communities.

Needs and Benefits:

New York State currently has 24 SEPs. The reach of these SEPs is limited by their staffing and geography. Having a second-tier of programs authorized to furnish syringes will more comprehensively address the needs of persons who inject drugs, particularly in areas where there are no SEPs. Pharmacies participating in ESAP are a

complementary means for individuals to obtain their injection equipment. However, those syringes must be paid for by the consumer, and for many persons who inject drugs this is a hardship. Persons who inject drugs may also fear being stigmatized in pharmacies. Second-tier syringe exchange programs may also serve as a source of syringes for individuals who have already been enrolled in a SEP, but who are located too far away from that SEP to routinely obtain syringes there.

The second-tier syringe exchange programs will also incorporate overdose response training in their work. These programs are well-positioned to ensure that the individuals they work with are educated regarding hygienic injection practices and are engaged in strategies to avoid overdosing.

Costs for the Implementation of, and Continuing Compliance with the Regulation to the Regulated Entity:

The NYSDOH will be providing the harm reduction supplies at no cost to programs that are approved as second-tier syringe exchange programs. Quantities will be individually assessed and determined for each site. Included among those supplies are syringes, sharps containers, alcohol pads, and non-latex gloves. The estimated cost of providing these supplies is \$250,000 annually. There will be added responsibility for regulated entities deploying these second-tier programs, but the furnishing and collection of syringes will have a negligible impact on the current staff job responsibilities.

Costs:

Costs to State and Local Governments:

NYSDOH will be covering the cost of harm reduction supplies for local government agencies that voluntarily choose to have second-tier syringe exchange programs. Included among those supplies are syringes, sharps containers, alcohol pads, and non-latex gloves. There will be added responsibility for local government agency staff if they choose to become second-tier syringe exchange programs, but the furnishing and collection of syringes will have a negligible impact on their current job responsibilities.

Costs to the Department of Health:

Agencies approved to be second-tier syringe exchange programs will not receive funding from the NYSDOH to operate the second-tier syringe exchange programs. The NYSDOH will provide the harm reduction supplies at no cost to programs that are approved as second-tier syringe exchange programs. Quantities will be individually assessed and determined for each site. The estimated cost of providing these supplies is \$250,000 annually. The NYSDOH already has a contract to purchase, store and distribute harm reduction supplies. Agencies approved to be second-tier syringe exchange programs will be able to order harm reduction supplies through this contract. Second-tier syringe exchange programs are limited to not-for-profit organizations and government entities, including but not limited to, LGBTQ centers, STD clinics, and local health departments.

Local Government Mandates:

The proposed regulation does not impose any new programs, services, duties or responsibilities upon any county, city, town, village, school district, fire district or other special district.

Paperwork:

Agencies that apply to have a second-tier syringe exchange program will complete an application and submit it to NYSDOH. Once a program is approved, the agency will be required to submit quarterly reports.

Duplication:

There is no duplication of effort or of expenses in implementing the second-tier syringe exchange programs. SEP, ESAP and the second-tier syringe access programs are complementary, each meeting distinct needs.

Alternatives:

There are no viable alternatives that meet the objectives of this regulation. Applications from agencies to become syringe exchange programs (first tier) will continue to be reviewed and approved when all of the requirements are met and funding is available. The second-tier syringe exchange programs are lower threshold in terms of the application process, and this is likely to provide a meaningful adjunct to current syringe access capacity. The agencies anticipated to apply to become a second-tier

syringe exchange program will reach individuals who may not come to a syringe exchange program. Once an agency is approved to become a second-tier syringe exchange program, individuals receiving services at these agencies can receive syringes as well.

Federal Standards:

The proposed second-tier syringe exchange programs are consistent with Federal support for syringe services programs (SSPs). No federal funding, under federal regulation, can be used for supporting the provision of syringes. However, federal funding can be used for ancillary services.

Compliance Schedule:

Syringe exchange programs are subject to comprehensive monitoring by NYSDOH staff every two years. A similar standard will be applied for the second-tier syringe access programs.

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REGULATORY FLEXIBILITY ANALYSIS FOR SMALL BUSINESSES AND LOCAL GOVERNMENTS

Effect of Rule:

Second-tier syringe exchange programs are limited to not-for-profit organizations and government entities, including but not limited to, LGBTQ centers, STD clinics, and local government agencies. This regulation's provisions related to second-tier syringe exchange programs will therefore not impact small businesses or local governments, except those local government agencies that voluntarily choose to have second-tier syringe exchange programs. NYSDOH will be covering the cost of harm reduction supplies for these local government agencies. Included among those supplies are syringes, sharps containers, alcohol pads, and non-latex gloves. There will be added responsibility for local government agency staff if they choose to become second-tier syringe exchange programs, but the furnishing and collection of syringes will have a negligible impact on their current job responsibilities.

There are more than 5,450 pharmacies throughout New York State of which 3,385 participate in ESAP, some of which are small businesses. The rule change will give the ESAP-participating pharmacies the ability to have signage within their stores indicating that syringes without a prescription are available for sale. This will enhance the revenue of these stores.

Compliance Requirements:

The second-tier syringe exchange programs will be required to develop policies and procedures for 1) the proper safeguarding and handling and disposal of hypodermic syringes and needles, including inventory control, and securing injection equipment from theft; 2) adherence to appropriate infection control practices; 3) appropriate disposal of used hypodermic syringes and needles; and 4) enlisting community support for the program, including responding to concerns from the community and law enforcement agencies. The Department has developed guidance for these programs for the development of these policies and procedures.

The second-tier syringe exchange programs are required to submit quarterly reports to NYSDOH pursuant to guidance from the Department.

ESAP-participating pharmacies advertising the availability of syringes will have no additional compliance requirements.

Professional Services:

No additional professional services are associated with the rule change. Programs choosing to become a registered opioid overdose prevention programs under Public Health Law Section 3309 and the regulations in 10 NYCRR 80.138 will need to have the services of a prescriber to serve as the clinical director of that program. All SEPs already maintain registered opioid overdose prevention programs. It will be advisable, though not mandated, that second-tier syringe exchange programs become registered programs to

ensure that the individuals with which they are working have low-threshold access to naloxone.

Compliance Costs:

No capital costs are required to comply with these regulations. The costs associated with the quarterly reporting requirement for second-tier syringe exchange programs is minimal.

Economic and Technology Feasibility:

There are no economic or technology impediments to any of the proposed rule changes.

Minimizing Adverse Impact:

There is no adverse impact expected. Participation in the second-tier syringe exchange program is voluntary. There are no capital costs required to comply with these regulations, and costs associated with quarterly reporting requirements are expected to be minimal. In addition, NYSDOH will be covering the cost of harm reduction supplies for local government agencies that voluntarily choose to participate in second-tier syringe exchange programs.

Small Business and Local Government Participation:

Copies of these proposed regulations will be transmitted to the Pharmacists Society of the State of New York and to local pharmacy societies for comment.

RURAL AREA FLEXIBILITY ANALYSIS

Types and Estimated Numbers of Rural Areas:

This rule applies uniformly throughout the state, including rural areas. Rural areas are defined as counties with a population less than 200,000 and counties with a population of 200,000 or greater that have towns with population densities of 150 persons or fewer per square mile. The 43 counties listed below have a population of less than 200,000 based upon the United States Census estimated county populations for 2010 (<https://www.census.gov/quickfacts/>). Thirteen of the 24 Syringe Exchange Programs (SEPs) and 525 of the 3,385 Expanded Syringe Access Program (ESAP) pharmacies are in rural areas.

Allegany County	Greene County	Schoharie County
Cattaraugus County	Hamilton County	Schuyler County
Cayuga County	Herkimer County	Seneca County
Chautauqua County	Jefferson County	St. Lawrence County
Chemung County	Lewis County	Steuben County
Chenango County	Livingston County	Sullivan County
Clinton County	Madison County	Tioga County
Columbia County	Montgomery County	Tompkins County
Cortland County	Ontario County	Ulster County
Delaware County	Orleans County	Warren County
Essex County	Oswego County	Washington County
Franklin County	Otsego County	Wayne County
Fulton County	Putnam County	Wyoming County
Genesee County	Rensselaer County	Yates County
	Schenectady County	

The following counties have a population of 200,000 or greater and towns with population densities of 150 persons or fewer per square mile. Data is based upon the United States Census estimated county populations for 2010.

Albany County	Monroe County	Orange County
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Broome County
Dutchess County
Erie County

Niagara County
Oneida County
Onondaga County

Saratoga County
Suffolk County

Ten existing SEPs and 883 ESAP pharmacies are located in these rural areas.

The second-tier syringe exchange programs are likely to be particularly important in rural parts of New York State where SEPs are not currently situated and where the stigma of going into a pharmacy to acquire syringes may be particularly onerous.

Reporting, Recordkeeping and Other Compliance Requirements; and Professional Services:

The second-tier syringe exchange programs will be required to develop policies and procedures for 1) the proper safeguarding and handling and disposal of hypodermic syringes and needles, including inventory control, and securing injection equipment from theft; 2) adherence to appropriate infection control practices; 3) appropriate disposal of used hypodermic syringes and needles; and 4) enlisting community support for the program, including responding to concerns from the community and law enforcement agencies. The Department has developed guidance for these programs for the development of these policies and procedures.

The second-tier syringe exchange programs will be required to submit quarterly reports to NYSDOH pursuant to guidance from the Department.

ESAP-participating pharmacies advertising the availability of syringes will have no additional compliance requirements.

No additional professional services are associated with the rule change. Programs choosing to become a registered opioid overdose prevention program under Public Health Law Section 3309 and the regulations in 10 NYCRR 80.138 will need to have the services of a prescriber to serve as the clinical director of that program. All SEPs already maintain registered opioid overdose prevention programs. It will be advisable, though not mandated, that second-tier syringe exchange programs become registered programs to ensure that the individuals with which they are working have low-threshold access to naloxone.

Costs:

No capital costs are required to comply with these regulations. The costs associated with the quarterly reporting requirement for second-tier syringe access programs is minimal.

Minimizing Adverse Impact:

There is no adverse impact expected. Participation in the second-tier syringe exchange program is voluntary. There are no capital costs required to comply with these regulations, and costs associated with quarterly reporting requirements are expected to be minimal. In addition, NYSDOH will be covering the cost of harm reduction supplies for local government agencies that voluntarily choose to participate in second-tier syringe exchange programs.

Rural Area Participation:

Copies of these proposed regulations will be transmitted to the Pharmacists Society of the State of New York and to local pharmacy societies.

STATEMENT IN LIEU OF JOB IMPACT STATEMENT

No job impact statement is required pursuant to section 201-a(2)(a) of the State Administrative Procedure Act. No adverse impact on jobs and employment opportunities is expected as a result of these proposed regulations.

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ASSESSMENT OF PUBLIC COMMENT

The New York State Department of Health (“Department”) received public comments in response to the proposed rulemaking amending Part 80 of Title 10 of the Codes, Rules and Regulations of the State of New York relating to syringe exchange programs. The comments and the Department’s responses are summarized below.

Comment:

One commenter suggested incorporating specific reporting elements in the regulation, including the number of syringes furnished and collected as well as the number of participant encounters by each Syringe Exchange Program (SEP).

Response:

Reporting requirements will be further clarified, as necessary, in policy and guidance documents to be developed upon the adoption of the proposed regulation and Department review as the need for specific reporting elements will evolve over time. No changes were made to the regulation in response to this comment.

Comment:

One commenter suggested that the Department provide programmatic support to the second-tier SEPs in the areas of syringe disposal, training materials and coordination with first-tier programs.

Response:

This comment is beyond the scope of these regulations. Nevertheless, in accordance with proposals developed prior to the release of these regulations, the Department is moving forward with plans to provide second-tier SEPs with program support as suggested by this comment. No changes were made to the regulation in response to this comment.

Comment:

One commenter suggested that the Department produce and distribute participant identification cards to the second-tier syringe exchange program.

Response:

This comment is beyond the scope of these regulations. Nevertheless, the Department intends to provide participant identification cards to the second-tier syringe SEPs in the same manner that it does for conventional SEPs. No changes were made to the regulation in response to this comment.

Comment:

One commenter suggested that the Department include in the second-tier SEP application form a methodology for prioritizing applications.

Response:

This comment is beyond the scope of these regulations. Nevertheless, the Department does not anticipate any need to prioritize certain applications. No changes were made to the regulation in response to this comment.

Comment:

One commenter suggested that the regulations should allow SEPs that currently receive Department funding to operate second-tier syringe exchange operations at sites for which there is no such Department funding.

Response:

The Department made a technical amendment to the Final Rule to clarify that currently funded syringe exchange programs are eligible to have second-tier syringe exchange programs at unfunded sites. The Department also revised the regulatory impact statement to make clear that agencies approved to be second-tier syringe exchange programs may already be receiving funding from the Department to operate hypodermic syringe or needle exchange programs, but at this time there is no additional funding from the Department to operate second-tier syringe exchange programs.

Comment:

One commenter proposed amending the regulations to integrate hepatitis B and C screening; hepatitis A, B and C prevention education and counseling; and direct provision of, or referral for, HIV and viral hepatitis treatment, into SEP operations.

Response:

SEPs vary in their capacity to deliver the above referenced services, depending on the availability of funding and other resources. The Department will continue to support these services to the extent possible, however mandating these services by regulation would place a significant and undue burden upon SEPs that could limit their ability to provide important core services. No changes were made to the regulation in response to this comment.