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

Paragraph (1) of subdivision (a) of Section 80.137 is amended to read as follows:

(1) *Authorized provider* for the purposes of this section shall mean any of the following [who have registered with the Department]:

* * *

Subdivisions (b) through (g) of Section 80.137 are amended to read as follows:

(b) [*Registration.*

(1) Authorized providers must register with the Department in order to sell or furnish hypodermic needles and/or syringes without a prescription pursuant to this section.

(2) Authorized providers must register with the Department in order to accept hypodermic needles and/or syringes for purposes of disposal. Failure of an entity to register shall not affect its obligations to accept needles and syringes originating from a private residence when such entity is already obliged to do so pursuant to Section 1389-dd of the Public Health Law.

(3) Registration shall be limited to authorized providers in good standing and will consist of submission to the Department of a completed application in a form prescribed by the commissioner, and receipt of the acceptance from the commissioner of such registration, prior to the initiation of the selling or furnishing of hypodermic needles and syringes without a prescription and or accepting hypodermic needles and/or syringes for disposal.

(4) The registration form must include, at a minimum, the following information:

(i) the name, address, license number, telephone number and fax number (if available) of the authorized provider;

(ii) the name, address, telephone and electronic mail address, if available, of the individual designated by the authorized provider to have administrative responsibility for the provider's participation in the expanded syringe access program;

(iii) an attestation that the authorized provider will abide by the provisions of this section and the provisions contained in the registration form with regard to the selling or furnishing of hypodermic needles or syringes without a prescription;

(iv) a description of how the registrant will cooperate in the safe disposal of used hypodermic needles or syringes, or will provide such services (pharmacies and health care practitioners are not required to provide such services); and

(v) the signature of the individual authorized to sign the registration form on behalf of the applicant.

(5) The registration period shall commence upon the acceptance of such registration by the commissioner and shall remain valid for a period to coincide with the maximum allowed at the time of registration under Section 3381 of the Public Health Law or until notice of termination by the Department. Authorized providers shall notify the Department of any changes in the information provided to the Department. Changes or corrections to such information shall be submitted to the Department by the completion of a revised registration form as soon as possible but no later than 30 days after such change. Should an authorized provider choose to withdraw its registration, written notification of such intent must be provided to the Department. Such withdrawal shall not be effective until receipt of such written notice is acknowledged by the Department in writing.

(6) The name, address, and telephone number of the authorized provider may be used in the development of, or included in, a registry of authorized providers for the purpose of informing consumers of available authorized providers for the purposes of sale, furnishing, and/or disposal, as specified on the registration form.

(c) Upon the finding of a violation of this section or when a registrant is no longer in good standing, the commissioner may suspend, for a period up to one year, an authorized provider's ability to sell or furnish hypodermic needles or syringes, or to accept hypodermic needles or syringes for disposal under this Section.] Entities [otherwise] obliged to accept hypodermic needles or syringes for disposal pursuant to Section 1389-dd of the Public Health Law shall not be relieved from such obligation.

[(d)] (c) *Requirements for authorized providers for the purpose of selling and furnishing of hypodermic needles and syringes without a prescription.*

(1) [After acceptance of the registration by the commissioner, an] An authorized provider may obtain and possess such hypodermic syringes and needles for such purpose, provided that:

(i) such sale or furnishing shall only be to a natural person eighteen years of age or older; and

(ii) [each sale or furnishing is limited to a quantity of ten or less; and

(iii)] the sale or furnishing shall be accompanied by a safety insert as described in paragraph (a)(2) of this section. Such insert shall be attached to or included in the hypodermic syringe and/or needle packaging, or provided in brochure form, at the point of sale or furnishing.

(2) In addition, a pharmacy[:

(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

(ii)] shall, at any location where hypodermic syringes and needles are kept for retail furnishing, store such syringes and needles in a manner that makes them available only to authorized personnel and not openly available to customers.

[(e)] (d) Authorized providers that accept needles and/or syringes for purposes of disposal shall adhere to State and local public health and environmental conservation laws, rules, and regulations related to the disposal of regulated medical waste.

[(f)] (e) *Possession*. A natural person 18 years of age or older may obtain and possess hypodermic syringes and needles obtained pursuant to this section.

[(g)] (f) *Applicability*. The provisions of this section shall not apply to any sale, furnishing, or possession of hypodermic needles or syringes which is lawful under section 3381(a) or (b) of the Public Health Law.

REGULATORY IMPACT STATEMENT

Statutory Authority:

Under New York State Public Health Law (PHL) Section 3308(2), the New York State Department of Health 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). Under PHL Section 3381(3) and (4), NYSDOH has specific authority to establish regulations for expanded syringe access programs (ESAPs), which are pharmacies, health care facilities and health care practitioners that furnish syringes without a prescription.

Legislative Objectives:

Laws of 2021, Chapter 433, § 4, amended PHL Section 3381 removing the limitation that ESAPs only furnish a quantity of 10 or fewer syringes at a time, the requirement that ESAPs register with the Department, and the prohibition on advertising the availability of syringes.

The legislative objective was to expand the availability of clean syringes in order to prevent the spread of communicable diseases caused by the reuse of syringes.

Needs and Benefits:

This regulation implements Laws of 2021, Chapter 433, § 4, to remove regulatory requirements that make it more difficult for individuals to get clean syringes. New York State needs to remove these legal barriers to ensure that people do not reuse syringes, a practice that

increases morbidity and mortality. In particular, this regulation is needed to decrease the spread of HIV and hepatitis C virus (HCV).

Costs:

Costs to Regulated Parties:

This regulation imposes no costs on regulated parties. It reduces regulation of syringes.

Costs to State and Local Governments:

This regulation imposes no costs on State and local governments. It reduces regulation of syringes.

Paperwork:

This regulation creates no new paperwork requirements.

Local Government Mandates:

This amendment does not impose any new programs, services, duties or responsibilities on local government.

Duplication:

These regulations will not conflict with any State or federal rules.

Alternatives:

The alternative to this regulatory is to not conform the regulations with Chapter 433, § 4 of the Laws of 2021. This is not a viable alternative as the Department of Health is obligated to implement these legislative amendments. This regulation is further necessary to expand the availability of clean syringes in order to prevent the spread of communicable diseases caused by the reuse of syringes.

Federal Standards:

This regulation is consistent with federal standards.

Compliance Schedule:

This regulation is effective upon publication of a Notice of Adoption in the New York State Register.

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STATEMENT IN LIEU OF REGULATORY FLEXIBILITY ANALYSIS

No regulatory flexibility analysis is required pursuant to section 202-(b)(3)(a) of the State Administrative Procedure Act. The proposed amendment does not impose an adverse economic impact on small businesses or local governments, and it does not impose reporting, record keeping or other compliance requirements on small businesses or local governments.

STATEMENT IN LIEU OF
RURAL AREA FLEXIBILITY ANALYSIS

A Rural Area Flexibility Analysis for these amendments is not being submitted because amendments will not impose any adverse impact or significant reporting, record keeping or other compliance requirements on public or private entities in rural areas. There are no professional services, capital, or other compliance costs imposed on public or private entities in rural areas as a result of the proposed amendments.

JOB IMPACT STATEMENT

The Department of Health has determined that these regulatory changes will not have a substantial adverse impact on jobs and employment, based upon its nature and purpose.

ASSESSMENT OF PUBLIC COMMENT

Comment: The New York State Association of County Health Officials (NYSACHO) supports conforming the regulations to the current Public Health Law by removing the requirement that Expanded Syringe Access Programs (ESAPs) may only furnish a quantity of 10 or fewer syringes at a time and by eliminating registration requirements for authorized providers, noting that the current quantity limit presents a barrier for people who use drugs (PWUD) to accessing sterile syringes, particularly for those in rural areas.

Response: The Department appreciates the support of NYSACHO for this regulation amendment.