55 NJR 7(2)
July 17, 2023
Filed June 23, 2023

HEALTH

PUBLIC HEALTH SERVICES BRANCH

DIVISION OF HIV, STD, AND TB SERVICES

Harm Reduction Services

Adopted Special Repeals and New Rules and Concurrent Proposed Readoption of Specially Adopted Repeals and New Rules: N.J.A.C. 8:63

Special Repeals and New Rules Adopted and Concurrent Proposed Readoption of Special Repeals and New Rules Authorized: June 12, 2023, by Judith M. Persichilli, RN, BSN, MA, Commissioner, Department of Health, in consultation with the Public Health Council.

Filed: June 12, 2023, as R.2023 d.086.

Authority: N.J.S.A. 26:5C-25 through 31.

Calendar Reference: See Summary below for explanation of exception to calendar requirement.

Concurrent Proposal Number: PRN 2023-069.

Effective Date: June 12, 2023.

Expiration Date: June 6, 2024.

Submit written comments electronically by September 15, 2023, to http://www.nj.gov/health/legal/ecomments.shtml or by regular mail postmarked on or before September 15, 2023, to:

Joy L. Lindo, Director

Office of Legal and Regulatory Compliance

Office of the Commissioner

New Jersey Department of Health

PO Box 360

Trenton, NJ 08625-0360

Take notice that pursuant to N.J.S.A. 26:5C-31.b, the Department of Health (Department) hereby repeals existing N.J.A.C. 8:63, Sterile Syringe Access Program Demonstration Project Rules, and pursuant to N.J.S.A. 26:5C-31.c, adopts and concurrently proposes to readopt special new rules at N.J.A.C. 8:63, Harm Reduction Centers.

Pursuant to N.J.S.A. 26:5C-31.c, N.J.A.C. 8:63, Harm Reduction Centers, is effective through December 9, 2023. Pursuant to N.J.S.A. 52:14B-5.1.c(2), the concurrent filing of the notice of proposal to readopt this chapter operates to extend the expiration date of the chapter by an additional 180 days to June 6, 2024.

The agency proposal to readopt the specially adopted new rules at N.J.A.C. 8:63 follows.

Summary

On December 19, 2006, Governor McGreevey approved the Bloodborne Disease Harm Reduction Act (Act), P.L. 2006, c. 99, codified in part at N.J.S.A. 26:5C-25 through 31. N.J.S.A. 26:5C-27 authorized the Commissioner of the Department of Health (Commissioner) to establish a demonstration program to permit up to six municipalities to operate sterile syringe access programs, and N.J.S.A. 26:5C-31 directed the Commissioner, in consultation with the Commissioner of the Department of Environmental Protection (DEP) to promulgate rules to implement the Act. In addition, the Act directed the Commissioner to promulgate rules implementing N.J.S.A. 26:5C-27

and 28, which would become immediately effective upon filing with the Office of Administrative Law, and which would remain effective until the adoption of rules in the ordinary course. N.J.S.A. 26:5C-31.

Pursuant to this authority, the Commissioner, in consultation with the DEP Commissioner, filed a notice of special adoption of new rules at N.J.A.C. 8:63, Sterile Syringe Access Program Demonstration Project Rules, which became effective on the filing date of April 9, 2007, and have remained in place without change since that date. 39 N.J.R. 1805(a).

N.J.S.A. 26:5C-29 required the Commissioner to submit certain periodic reports to the Governor and the New Jersey Legislature on the progress of the demonstration program. Pursuant to this mandate, the Commissioner issued several reports, among which were the *New Jersey Syringe Access Program Demonstration Project Interim Report* (January 2010), https://dspace.njstatelib.org//handle/10929/29745, and the *New Jersey Syringe Access Program Demonstration Project: Final Report* (October 2012) (hereinafter Final Report), available at https://dspace.njstatelib.org//handle/10929/29746. In both reports, the Commissioner recommended the continued existence and support of sterile syringe access programs in the State, because, among other findings, the demonstration project had "served a hard-to-reach and at-risk population, successfully helping [injection drug users] reduce their chance of contracting and spreading HIV, [and hepatitis B and C viruses] through the use of unsterile needles. Through its educational component, a large percentage of participants [had] been admitted into drug treatment programs." Final Report at 10.

On February 5, 2015, Governor Christie approved P.L. 2015, c. 10, concerning overdose prevention and sterile syringe access programs. The 2015 law, among other things, amended the Act at N.J.S.A. 26:5C-27 through 29 to permit a sterile syringe access program to obtain a standing order for opioid antidote dispensation, and authorize program staff, with immunity from prosecution, to carry and dispense naloxone hydrochloride or another opioid antidote to consumers and consumers' family members and friends.

On August 31, 2016, Governor Christie approved P.L. 2016, c. 36, concerning sterile syringe access programs. The 2016 law amended the Act by removing the limitation of sterile syringe access programs to six municipalities, thereby allowing any municipality in the State to authorize sterile syringe access programs and making the availability of such programs permanent by removing the "demonstration project" aspect of the program.

On January 18, 2022, Governor Murphy approved P.L. 2021, c. 396, concerning authorized harm reduction services. The 2022 law amended the Act to broaden the concept of harm reduction services in the State to encompass other services in addition to access to sterile syringes. P.L. 2021, c. 396, § 1, established a definition of the term "authorized harm reduction services," which permits an "eligible entity" to provide a "suite of harm reduction services approved by the Department of Health …, which services include, but shall not be limited to: syringe access, syringe disposal, referrals to health and social services, harm reduction counseling and supplies including, but not limited to, fentanyl test strips, and HIV and hepatitis C testing." P.L. 2021, c. 396, § 1, amended the Act at N.J.S.A. 26:5C-26.1 to define the term "harm reduction supplies," to

mean “any materials or equipment designed to identify or analyze the presence, strength, effectiveness, or purity of controlled dangerous substances or controlled substance analogs, including, but not limited to, fentanyl test strips; opioid antidotes and associated supplies; and any other materials or equipment that may be used to prevent, reduce or mitigate … disease transmission, overdose, and other harms associated with personal drug use.”

P.L. 2021, c. 396, §§ 4 and 5, amended the Act at N.J.S.A. 26:5C-28 and 29 to eliminate municipal authority over the establishment of harm reduction programs, subject to applicable land use considerations, and made the Department the sole regulatory authority with respect to the establishment and operation of harm reduction services centers by “eligible entities.” The Act left unchanged, the ability of eligible entities to provide authorized harm reduction services at a fixed location and/or a mobile access component, both directly and by contracting with other entities, and amended the Act to allow eligible entities to deliver authorized harm reduction services or related supplies to consumers by postal mail or another delivery service. P.L. 2021, c. 396, § 6, added new N.J.S.A. 26:5C-31.c, which authorizes the Commissioner to promulgate rules to implement P.L. 2021, c. 396, that would be effective upon filing and for 180 days thereafter, and to amend, adopt, or readopt those rules in the ordinary course in accordance with the Administrative Procedure Act, N.J.S.A. 52:14B-1 et seq.

Pursuant to this rulemaking authority, the Department hereby repeals existing N.J.A.C. 8:63, Sterile Syringe Access Program Demonstration Project Rules, and adopts, and concurrently proposes to readopt, special new rules at N.J.A.C. 8:63, Harm Reduction Centers.

Subchapter 1, General Provisions, establishes the purpose and scope of the chapter and definitions the chapter uses and incorporates by reference publications to which the chapter refers.

N.J.A.C. 8:63-1.1, Purpose and scope, establishes the purpose and scope of the chapter.

N.J.A.C. 8:63-1.2, Definitions, establishes definitions of words and terms that the chapter uses. N.J.A.C. 8:63-1.2(a) incorporates by reference the definitions the Act establishes for the following terms: "authorized harm reduction services," "eligible entity," and "harm reduction supplies." N.J.A.C. 8:63-1.2(b) defines the following additional words and terms that the chapter uses: "Act," "administrator," "AIDS service organizations," "bloodborne pathogens," "Commissioner," "consumer," "delivery," "Department," "Division," "fixed location," "harm reduction center," "HIV," "mobile access component," "needlestick injury," "registration," "regulated medical waste," "secondary distribution," "sharps waste," "staff," "viral hepatitis," and "volunteer."

N.J.A.C. 8:63-1.3, Publications and forms incorporated by reference, at subsection (a), incorporates by reference, as amended and supplemented, the following publications of the Centers for Disease Control and Prevention (CDC) and U.S. Department of Health and Human Services: *Integrated Prevention Services for HIV Infection, Viral Hepatitis, Sexually Transmitted Diseases, and Tuberculosis for Persons Who Use Drugs Illicitly: Summary Guidance* (2012) (CDC HIV Summary Guidance); and *Data Security and Confidentiality Guidelines for HIV, Viral Hepatitis, Sexually Transmitted Disease, and Tuberculosis Programs: Standards to Facilitate Sharing and Use of Surveillance Data for Public Health Action* (2011). N.J.A.C. 8:63-1.3(b)

incorporates by reference the following forms that appear in the chapter appendices: Harm Reduction Center Registration Application (Appendix A); and the Harm Reduction Center Membership Card (Appendix B).

N.J.S.A. 26:5C-27, as amended at P.L. 2021, c. 369, directs the Department to promulgate rules establishing registration and operational requirements for entities seeking to register as harm reduction centers in accordance with the Act and to establish the criteria for registration approval. Subchapter 2, Registration, implements this rulemaking requirement. N.J.A.C. 8:63-2.1, Application for registration, establishes the form, content, and process for an application for registration, which must contain the information provided in the form at Appendix A. N.J.A.C. 8:63-2.2, Issuance and term of registration, establishes the procedure for issuance, and the effective period of, a registration to operate a harm reduction center. N.J.A.C. 8:63-2.3, Renewal of registration, establishes the process by which the Department will renew a harm reduction center's registration. N.J.A.C. 8:63-2.4, Change of information notification requirements, requires registrants to notify the Department of relocation through a new registration, requires 14 days before discontinuation of services, and requires any change in the information submitted in support of a registration within 14 days.

The Act, at N.J.S.A. 26:5C-28.b, requires the Department to establish standards by which an authorized entity is to provide harm reduction services; train harm reduction center staff and maintain records of training; distribute information to consumers about certain matters; issue membership cards to consumers, staff, and volunteers; and implement confidentiality standards, medical waste handling protocols, and data

collection methods and procedures. Subchapter 3, Requirements for Operation of a Harm Reduction Center, implements these requirements.

N.J.A.C. 8:63-3.1, Harm reduction services provision; plans and protocols, requires a harm reduction center to provide services at no cost to consumers, pursuant to its registration, in accordance with the Act and the new rules, and consistent wit the CDC HIV Summary Guidance, and identifies the plans that a harm reduction center must establish. N.J.A.C. 8:63-3.2, Provision of information, identifies the information and referrals that harm reduction centers are to provide consumers. N.J.A.C. 8:63-3.3, Membership card, identifies the content of and provides a template for a uniform membership card, which the chapter incorporates by reference at Appendix B. N.J.A.C. 8:63-3.4, Data collection, reporting, and evaluation, establishes data reporting requirements and collection methods. N.J.A.C. 8:63-3.5, Training, policies, and procedures, requires harm reduction centers to train staff and volunteers, and establish and adhere to procedures addressing consumer confidentiality, regulated medical waste protocols, and nonoccupational HIV post-exposure prophylaxis, in accordance with the CDC nPEP Guidelines.

N.J.S.A. 26:5C-28.c, specifies that the Department has sole authority to terminate the registration of a harm reduction center. Subchapter 4, Enforcement, implements that authority. N.J.A.C. 8:63-4.1, Denial, suspension, or revocation of registration, establishes procedures for Department actions against a registrant. N.J.A.C. 8:63-4.2, Hearings on registration or enforcement actions, establishes hearing procedures, and establishes that applicants have 30 calendar days to submit a written request for a hearing.

As the Department has provided a 60-day comment period on the notice of proposal, this notice is excepted from the rulemaking calendar requirement pursuant to N.J.A.C. 1:30-3.3(a)5.

Social Impact

The proposed readoption of the specially adopted new rules at N.J.A.C. 8:63 would have a beneficial social impact by providing eligible entities instruction as to the process by which they can establish harm reduction centers in accordance with the Act. Facilitation of the establishment of harm reduction centers would continue to have a beneficial impact on the State by expanding access to services and treatment resources for people who use drugs, thereby reducing the morbidity and mortality associated with drug use. Harm reduction centers decrease the stigma associated with substance use disorder and HIV testing, increase opportunities for education on safer substance use and sexual practices, and connect people who use drugs with health and social services, such as support groups, food banks, mental health services, wound care, homeless shelters, and substance use disorder treatment services.

In the Act, the New Jersey Legislature, at N.J.S.A. 26:5C-26.e, "finds and declares that [e]very scientific, medical, and professional agency or organization that has studied this issue, including the [Federal] Centers for Disease Control and Prevention [(CDC)], the American Medical Association, the American Public Health Association, the National Academy of Sciences, the National Institutes of Health Consensus Panel, the American Academy of Pediatrics, and the United States Conference of Mayors, has found harm reduction services to be effective in reducing the transmission of HIV"; at subsection k, N.J.S.A. 26:5C-26 notes that the CDC

recognizes “harm reduction services as an effective component of a comprehensive and integrated approach to HIV prevention”; and at subsection l, notes that the “[United States] Department of Health and Human Services has stated that there is conclusive scientific evidence that harm reduction services, as part of a comprehensive HIV prevention strategy, are an effective public health intervention that reduces the transmission of HIV and does not encourage the use of illegal drugs.”

Economic Impact

The proposed readoption of the specially adopted repeal and new rules at N.J.A.C. 8:63 would impose administrative costs on the Department associated with the modification of the Department’s existing unit that oversees syringe access services programs to implement its expanded role with respect to the “suite of harm reductions services” that eligible entities can now provide. The Department would incur costs to inform the regulated community of the opportunity to establish harm reduction centers, encourage the submission of applications for registration, review and process registration and registration renewal applications, and conduct oversight and enforcement activities.

Costs incurred by an eligible entity to establish a harm reduction center will vary depending on whether the entity applying for registration has an existing infrastructure for the provision of services. Reporting, recordkeeping, and compliance costs that applicants for registration and registered harm reduction centers may incur include premises’ rental or purchase costs and associated maintenance expenses, staff salaries and training expenses, costs to produce and publish required informational and other materials, and costs to acquire medical supplies and equipment, such as syringes and

test strips, and non-medical resources, such as information technology and internet access and the establishment of links to health and social services providers.

Consumers of harm reduction centers realize an economic benefit from the new rules because harm reduction centers provide services at no cost to consumers. Moreover, consumers might realize economic benefits by engaging with health and social services to which harm reduction centers offer access, such as increased employability and fitness to work resulting from referrals to, and/or provision of, health care services and treatment to mitigate the physical effects of injection drug use and infectious disease, which facilitate recovery from substance use disorder.

Health systems and health insurance companies may realize an indirect benefit from the proposed readoption of the specially adopted new rules. The high cost of treating HIV infection greatly outweighs the investment in harm reduction services to prevent the contraction of HIV. In cases of overdose, harm reduction centers can lower the rate of ambulance runs, emergency department visits, inpatient hospitalizations for overdose care, and prevent new infections of HIV and viral hepatitis. This is accomplished through the dissemination of naloxone and counseling to consumers and the public to prevent overdose incidents and the necessity for responsive emergency medical services. The distribution of sterile syringes would prevent new HIV and viral hepatitis infections. The proposed readoption of the specially adopted new rules will reduce healthcare spending on overdose incidents by connecting consumers with preventative healthcare services.

A recent cost-benefit analysis of harm reduction centers in Rhode Island found that the economic benefits realized from the establishment and maintenance of harm

reduction centers far outweighed the cost to fund them. Rhode Island Department of Health, *Harm Reduction Centers Cost Benefit Analysis* (2021), available at https://risos-apa-production-public.s3.amazonaws.com/DOH/11465/ADDDOC_11465_20211202114753.pdf (finding that the annual operating cost to operate a harm reduction center was $1,602,334; that a harm reduction center is estimated to prevent 1.9 deaths per year (equivalent to preventing 19 deaths every 10 years), 261.3 ambulance runs, 244 emergency department visits, and 117.1 inpatient hospitalizations for emergency overdose care; that a harm reduction center would prevent 0.5 HIV infections and 2.8 hepatitis C virus infections; and that in total, accounting for the annual operating costs of a harm reduction center and short-term medical costs of emergency overdose care, the harm reduction center would be cost-saving; specifically, the total short-term savings would be approximately $1,104,454 annually).

Federal Standards Statement

The specially adopted new rules at N.J.A.C. 8:63 fulfill the Department's rulemaking obligations pursuant to the Act. The specially adopted new rules are not proposed for readoption to implement, comply with, or participate in, any program established pursuant to Federal law or State law that incorporates or refers to any Federal law, standard, or requirement. The chapter incorporates by reference Federal (CDC) standards and recommendations for data security and confidentiality, regulated medical waste handling, bloodborne pathogens training, and HIV post-exposure prophylaxis, to the extent these standards are applicable to the services that a harm

reduction center elects to provide, and would meet, but not exceed, those standards. Therefore, a Federal standards analysis is not required.

Jobs Impact

The Department anticipates that the specially adopted new rules at N.J.A.C. 8:63 proposed for readoption would result in the generation of new jobs in the State. Existing harm reduction centers employ an array of staff to ensure their effective functioning. The establishment of new harm reduction centers is likely to result in the creation of jobs for medical and non-medical case managers, and administrative, social services, and outreach staff, especially among persons with lived experiences associated with injection drug use and substance use disorder.

The new rules will generate new jobs within the Department for personnel to support application review and registration, conduct inspections and enforcement activities, and provide technical assistance, grant management, and program operations for applicants for registration and registered harm reduction centers.

Agriculture Industry Impact

The specially adopted new rules at N.J.A.C. 8:63 proposed for readoption would have no impact on the agriculture industry of the State.

Regulatory Flexibility Analysis

The specially adopted new rules proposed for readoption, at N.J.A.C. 8:63, establish reporting, recordkeeping, and compliance requirements on the Department, applicants for registration and renewal of registration as harm reduction centers, and the seven existing harm reduction centers, formerly known as sterile syringe access programs. Of these applicants for registration and renewal of registration may be small

businesses within the meaning of the New Jersey Regulatory Flexibility Act, N.J.S.A. 52:14B-16 et seq. Pursuant to the Act, these entities would be Federally qualified health centers, public health agencies, substance abuse treatment programs, AIDS service organizations, and other entities that the Department determines to have the capacity to provide harm reduction services. The Department is unable to estimate the number of eligible entities that might apply for registration. Most, or all, of the seven existing harm reduction centers, formerly known as sterile syringe access programs, are small businesses within the meaning of the Act.

An eligible entity that elects to establish and register, or renew its registration, as a harm reduction center is subject to reporting, recordkeeping, and compliance requirements, and incurs compliance costs, regardless of business size. The Summary, Social Impact, and Economic Impact above, describe these requirements and costs.

The rules proposed for readoption do not require a registrant to retain the services of professionals to comply. An eligible entity electing to offer ancillary harm reduction services that only licensed professionals can provide would need to retain the services of professionals whose respective scopes of practice include the provided ancillary services. The cost to retain these professionals would depend on the services provided, the number of hours of operation, the requisite skill level of the professional to perform the service, and whether the professional is serving in a volunteer or compensated capacity.

The rules would oblige an applicant and a registrant to provide the minimum core services to consumers. Beyond the initial costs to establish these mandatory services, the compliance requirements and costs are self-scaling as to business size, relative to

the ancillary harm reduction services a registrant elects to provide, the size of the service area from which it draws consumers and relative demand for services in that service area, and the resulting number of consumers it serves. The Department proposes no lesser or differing standards based on facility size because the Department has determined that the rules at N.J.A.C. 8:63 establish the minimum standards necessary to ensure registrants' provision of core harm reduction services, and thereby facilitate the uniform operation, and Department registration and oversight, of harm reduction centers.

Housing Affordability Impact Analysis

The proposed readoption of the specially adopted new rules at N.J.A.C. 8:63 would have no impact on the affordability of housing in New Jersey and would not evoke a change in the average costs associated with housing, because the rules establish standards for registration and operation of harm reduction centers and will not have any effect on housing costs.

Smart Growth Development Impact Analysis

The proposed readoption of the specially adopted new rules at N.J.A.C. 8:63 would not evoke a change in the housing production within Planning Areas 1 or 2, or within designated centers, under the State Development and Redevelopment Plan, because the rules proposed for readoption establish standards for registration and operation of harm reduction centers and will not have any effect on housing production.

Racial and Ethnic Community Criminal Justice and Public Safety Impact

The Department has evaluated N.J.A.C. 8:63 and determined that the chapter will not have an impact on pretrial, detention, sentencing, probation, or parole policies

concerning adults and juveniles in the State. Accordingly, no further analysis is required.

Full text of the specially adopted repealed rules may be found in the New Jersey Administrative Code at N.J.A.C. 8:63.

Full text of the specially adopted new rules follows:

CHAPTER 63

HARM REDUCTION CENTERS

SUBCHAPTER 1. GENERAL PROVISIONS

8:63-1.1 Purpose and scope

(a) The purpose of this chapter is to implement the Bloodborne Disease Harm Reduction Act, N.J.S.A. 26:5C-25 et seq.

(b) This chapter applies to eligible entities in the State that provide or seek to provide authorized harm reduction services.

(c) An eligible entity that provided authorized harm reduction services on or before January 18, 2022, pursuant to the Act as it existed up to that date and former N.J.A.C. 8:63, the Sterile Syringe Access Program Demonstration Project Rules (repealed and replaced by this chapter), need not apply for registration but shall adhere to the renewal schedule that the Act and this chapter establish.

8:63-1.2 Definitions

(a) The following words and terms, as used in this chapter, shall have the meanings that N.J.S.A. 26:5C-26.1 establishes:

"Authorized harm reduction services";

“Eligible entity”; and

“Harm reduction supplies.”

(b) The following words and terms, as used in this chapter, shall have the following meanings, unless the context clearly indicates otherwise:

“Act” means N.J.S.A. 26:5C-25 through 31.

“Administrator” means a person having the authority and responsibility for the operation of the harm reduction center and serves as the contact for communication with the Department.

“AIDS service organization” means a non-governmental organization that provides services related to the prevention and treatment of HIV or acquired immunodeficiency syndrome (AIDS).

“Bloodborne pathogen” means “bloodborne pathogens,” as 29 CFR 1910.1030 defines that term.

“Commissioner” means the Commissioner of the New Jersey Department of Health.

“Consumer” means a person who receives authorized harm reduction services from a harm reduction center.

“Delivery” means the provision of authorized harm reduction services and/or supplies by a staff member or volunteer of a harm reduction center to consumers at a location other than a fixed location or mobile access component of a harm reduction center, including by means of postal mail or another means of delivery.

“Department” means the New Jersey Department of Health.

"Division" means the Division of HIV, STD, and TB Services, of the Department, for which the contact information is Division of HIV, STD, and TB Services, Department of Health, PO Box 363, Trenton, NJ 08625-0363, telephone (609) 984-5874, electronic mail HRC@doh.nj.gov.

"Fixed location" means a building, structure, or other premises with a physical address at which a registrant regularly provides authorized harm reduction services.

"Harm reduction center" means an entity that the Department registers to provide authorized harm reduction services in accordance with the Act and this chapter.

"HIV" means human immunodeficiency virus, the etiologic virus of AIDS.

"Mobile access component" means a movable unit that provides authorized harm reduction services and/or supplies at one or more temporary locations by using a vehicle, such as a car, truck, van, trailer, or another movable unit.

"Needlestick injury" means a penetrating wound from a needle that may result in exposure to blood.

"Registration" means the Department's approval of an application for registration as a harm reduction center pursuant to the Act at N.J.S.A. 26:5C-27 and this chapter.

"Regulated medical waste" means "regulated medical waste" or "medical waste" as N.J.S.A. 13:1E-48.3 and N.J.A.C. 7:26-3A, particularly N.J.A.C. 7:26-3A.5 and 3A.6, define and describe that term.

"Secondary distribution" means the provision of harm reduction supplies by a consumer who obtained the supplies from a harm reduction center, and who distributes the supplies to other persons at a location other than the harm reduction center, provided the consumer is authorized by the harm reduction center of which they are a

member to engage in such secondary distribution, and the consumer receives no compensation from any person for the act of distribution to others or for the distributed supplies.

"Sharps waste" means used needles, syringes, and lancets.

"Staff" means a person that works for a harm reduction center and receives remuneration or other tangible benefits from the harm reduction center for the performance of authorized harm reduction services on behalf of the harm reduction center.

"Viral hepatitis" means any of the forms of hepatitis caused by a virus.

"Volunteer" means a person that works for a harm reduction center who does not receive remuneration from the harm reduction center for the performance of authorized harm reduction services on behalf of the harm reduction center.

8:63-1.3 Publications and forms incorporated by reference

(a) The following publications and resources issued by the Centers for Disease Control and Prevention, Atlanta, GA, of the United States Department of Health and Human Services, are incorporated herein by reference, as amended and supplemented:

1. *Integrated Prevention Services for HIV Infection, Viral Hepatitis, Sexually Transmitted Diseases, and Tuberculosis for Persons Who Use Drugs Illicitly: Summary Guidance,* MMWR, Vol. 61, No. 5 (November 9, 2012), available at https://www.cdc.gov/mmwr/preview/mmwrhtml/rr6105a1.htm (hereinafter referred to as "CDC HIV Summary Guidance");

2. *Data Security and Confidentiality Guidelines for HIV, Viral Hepatitis, Sexually Transmitted Disease, and Tuberculosis Programs: Standards to Facilitate Sharing and Use of Surveillance Data for Public Health Action* (2011), available at https://www.cdc.gov/nchhstp/programintegration/data-security.htm, and at https://www.cdc.gov/nchhstp/programintegration/docs/pcsidatasecurityguidelines.pdf (hereinafter referred to as "CDC HIV Data Security and Confidentiality Guidelines"); and

3. *Updated Guidelines for Antiretroviral Postexposure Prophylaxis After Sexual, Injection Drug Use, or Other Nonoccupational Exposure to HIV—United States, 2016* (April 18, 2016, updated May 23, 2018), available at https://stacks.cdc.gov/view/cdc/38856 (hereinafter referred to as "CDC nPEP Guidelines").

(b) The following forms are incorporated herein by reference and available at the Department's forms page at https://www.nj.gov/health/forms, and upon request to the Division:

1. N.J.A.C. 8:63 Appendix A, Harm Reduction Center Registration Application; and

2. N.J.A.C. 8:63 Appendix B, Harm Reduction Center Membership Card.

SUBCHAPTER 2. REGISTRATION

8:63-2.1 Application for registration

(a) An eligible entity shall apply to the Department for registration as a harm reduction center before providing authorized harm reduction services in the State.

(b) An eligible entity seeking to establish and operate a harm reduction center shall submit to the Division by electronic or regular mail:

1. A completed registration application in the form at chapter Appendix A; and

2. A data collection and program evaluation plan by which the harm reduction center will collect the following data elements, which are to be reported to the Department by means of a Department-designated data platform:

i. The number of unduplicated consumers;

ii. The number of syringes and needles dispensed;

iii. An estimate of the number of returned and disposed of syringes, provided that under no circumstances is a harm reduction center to require hand-counting of used syringes;

iv. The number of tests the harm reduction center performs for HIV, viral hepatitis, and sexually transmitted infections, if applicable, including the number of positive and negative results;

v. The number of referrals the harm reduction center issues for HIV, viral hepatitis, and sexually transmitted infection testing;

vi. The number of referrals to substance use disorder treatment services, and, if known, the number of consumers who enrolled or participated in substance use disorder treatment services following referral; and

vii. The number of referrals the harm reduction center issues for services other than testing and substance use disorder treatment.

(c) An eligible entity seeking to establish and operate a harm reduction center that will provide sterile syringes to consumers under 18 years of age shall submit to the Division

with its application for registration a justification establishing the need for sterile syringes to be provided to consumers under 18 years of age that includes substantive qualitative and quantitative reasons.

8:63-2.2 Issuance and term of registration

(a) The Department shall review the application for completeness and compliance with the Act and this chapter.

(b) The Department shall issue a written determination to an applicant within 30 business days from the date it receives an application, in which it will:

1. Approve or deny the application in accordance with (c), (d), and (e) below;

2. Advise the applicant that the application is incomplete and specify the information or material needed to complete the application; or

3. Advise the applicant that the Department requires additional time within which to review the application and indicate the date by which the Department will provide a determination to approve or deny the application.

(c) The Department shall approve an application and register the applicant as a harm reduction center if:

1. The applicant fully and accurately completes all parts of the registration application form prescribed by the Department; and

2. The Department determines that the applicant and proposed harm reduction center comply with the requirements of the Act and this chapter.

(d) If an applicant for registration seeks to provide sterile syringes to consumers under the age of 18, the Department shall identify, in the written notice of approval of

registration it issues to an applicant, whether it authorizes the harm reduction center to provide sterile syringes to persons under the age of 18.

(e) If the Department denies an application pursuant to (c) or (d) above, the Department shall notify the applicant, in writing, and provide the applicant an opportunity to complete the application or provide additional information.

(f) A registration shall be valid for three calendar years beginning on January 1 of each year and ending on December 31 of each year.

(g) A registration is not assignable or transferable.

(h) The Department shall maintain an up-to-date list of the entities that are authorized pursuant to N.J.A.C. 8:63-1.1(c) to operate harm reduction centers and the entities to which it issues registration pursuant to this chapter, which will contain the information that an entity specifies for inclusion therein in its application for registration.

(i) Upon registration, a harm reduction center shall request database access and training for submission of data by contacting the Division at HRC@doh.nj.gov.

8:63-2.3 Renewal of registration

(a) The Department shall renew a registration to operate a harm reduction center, provided:

1. The harm reduction center submits to the Department, no fewer than 30 calendar days prior to the expiration of the existing registration, a fully and accurately completed form of application for renewal of its registration, containing the information listed in the form at chapter Appendix A;

2. The Department has not suspended or revoked the registration of the harm reduction center; and

3. The Department determines that the applicant remains in compliance with the requirements of the Act and this chapter.

(b) If a harm reduction center timely files an application for renewal of its registration in accordance with (a) above, the existing registration of the harm reduction center shall not expire until the Department makes a final determination on the application for renewal of the registration.

(c) If a harm reduction center fails to timely file an application for renewal of its registration in accordance with (a) above, then the Department shall treat the application for registration as if it were an application for initial registration, which may result in service interruption.

8:63-2.4 Change of information notification requirements

(a) A harm reduction center seeking to relocate from the fixed location at which it registers to provide services shall apply for registration at the proposed new location in accordance with N.J.A.C. 8:63-2.1 and 2.2 and shall not provide services at the proposed new location until the Department approves registration of the harm reduction center at the proposed new location.

(b) A harm reduction center shall notify the Department, in writing, in care of the Division, at least 14 days before it plans to discontinue the provision of authorized harm reduction services in accordance with its registration application and/or supplements thereto.

(c) Subject to (a) and (b) above, a harm reduction center shall notify the Department, in writing, in care of the Division, no later than 14 calendar days after any change in the information on file with the Department in its registration application and/or supplements thereto, including hours of operation, services offered, or methods of service.

SUBCHAPTER 3. REQUIREMENTS FOR OPERATION OF A HARM REDUCTION CENTER

8:63-3.1 Harm reduction services provision; plans and protocols

(a) A harm reduction center shall provide authorized harm reduction services and harm reduction supplies to consumers at no cost, pursuant to its registration, in accordance with the Act and this chapter, and consistent with CDC HIV Summary Guidance.

(b) A harm reduction center shall establish and implement plans by which it will comply with each of the requirements at N.J.S.A. 26:5C-28.b(1) through (10) and shall make these plans available to all harm reduction center personnel, and the Department, upon request.

(c) A harm reduction center shall establish and implement a plan for its compliance pursuant to N.J.S.A. 26:5C-28.b(11) and shall submit the plan with its application for registration.

(d) A harm reduction center may obtain and distribute naloxone hydrochloride or another opioid antidote to family members and friends of consumers, and any member of the public in accordance with the Overdose Prevention Act, N.J.S.A. 24:6J-1 et seq.

(e) A harm reduction center that authorizes consumers to engage in secondary distribution pursuant to the Act and this chapter shall maintain a policy for such

secondary distribution, which may include a policy that authorizes all of the center's consumers to engage in secondary distribution in accordance with its policy. Except as otherwise provided in this section, nothing in this chapter shall be interpreted to restrict secondary distribution of harm reduction supplies, including syringes.

(f) A harm reduction center that contracts with a third-party entity pursuant to N.J.S.A. 26:5C-28.a(1) need not obtain the Department's prior approval of the contract.

8:63-3.2 Provision of information

(a) A harm reduction center shall provide the following information to consumers:

1. A schedule of the harm reduction center's operating hours and locations; and

2. Spoken education about HIV, viral hepatitis, overdose prevention, harm reduction services, and substance use disorder treatment services, and, at the election of the harm reduction center, printed materials and links to electronic materials on these topics.

i. A list of trusted sources of information and material for distribution to consumers is available on the Division's website at https://www.nj.gov/health/hivstdtb/hrc.shtml.

(b) A harm reduction center shall:

1. Provide information and referrals based on the harm reduction center's determination of consumer need;

2. Educate all consumers about safe and proper disposal of needles and syringes;

3. Encourage consumers to receive HIV, viral hepatitis, and sexually transmitted infection tests; and

4. Provide overdose prevention information to consumers, family members and friends of consumers, and members of the public, in accordance with N.J.S.A. 24:6J-5.

8:63-3.3 Membership card

(a) A harm reduction center shall issue a Harm Reduction Center Membership Card in the form at chapter Appendix B to:

1. Consumers; and

2. Staff and volunteers of the harm reduction center.

(b) Each membership card shall contain a registration number, which shall be a unique identifying number based on a confidential formula that the harm reduction center establishes and maintains.

8:63-3.4 Data collection, reporting, and evaluation

(a) With respect to each consumer it serves, a harm reduction center shall collect and record, to the extent practicable and with the consumer's consent, at least the following information:

1. The consumer's age, race, ethnicity, sex at birth, and current gender identity;

2. The substances the consumer uses and the modes of use;

3. The dates on which the harm reduction center delivers authorized harm reduction services to the consumer; and

4. A list of the authorized harm reduction services and referrals, if any, that the harm reduction center provides during each encounter with a consumer.

(b) Each harm reduction center shall submit to the Department, on a quarterly basis, data it collects pursuant to its data collection and program evaluation plan and this section.

(c) A harm reduction center shall submit reports of communicable and reportable diseases such as HIV, viral hepatitis, and sexually transmitted infections in accordance with applicable provisions at N.J.A.C. 8:57 and 8:65.

(d) At its discretion, the Department may conduct onsite and remote evaluations and surveys of harm reduction centers to confirm compliance with the Act and this chapter, following which, the Department will provide the harm reduction center a written report of its findings that specifies any deficiencies in compliance and, if deficiencies exist, shall:

1. Require the registered harm reduction center to submit, within 30 days of receipt of the notice of deficiencies, a plan of correction specifying the methods and schedule by which it will correct the deficiencies;

2. Review the plan and notify the harm reduction center as to the plan’s acceptability; and

3. Upon the Department’s acceptance of the plan, require the harm reduction center to comply with the plan.

8:63-3.5 Training, policies, and procedures

(a) A harm reduction center shall:

1. Ensure that staff and volunteers receive training as required at N.J.S.A. 26:5C-28.b(2), and maintain records of staff and volunteer training;

2. Establish appropriate administrative, technical, and physical controls and safeguards that protect the confidentiality, integrity, and availability of individually identifiable information about consumers, in compliance with applicable provisions of the CDC HIV Data Security and Confidentiality Guidelines;

3. Establish procedures for compliance with the Bloodborne Pathogens Standard; and

4. Develop and maintain protocols for HIV post-exposure prophylaxis in accordance with guidelines of the Centers for Disease Control and Prevention available at https://www.cdc.gov/hiv/risk/pep/index.html.

SUBCHAPTER 4. ENFORCEMENT

8:63-4.1 Denial, suspension, or revocation of registration

(a) If the Department determines that a registered harm reduction center is in violation of any provisions of the Act or this chapter, or if necessary to abate a threat to the public health, safety, or welfare, the Department may:

1. Issue a formal written warning; or

2. Suspend, revoke, or refuse to issue or renew, a registration to operate a harm reduction center.

(b) If the Department suspends, revokes, or refuses to issue or renew, a registration to operate a harm reduction center, it shall issue a written notice thereof to the applicant or harm reduction center, stating the reasons for the denial, suspension, or revocation, and

informing the applicant or harm reduction center of its ability to request a hearing to contest the action.

(c) The Department shall post on its Internet website any action it takes pursuant to this section in accordance with applicable provisions of Executive Order No. 227 (2017).

8:63-4.2 Hearings on registration or enforcement actions

(a) An applicant or harm reduction center seeking a hearing pursuant to N.J.A.C. 8:63-4.1(b) shall submit to the Department a written request for a hearing within 30 calendar days from the date of the notice of denial, suspension, or revocation.

(b) Failure to submit a timely written request pursuant to (a) above shall result in the applicant or harm reduction center forfeiting all rights to such a hearing.

(c) Hearings shall be conducted pursuant to the Administrative Procedure Act, N.J.S.A. 52:14B-1 et seq., and 52:14F-1 et seq., and the Uniform Administrative Procedure Rules, N.J.A.C. 1:1.