



## **Rhode Island Department of Health Public Advance Notice of Proposed Rulemaking**

In accordance with Rhode Island Gen. Laws § 42-35-2.5, advance notice is hereby given that the Rhode Island Department of Health (RIDOH) proposes to adopt rules and regulations for Harm Reduction Centers (216-RICR-40-10-25).

**Timetable for Action on the Proposed Rule:** The public comment period ends on Wednesday, September 29, 2021. An open meeting regarding this proposed rule will be held on Wednesday September 22<sup>nd</sup> at 2:30 to 3:30 PM.

**Summary of Proposed Rule:** The RIDOH is proposing rulemaking to adopt regulations on Harm Reduction Centers that covers requirements for licensure, organization and management, management of clinical services, environmental management, physical plant and equipment, and practices and procedures.

**Comments Invited:** All Interested parties are invited to submit written comments concerning the proposed regulations. Oral/written comments can be submitted by the public at an open meeting to be held:

**Wednesday, September 22, 2021  
2:30 PM to 3:30 PM**

Join Zoom Meeting

<https://riema.zoom.us/j/95532513902>

Meeting ID: 955 3251 3902

Dial In: 646-876-9923

Also, written comments can be submitted by mail to Paula Pullano, Rhode Island Department of Health, 3 Capitol Hill, Providence, RI 02908-5097 or by email at [paula.pullano@health.ri.gov](mailto:paula.pullano@health.ri.gov) by the close of Wednesday, September 29, 2021. Please note that comments submitted to RIDOH by other means than the prescribed mailing and email address may not be received. To ensure that your comments are received, please send them to the prescribed mailing and email address.

**For Further Information Contact:** Paula Pullano, Rhode Island Department of Health, Division of Policy, Information, and Communications, 3 Capitol Hill, Providence, Rhode Island 02908-5097, 401-222- 1042, paula.pullano@health.ri.gov.

**Authority for Rulemaking:** R.I. Gen. Laws § 23-12.10

## TITLE 216 – DEPARTMENT OF HEALTH

### CHAPTER 40 – PROFESSIONAL LICENSING AND FACILITY REGULATION

#### SUBCHAPTER 10 - FACILITIES REGULATION

##### PART 25 – Harm Reduction Centers

### 25.1 Authority

These regulations are promulgated pursuant to the authority conferred under R.I. Gen. Laws Chapter 23-12.10 for the purpose of establishing minimum standards for Harm Reduction Centers that are consistent with acceptable international standards of practice and that will provide services in such a manner as to safeguard the health, safety, and welfare of clients.

### 25.2 Definitions

- A. Wherever used in this Part the following terms shall be construed as follows:
1. "Change in owner" means a transfer by the governing body or operator of a healthcare facility to any other person (Excluding delegations of authority to the medical or administrative staff of the facility) of the governing body's authority to:
    - a. Hire or fire the chief executive officer of the healthcare facility;
    - b. Maintain and control the books and records of the healthcare facility
    - c. Dispose of assets and incur liabilities on behalf of the healthcare facility; or
    - d. Adopt and enforce policies regarding operation of the healthcare facility.
  2. "Client" means a person who uses the services of a harm reduction center.
  3. "Department" or "RIDOH" means the Rhode Island Department of Health.
  4. "Director" means the Director of the Rhode Island Department of Health or his or her designee.
  5. "Drug consumption" means smoking, injecting, snorting, inhaling, swallowing, or otherwise consuming pre-obtained, controlled substances.

6. "Harm Reduction Center" or "Center" means a community-based resource for health screening disease prevention and recovery assistance where persons may safely consume pre-obtained controlled substances in a non-judgmental, supportive environment. Each harm reduction center must provide the necessary health care and/or harm reduction professionals and supplies/equipment to prevent overdose and must also provide resources and referrals for additional harm reduction, social services, counseling or other medical treatment that may be appropriate for persons utilizing the harm reduction center.
7. "Licensed capacity" means the number of drug consumption stations a center is licensed to operate within the facility.
8. "Medical Director" means a physician licensed to practice medicine in Rhode Island in accordance with R.I. Gen. Laws Chapter 5-37.
9. "Mobile Service Site" means the location where a mobile unit is parked when providing a service to a client.
10. "Mobile Unit Staging Site" means any location that serves as a base for maintaining a mobile unit
11. "Mobile Unit" means a motor vehicle that is specially designed, constructed, and equipped to provide any of the harm reduction services set forth in this Part.
12. "Municipal authorization and approval" means an express affirmative vote by the city or town council, or the equivalent governing body, of any municipality where a harm reduction center is proposed to be located, which affirmative vote approves the opening and operation of the harm reduction center.
13. "Nurse" means an individual licensed to practice as a professional (registered)(RN) or licensed practical nurse (LPN) in Rhode Island pursuant the provisions of R.I. Gen. Laws Chapter 5-34.
14. "Opioid" means any opiate, synthetic or natural, or opium derivative, listed in [R.I. Gen. Laws § 21-28-2.08](#).
15. "Opioid antagonist" means a drug used to reverse the effects of opioids, such a naloxone hydrochloride, commonly referred to as naloxone or by the brand name Narcan, which is a competitive antagonist that binds to opioid receptors with higher affinity than agonists but does not activate the receptors. For the purposes of this Part, opioid antagonist does not include any drugs, such as naltrexone hydrochloride, used for addiction treatment.

16. "Overdose" means a condition including, but not limited to, extreme physical illness, decreased level of consciousness, respiratory depression, coma, or death resulting from the consumption or use of an opioid, or another controlled substance. This would include an overdose that requires medical assistance, clinical suspicion for drug overdose (respiratory depression, unconsciousness, altered mental status) and either a urine toxicology screen positive for opiates or negative urine toxicology screen without other conditions to explain the clinical condition.
17. "Peer support worker" means people who have been successful in the recovery process who help others experiencing similar situations, using shared understanding, respect, and mutual empowerment.
18. "Person" means any individual, trust or estate, partnership, corporation (including associations, joint stock companies), limited liability company, state, or political subdivision or instrumentality of the state.
19. "Premises" means a tract of land and the buildings thereon where direct patient care services are provided.
20. "Smoking" or "smoke" means inhaling, exhaling, burning, vaporizing, or carrying any lighted or heated cigar, cigarette, pipe, weed, plant, other tobacco product or pharmacologically active chemical or other combustible substance in any manner or in any form intended for inhalation in any manner or form. "Smoking" or "smoke" also includes the use of electronic cigarettes, electronic cigars, electronic pipes, electronic nicotine

## **25.3 Licensing Procedures**

### **25.3.1 General Requirements for Licensure**

- A. No person or governmental unit acting severally or jointly with any other person or governmental unit shall establish, conduct, maintain or operate or hold itself out as a Harm Reduction Center in Rhode Island without a license in accordance with the requirements of R.I. Gen. Laws § 23-12.10 and this Part.
- B. Each Harm Reduction Center application shall specify the licensed capacity within the Center.
- C. Proposed changes in Center capacity shall be submitted in writing to the Department and shall be subject to the approval of the Department.
- D. Notwithstanding the requirements of § 25.3 of this Part, a facility licensed as a Harm Reduction Center in Rhode Island, may provide services at other premises or Mobile Service Sites operated by that licensed Harm Reduction Center, without the requirement of a separate Harm Reduction Center license for such other locations.

- E. Each premises or Mobile Service Sites proposed for addition to a Harm Reduction Center license pursuant to § 25.3.6 of this Part shall be approved by the Department prior to the inclusion of that premises or Mobile Service Site on the Harm Reduction Center license and commencement of operations at such location.
- F. Each premises or Mobile Unit of a licensed Harm Reduction Center shall comply with all pertinent provisions of this Part consistent with the scope of services provided.

### **25.3.2 Application for License, Initial License or Changes in Owner, Operator, or Lessee**

- A. Application for a license to conduct, maintain or operate a Harm Reduction Center shall be made to the Department upon provided forms, and shall contain such information as the Department reasonably requires, including but not limited to evidence of ability to comply with this Part.
  - 1. Each Harm Reduction Center shall establish and maintain a facility specific electronic mail address (i.e., e-mail address) to be provided to the Department for the purposes of contacting the Harm Reduction Center with both routine communications and emergency notices. The Harm Reduction Center shall be responsible for providing notice to the Department at any time that the Center's specific electronic mail address is changed or updated.
- B. A listing of names and addresses of direct and indirect owners whether individual, partnership or corporation with percentages of ownership designated shall be provided with the application for licensure and shall be updated annually. The list shall also include all officers, directors and other persons or any subsidiary corporation owning stock, if the Center is organized as a corporation, and all partners if the Center is organized as a partnership. If the Center is organized as a not-for-profit corporation, the list shall include the names of all officers and Directors of the non-profit corporation.
- C. When a change of ownership or operation or location of a Harm Reduction Center is planned or when discontinuation of services is contemplated, the Department shall be given written notice of pending changes within forty-five (45) days of such pending changes.
- D. A license shall immediately expire and become void and shall be returned to the Department when operation of a Harm Reduction Center is discontinued or when any changes in ownership occur.
- E. Prior to operating under a new owner or operator, the Harm Reduction Center shall apply for a new license in accordance with § 25.3.3 of this Part.

- F. When there is a change in operation or ownership of the Harm Reduction Center, the Department reserves the right to extend the expiration date of such license, allowing the Harm Reduction Center to operate under the same license which applied to the prior licensee for such time as shall be required for the processing of a new application or reassignment of participants, not to exceed six (6) weeks.

### **25.3.3 Issuance and Renewal of License**

- A. Upon receipt of an application for license, the Department shall issue a license or renewal thereof for a period of no more than one (1) year if the applicant meets the requirements of this Part. Said license, unless sooner suspended or revoked, shall sunset on March 1, 2024.
- B. The Harm Reduction Center operator must submit written documentation of municipal authorization and approval with the licensure application. A license will not be issued without written documentation of municipal authorization.
- C. Prior to issuing a license, RIDOH will conduct an inspection of the Center.
- D. A license shall be issued to a specific licensee for a specific premise and/or Mobile Service Site(s) and shall not be transferable. The license shall be issued only for the premises and the individual owner, operator or lessee, or to the corporate entity responsible for its governance.
- E. A license issued hereunder shall be the property of the State of Rhode Island loaned to such licensee and it shall be kept posted in a conspicuous place on the licensed premises.

### **25.3.4 Inspections**

- A. The Department shall make or cause to be made such inspections and investigations as it deems necessary.
- B. Every Center shall be given notice within fifteen (15) business days by the Department of any deficiencies reported as a result of an inspection or investigation.
- C. A duly authorized representative of the Department shall have the right to enter at any time without prior notice to inspect the entire premises and services, including all records of any Center for which an application has been received or for which a license has been issued. Any application shall constitute permission for and willingness to comply with such inspections.
- D. Refusal to permit inspections shall constitute a valid ground for license revocation.

### **25.3.5 Denial, Suspension, Revocation of License, or Curtailment of Activities**

- A. The Department is authorized to deny, suspend, or revoke the license of or to curtail the activities of any Center that:
  - 1. Failed to comply with the provisions of R.I. Gen. Laws Chapter 23-12.10 and these regulations promulgated thereunder.
  - 2. Reports of deficiencies noted in inspections conducted in accordance with § 25.3.4 of this Part shall be maintained on file in the Department and shall be considered by the Department in rendering determinations to deny, suspend or revoke the license or to curtail activities of a Center.
- B. Whenever an action shall be proposed to deny, suspend or revoke the license of or to curtail the activities of a Center, the Department shall notify the Center by certified mail, setting forth reasons for the proposed action, and the applicant or licensee shall be given an opportunity for a prompt and fair hearing in accordance with R.I. Gen. Laws § 42-35-9 and in accordance with the provisions of § 25.8.3 of this Part.
  - 1. However, if the Department finds that public health, safety, or welfare imperatively requires emergency action and incorporates a finding to that effect in its order, the Department may order summary suspension of license or curtailment of activities pending proceedings for revocation or other action in accordance with R.I. Gen. Laws §§ 23-1-21 and 42-35-14(c).
- C. The appropriate state agencies shall be notified of any action taken by the Department pertaining to denial, suspension, revocation of license, or curtailment of activities.

### **25.3.6 Licensing of Mobile Units**

- A. In addition to a physical location, A Harm Reduction Center is permitted to provide harm reduction services through a Mobile Unit. A Mobile Unit may operate under the existing Center license but must be approved by the Department prior to use.
- B. The provider must comply with the following additional requirements and codes for the mobile unit. Variances are not permitted for these items:
  - 1. The unit must have a current motor vehicle registration and inspection sticker from the Rhode Island Division of Motor Vehicles.
  - 2. The driver of the mobile unit shall maintain a Rhode Island state issued driver's license in good standing.
  - 3. The provider must obtain and maintain appropriate levels of motor vehicle insurance as recommended by their insurance carrier.



4. Provider must obtain and maintain General Liability insurance for the amount of \$1,000,000 each occurrence and \$1,000,000 general aggregate.
5. Compliance to Life Safety Code NFPA 101 as evidence by inspection report from the State Fire Marshal or local Fire Department.
6. All electrical material and equipment shall be installed with applicable sections of NFPA 70: National Electric Code.

## **25.4 Organization and Management**

### **25.4.1 Governing Body and Management**

- A. Each Center shall have an organized governing body or equivalent legal authority ultimately responsible for:
  1. The management and control of the operation;
  2. The assurance of quality care and services;
  3. Compliance with all state and local laws and regulations; and
  4. All relevant health and safety requirements, including compliance with this Part.
- B. The governing body or equivalent legal authority shall be responsible to provide a sufficient number of appropriately qualified personnel, physical resources, equipment, supplies, and services for the provision of safe, effective, and efficient delivery of care services to clients as defined in this Part.
- C. The governing body or equivalent legal authority shall appoint and assure the competence of:
  1. A Medical Director who is responsible for overseeing clinical practices and services and for achieving and maintaining quality services; and
  2. A Harm Reduction Center Director who is responsible for the day-to-day administrative management of the Center.
- D. The governing body or equivalent legal authority shall furthermore be responsible to establish a mechanism through the organization's by-laws and/or policies to assure that the Medical Director, the Center Director, and other staff are duly qualified by education, training, and experience and meet the requirements of this Part.
- E. The governing body shall be responsible for ensuring that the perspectives of persons with current or former lived experience of substance use are part of the

design, implementation, operations, and evaluation of the Harm Reduction Center.

- F. The governing body or equivalent legal authority shall adopt and maintain by-laws defining responsibilities for the operation and performance of the organization, identifying purposes and means of fulfilling such, and in addition the by-laws shall include but not be limited to:
1. A statement of qualifications and responsibilities of the Medical Director and the Center Director;
  2. A statement of the governing body's responsibility for the quality care and services;
  3. A statement of policy pertaining to the criteria for the selection, and transfer or referral of clients in accordance with the requirements of this Part;
  4. A statement relating to development and implementation of long- and short-range plans;
  5. A statement relating to conflict of interest on the part of the governing body and staff;
  6. A statement describing how the perspectives of persons with current or former lived experience of substance use will be or were included in the design, implementation, evaluation, and operations of the Harm Reduction Center;
  7. A policy statement concerning the publication of an annual report; and
  8. Such other matters as may be relevant to the organization of the Center.
- G. Furthermore, the governing body or equivalent legal authority in consultation with the Medical Director shall be ultimately responsible to develop and implement policies governing no less than the following:
1. Modalities of health and medical services to be provided;
  2. Client consent for the provision of services;
  3. Referrals and written agreements with health care facilities, including treatment facilities for substance use disorder, community agencies and medical personnel to insure back-up services and continuity of care in accordance with § 25.5 of this Part;
  4. Effective review of clinical practices;

5. Quality assurance for care and services; and
6. Such other matters as may be relevant to the organization and operation of the Center, the delivery of services, and as may be required under the rules and regulations of this Part.

#### **25.4.2 Personnel**

- A. Each Center shall provide the necessary health care professionals to prevent overdose.
  1. There shall be on the premises at all times when clients are present, a staff person who:
    - a. Holds a current certificate in cardiopulmonary resuscitation from a recognized program such as the American Heart Association or the American Red Cross;
    - b. Has been trained in overdose response; and
    - c. Is able to administer an opioid antagonist.
- B. Each Center shall establish a job description for each classification of position, which clearly delineates qualifications, duties, authority and responsibilities inherent in each position.
- C. Records shall be maintained on the premises for all personnel which shall contain no less than:
  1. Current background information pertaining to qualifications, including evidence of national criminal background checks for Center personnel whose employment involves routine contact with a client.
    - a. Any person who has a prior criminal conviction may be considered for employment, at the discretion of the employer.
  2. Evidence of registration, certification or licensure as may be required by law; and
  3. Each Center shall require all persons, including students, who examine, observe, or treat a client to wear a photo identification badge which states, in a reasonably legible manner, the first name, licensure/registration status, if any, and staff position of such person.
- D. Upon hire and prior to delivering services, a pre-employment health screening shall be required for each individual who has or may have direct contact with a client in the Harm Reduction Center. Such health screening shall be conducted in accordance with the rules and regulations pertaining to Immunization, Testing,

and Health Screening for Health Care Workers (Part 20-15-7 of this Title). Each Center shall also assure that staff members are in compliance with all applicable laws and regulations.

- E. Each Center must provide initial orientation for newly hired staff and provide ongoing education, including in-services, training, and other activities to maintain and improve staff competence. Trainings must include, but are not limited to:
  - 1. Overdose response;
  - 2. Basic first aid;
  - 3. Opioid Antagonist administration;
  - 4. Addiction treatment;
  - 5. Ancillary support services available in the community (including client referral to primary care and treatment supports);
  - 6. Confidentiality, including the topics of data collection and client information;
  - 7. Staff anti-harassment;
  - 8. The Codes of Conduct (§ 25.4.6 of this Part);
  - 9. De-escalation techniques; and
  - 10. Disposal and transportation of sharps and hazardous medical waste.
- F. Each Center must ensure that staff competence to perform job responsibilities is assessed, demonstrated, maintained, and documented.
  - 1. Each Center must conduct staff performance evaluations no less than once annually per staff member.
- G. Each Center must have a process to encourage staff to pursue ongoing professional development goals and provide feedback to the Center Director about the work environment.

### **25.4.3 Medical Director**

- A. The Medical Director shall be appointed by and be responsible to the governing body or equivalent legal authority and who has appropriate clinical experience to provide effective clinical oversight. The Medical Director shall be responsible for:
  - 1. Advising and consulting with the Center staff on all matters related to medical management of clients with health-related conditions including wound care, overdose, or other health related matters;

2. The approval of written policies, procedures, and protocols for client clinical care where appropriate or applicable;
  3. The coordination of all professional medical consultants to the Center (i.e., consulting physicians, nurses, and other clinical staff); and
  4. Such other functions deemed necessary and appropriate for the Center's operation under the rules and regulations of this Part.
- B. Depending on needs of the Center and resources, the Medical Director may be engaged in a consulting role and need not be a full-time employee of the Center.

#### **25.4.4 Harm Reduction Center Director**

- A. The Harm Reduction Center Director shall be the designated individual responsible for the administrative operation of the Center. The Center Director shall be a qualified professional and shall be responsible for:
1. Daily Center operations;
  2. Staff hiring, supervision, and support;
  3. Meeting the Center's stated goals and objectives;
  4. Reporting to Center's governing body or equivalent legal authority;
  5. Reporting (§§ 25.4.8 and 25.4.9 of this Part)
  6. Other functions deemed necessary and appropriate for the Center's operation under the rules and regulations of this Part, as directed by the Center's governing body or equivalent legal authority.

#### **25.4.5 Written Agreements**

- A. Each Center shall enter into signed written agreements to ensure accessibility to supportive services, and such agreements must clearly delineate the mutual responsibilities of the undersigned parties to ensure the provision of services as agreed upon. Such agreements shall be entered into with no less than:
1. A treatment facility in Rhode Island which the Center or with whom the Center has an established relationship, and which has addiction medicine services and other related treatment services for opioid use disorder and other substance use related services.
  2. Such other agencies, organizations, or other entities as may be required for the provision of supportive services (see § 25.5 of this Part) which are not provided directly by the Center.

#### **25.4.6 Rights of Clients & Code of Conduct**

- A. Each Harm Reduction Center shall develop a Code of Client Rights & Responsibilities for harm reduction services, acceptable to the Department, and shall include people with current or former lived experience of substance use in the development of the Code of Client Rights & Responsibilities.
- B. The Harm Reduction Center shall establish a system to inform clients of his or her rights and responsibilities and must include the right to lodge a complaint using the RIDOH electronic submission process: Submit A Complaint: Department of Health (ri.gov).
- C. Each Center must:
  - 1. Offer language assistance to clients who have limited English proficiency and/or other communication needs, at no cost to them, to facilitate timely access to all health care and services.
  - 2. Inform all clients of the availability of language assistance services clearly and in their preferred language, verbally and in writing.
  - 3. Ensure the competence of individuals providing language assistance.
  - 4. Provide easy-to-understand print and multimedia materials and signage in the languages commonly used by the populations in the service area.

#### **25.4.7 Confidentiality**

Disclosure of any health care information relating to individuals shall be subject to the provisions of R.I. Gen. Laws Chapter 5-37.3 and other relevant statutory requirements.

#### **25.4.8 Reporting of Client Deaths & Overdoses within the Center**

- A. The harm reduction center must develop and implement policies/protocols which address reporting of deaths and overdoses within the Harm Reduction Center, to the facility's medical director and to the Department.
- B. Client deaths as a result of a drug overdose or other cause within the Center shall be reported to the Director within twenty-four (24) hours by phone at 401-222-8022. All reports, as required by this Part, shall be provided to the licensing agency in writing via facsimile or electronic transmission to \_\_\_\_\_@health.ri.gov on forms supplied by the Department. A copy of each report shall be retained by the Harm Reduction Center for review during subsequent inspections by the Department.
- C. Client deaths as a result of a drug overdose or other cause within the Center shall also be reported to the Office of State Medical Examiners in accordance with R.I. Gen. Laws Chapter 23-4.

- D. Nonfatal opioid overdose incidents within the Center shall be reported to the Department within forty-eight (48) hours as specified by Opioid Overdose Prevention and Reporting (Part 20-20-5 of this Title).

### **25.4.9 Administrative Records and Reporting**

- A. Each Center shall maintain administrative records and reporting as may be deemed necessary by the Department. These records must include but are not limited to, the following:
  - 1. A deidentified, daily record of:
    - a. Number of client visits;
    - b. Time of visit;
    - c. Number of overdoses;
    - d. Use of an opioid antagonist; and
    - e. Amount of opioid antagonists administered per overdose.
  - 2. Each Center shall also report to the Department statistical data pertaining to its operations and services utilized. Such reports shall be made at such intervals and by such dates as determined by the Director.
  - 3. The directives issued by the Director pursuant to this Part shall be sent to each Center to which they apply. Such directives shall prescribe the form and manner in which the statistical data required shall be furnished to the Department.
  - 4. The Center shall provide other reports or records as deemed necessary and appropriate to document the Center's compliance with this Part or deemed necessary by RIDOH for the evaluation of the scope and effectiveness of the Harm Reduction Center Pilot Program under R.I. Gen. Laws Chapter 23-12.10.

## **25.5 Management of Clinical Services**

### **25.5.1 Selection of Clients**

- A. Each Center must have a policy and procedure that includes, at minimum, the following:
  - 1. Client eligibility criteria;
  - 2. Client termination criteria and process; and
  - 3. Client denial of services criteria.

- B. Clients shall be anonymous and do not need to present identification to utilize Center drug consumption services.
- C. An initial eligibility screening and assessment shall be made of every client seeking services at the Center.

### **25.5.2 Client Orientation**

- A. The Center shall assure that each person registering for services shall be given an orientation to the Center which includes information pertaining to no less than:
  - 1. The philosophy and goals of the Center;
  - 2. Services available directly at the Center;
  - 3. Services provided through consultation and referrals;
  - 4. Policies and procedures including:
    - a. Drug usage policy; and
    - b. Disposal of paraphernalia.
    - c. Client termination criteria and process;
  - 5. Client denial of services criteria; and
  - 6. Such other matters as may be deemed appropriate.

### **25.5.3 Buprenorphine Prescribing**

- A. Buprenorphine prescribing for treatment of opioid withdrawal or opioid use disorder is permitted at the Center, provided that a licensed prescriber meets all state and federal requirements including Drug Enforcement Agency (DEA) registration, state-controlled substance registration and any other applicable license, criteria or registration.
- B. If Buprenorphine is to be administered at the Center, it will be stored, dispensed and administered in accordance with §§ 40-15-1.5.16 and 40-15-1.5.17 of this Title.

### **25.5.4 Health Screenings, Care & Referrals**

- A. Harm Reduction Centers must offer the following referrals:
  - 1. Referrals to substance use disorder treatment; and
  - 2. Referrals to primary care and other health care providers.



- B. Harm Reduction Centers are permitted to offer the following additional health services and referrals, provided there is an appropriately licensed health care provider:
  - 1. Point of care pregnancy tests;
  - 2. Other sexual & reproductive health services, such as screening, testing, or referrals for Sexually Transmitted Infections (STIs), including Human Immunodeficiency Virus (HIV) and Hepatitis;
  - 3. Administering of pre-exposure prophylaxis (PrEP) or referral to PrEP services;
  - 4. Prescribing of birth control;
  - 5. Immunizations; and
  - 6. Tobacco cessation.
- C. The Center is permitted to dispense over the counter medications.
- D. The Center must have established referral pathways in place for all referrals it provides.
- E. Any Center that performs laboratory testing on human specimens for the diagnosis, prevention, or treatment of disease must comply with the provisions of the Clinical Laboratory Improvement Amendments of 1988 (CLIA).
- F. Centers that are performing CLIA-waived laboratory tests {List appears here: CLIA - Clinical Laboratory Improvement Amendments - Currently Waived Analytes (fda.gov)} must obtain a CLIA Certificate of Waiver from the Department.

### **25.5.5 Drug Checking**

- A. Harm Reduction Centers are permitted to offer drug checking of client's pre-acquired substances prior to consumption. Drug checking includes the use of fentanyl test strips or other means of drug testing as available.
  - 1. Unless using tests that have been approved to detect quantity and potency, clients utilizing the Center's drug checking resource will be notified at the time of testing that testing methods measure the presence of certain types of drugs, depending on the test being used, but do not measure the quantity or potency of the drug present in a sample and that even if the test returns a negative result, the sample may nonetheless contain an undesirable substance at a lower concentration than can be detected or an analog of the substance not detected by the test.

### **25.5.6 Wrap-around Services and Referrals**

- A. The Harm Reduction Center must provide at minimum, the following services and/or referrals:
  - 1. Harm reduction education/training and supplies; and
  - 2. Needle exchange services.
- B. The Harm Reduction Center is permitted to offer the following services and/or referrals)
  - 1. Basic needs (clothes, food, COVID-19 supplies, etc.) referrals and supplies;
  - 2. Referrals to housing services;
  - 3. Referrals to employment services; and
  - 4. Referrals to legal services.
- C. The Center must have established referral pathways in place for all referrals it provides.

### **25.5.7 Client Records**

- A. The Center shall maintain a clinical record for every client receiving clinical services at the Center.
  - 1. Client clinical records must contain at minimum, documentation of the following:
    - a. Time and date of service;
    - b. Consent and waiver of liability
    - c. Services utilized by the client (e.g., wound care, referrals, prescription of buprenorphine or birth control etc.);.
    - d. Circumstances regarding the following:
      - (1) Complications;
      - (2) Transfers;
      - (3) Referrals; and
      - (4) Any overdose that required reversal with an opioid antagonist.

- B. Clients shall be anonymous for drug consumption services. Centers are permitted to assign, or allow a client to choose, a non-identifying ID to allow for population-level tracking of drug consumption service utilization.
- C. Clients that utilize billable services, such as buprenorphine services, must provide personal identifying information in order to receive such services. Other non-billable services may also require clients to provide personal identifiable information in order to receive such services at the discretion of the Harm Reduction Center.
- D. Records requiring client identifiers will be kept separate from records documenting use of drug consumption services.
- E. All entries in the clinical records shall be dated and signed by the writer.

### **25.5.8 Infection Control**

- A. A mechanism shall be established by the Medical Director for the development of infection control policies and procedures which shall pertain to no less than:
  - 1. Infection surveillance activities;
  - 2. Sanitation and disinfection of all client areas;
  - 3. Handling and disposal of medical waste and contaminants;
  - 4. Reporting, recording, and evaluating occurrences of infections.
- B. The Center shall report promptly to the Department infectious diseases which may present a potential hazard to clients, personnel, and the public in accordance with the Rules and Regulations of Reporting and Testing of Infectious, Environmental, and Occupational Diseases (Part 30-05-1 of this Title).

### **25.5.9 Emergencies**

- A. Each Center must have policies and procedures for responding to life-threatening emergencies such as drug overdose, respiratory arrest, and cardiac arrest and other emergencies such as fire, loss of power, and hurricanes.
- B. Each Center must demonstrate its ability to respond to life-threatening emergencies according to the Center's policies and procedures.
- C. The HRC Director will develop rapid response protocols for addressing community/neighborhood concerns and must have designated community liaison representatives.

## **25.6 Environmental Management**

### **25.6.1 Housekeeping**

- A. The Center shall be maintained and equipped to provide functional, sanitary, safe and comfortable environment, with all furnishings in good repair, and the premises shall be kept free of hazards.
- B. Written policies and procedures shall be established pertaining to environmental controls to assure comfortable, safe and sanitary environment with well-lighted space. Policies and procedures must address cleaning of surfaces that may be contaminated with leftover drug residue and/or trash that may contain hazards such as needles or biomedical waste.
- C. Equipment and supplies shall be provided for cleaning of all surfaces. Such equipment shall be maintained in a safe and sanitary condition.
- D. Hazardous cleaning solutions, compounds, and substances shall be labeled, stored in a safe place and kept in an enclosed section separated from other cleaning materials.
- E. Cleaning shall be performed in a manner which minimizes the spread of pathogenic organisms in the atmosphere.
- F. Drug consumption spaces shall be thoroughly cleaned after (each) client use, in accordance with the Center's infection control policies and procedures. Staff must be provided access to adequate personal protective equipment for cleaning.
- G. Smoking shall be permitted only in designated areas, as specified under § 25.7.1(D) of this Part.

## **25.7 Physical Plant and Equipment**

### **25.7.1 General Provisions for Physical Facility**

- A. Each Center shall be constructed, designed, planned, equipped and maintained to protect the health and safety of clients, personnel and the public, and to facilitate emergency exit of clients and personnel in the event of emergency.
- B. Each Center shall have at least three (3) distinct, separate areas:
  - 1. A reception area where potential clients can learn about the Harm Reduction Center services and its operation;
  - 2. A dedicated drug consumption area; and

3. A common area for after-care where clients interact with healthcare professionals and peer support workers and receive after-care, referrals, education, and counseling.
- C. Each area of the center must allow for unimpeded, rapid access to an exit where emergency transportation vehicles may be accommodated.
1. There shall be adequate space for staff or volunteers to perform opioid antagonist administration and artificial respiration, if necessary.
  2. Hallways and doors providing access and entry into the reception, drug consumption and after care areas shall be of adequate width to accommodate ambulance stretchers and wheelchairs.
- D. The drug consumption area shall be spacious enough to accommodate staff to move freely and include, but not be limited to:
1. Mirrors strategically placed to facilitate monitoring and self-injection.
  2. Accessible sharps and biohazardous waste disposals for each consumption station/room/booth and washrooms.
  3. Non-permeable, non-flammable chairs, counters/tables, floor surfaces, and privacy partitions that can be easily cleaned with hospital grade cleaning supplies.
    - a. No carpeting is permitted in the Center.
    - b. The station/room/booth must allow for observation by Center staff.
    - c. Handwashing stations must be readily available.
  4. If a Harm Reduction Center chooses to allow clients to smoke or use inhalable drugs, smoking of tobacco products and drugs are only allowed in specifically designated smoking areas that meet the following criteria:
    - a. The drug consumption area must be well-ventilated with outdoor air through the use of adequate mechanical ventilation that is designed to run at all times that the building is occupied.
    - b. Smoking areas must be physically separated from non-smoking areas, including any staff-only areas.
    - c. Signs shall clearly indicate what areas allow smoking and what areas are non-smoking areas.
    - d. Indoor smoking areas shall be kept under negative pressure relative to other locations by a dedicated exhaust system

exhausting at least fifty cubic feet per minute (50 cfm) per occupant at maximum occupancy (staff and clients) plus eighteen hundredth (0.18) cfm per square foot of space.

- e. The exhaust system shall run at all times that the smoking area is occupied and for at least one hour afterwards.
  - f. Air from smoking areas shall be exhausted outdoors to a location secure from public access, such as the roof.
  - g. The smoking space shall be unoccupied for a total of fifteen (15) minutes out of each hour.
- E. The Harm Reduction Center must have adequate security policies and procedures to ensure the safety of both staff and clients.
- F. Acceptable toilet facilities shall be available to clients and staff.
- G. Utility and storage areas shall be designed and equipped for washing, sterilizing and storage of equipment, and supplies in a manner that ensures segregation of clean and sterile supplies and equipment from those that are soiled and/or contaminated.
- H. Storage areas shall be provided and equipped with locks.
- I. Heating and ventilation systems shall be capable of maintaining comfortable temperatures.
- J. Lighting and electrical services: Each Harm Reduction Center shall be adequately lighted with appropriate lighting in the drug consumption area(s).
- 1. An emergency source of electrical light shall be available for the protection of clients in the event the normal electrical power is interrupted.
  - 2. All electrical and other equipment used in the Harm Reduction Center shall be maintained free of defects which could be a potential hazard to clients and staff.
- K. An elevator shall be available where Harm Reduction Service resources are provided at different floor levels. The cab size of the elevator shall be large enough to accommodate a stretcher, an attendant and such equipment as may be needed.

#### **25.7.2 Initial licensure, New Construction, Modification, Additions, or Room Conversions**

All initial licenses, new construction, modification, additions, or room conversions of an existing center shall be subject to the provisions of Fire Safety Code-

General Provisions (R.I. Gen. Laws Chapter 23-28.1), State Building Code (R.I. Gen. Laws Chapter 23- 27.3), ANSI A117.1 - 2009 Accessible and Usable Buildings and Facilities, Americans with Disabilities Act (42 U.S.C. §§ 12101 through 12213), and such other applicable state and local laws, codes and regulations as may be applicable. Where there is a difference between codes, the code having the more stringent or higher standard shall apply.

### **25.7.3 Equipment and Supplies**

- A. Each Harm Reduction Center shall be equipped with a sufficient supply of those items needed to initiate emergency procedures in life threatening events to clients. Such equipment shall include no less than the following:
  - 1. Self-inflating bag valve mask;
  - 2. Mouth barriers for rescue breathing;
  - 3. Oral glucose;
  - 4. Epinephrine Auto-Injector (EpiPen);
  - 5. Oxygen and positive pressure masks;
  - 6. Automated External Defibrillator (AED);
  - 7. Opioid Antagonist; and
  - 8. Fire extinguisher
- B. The Harm Reduction Center shall be equipped with a sufficient supply of harm reduction supplies for safe drug use practices within the Center and/or for take home supplies, included but not limited to:
  - 1. Fentanyl test strips;
  - 2. Nitrile gloves;
  - 3. Sterile syringes and needles;
- C. Any Harm Reduction Center that utilizes latex gloves shall do so in accordance with the provisions of Use of Latex Gloves by Health Care Workers, in Licensed Health Care Facilities, and by Other Persons, Firms, or Corporations Licensed or Registered by the Department (Part 20-15-3 of this Title).
- D. The Harm Reduction Center must provide sharps containers at each consumption station and biohazard disposal containers and arrange for the disposal/removal of containers according to the R.I. Department of Environmental Management's Medical Waste Regulations (250-RICR-140-15-1) for disposal of hazardous medical waste.

- E. Each Center must identify a person(s) to intervene whenever conditions immediately threaten life or health or threaten damage to equipment or the facility.
- F. Each Center must ensure that all equipment is maintained appropriately and in proper working condition. 216-RICR-40-10-25.

#### **25.7.4 Plumbing**

All plumbing material and plumbing systems or parts thereof installed shall meet the minimum requirements of R.I. Gen. Laws Chapter 23-27.3.

#### **25.7.5 Water Supply**

Water shall be obtained from an approved water system and shall be distributed to conveniently located taps and fixtures throughout the facility and shall be adequate in volume and pressure for all Center purposes, including fire safety in accordance with R.I. Gen. Laws Chapter 23-27.3.

#### **25.7.6 Drug Disposal**

The Harm Reduction Center must develop and implement written policies and procedures for management and disposal of drugs and unknown substances in accordance with Disposal of Drugs (Part 20-20-1 of this Title)

#### **25.7.7 Design and Layout of Mobile Units**

- A. Each mobile unit facility shall be constructed, equipped, and maintained to protect the health and safety of clients and staff. All equipment and furnishings shall be maintained in good condition, properly functioning and replaced when necessary.
- B. The design of the mobile unit (e.g., Recreational Vehicles or buses converted into a mobile clinic) shall comply with § 25.7.1 of this Part. In the event of non-conformance for which the provider seeks a variance from this section, the general procedures outlined in § 25.8.1 of this Part shall be followed.
- C. The minimum required areas include at least the following:
  - 1. Reception area;
  - 2. Dedicated drug consumption area;
  - 3. A common area for aftercare;
  - 4. A toilet room;
  - 5. Handwashing station,;



6. Adequate mechanical ventilation with exhaust to the outdoors;
7. Heating and cooling systems;
8. Provisions for soiled holding;
9. An area for a client to lie down during an emergency;
10. An area for washing, sterilizing and storage of equipment and supplies or a segregated secure container for the storage and transport of equipment and supplies that must be sterilized before reuse;
11. An area for housekeeping and cleaning supplies; and
12. Ramps or a lift at the entrance of the unit which can accommodate wheel chairs.

## **25.8 Practices and Procedures**

### **25.8.1 Variance Procedure**

- A. The Department may grant a variance either upon its own motion or upon request of the applicant from the provisions of any rule or regulation in a specific case, if it finds that a literal enforcement of such provision will result in unnecessary hardship to the applicant and that such a variance will not be contrary to the public interest, public health and/or health and safety of clients.
- B. A request for a variance shall be filed by any applicant in writing, setting forth in detail the basis upon which the request is made.
  1. Upon the filing of each request for variance with the Department, and within thirty (30) days thereafter, the Department shall notify the applicant by certified mail of its approval or in the case of a denial, a hearing date, time and place may be scheduled if the facility appeals the denial and in accordance with the provisions of § 25.8.3 of this Part.

### **25.8.2 Deficiencies and Plans of Correction**

- A. The Department shall notify the governing body or other legal authority of a facility of violations of individual standards through a notice of deficiencies which shall be forwarded to the facility within fifteen (15) days of inspection of the Harm Reduction Center unless the Director determines that immediate action is necessary to protect the health, welfare, or safety of the public or any member thereof through the issuance of an immediate compliance order in accordance with R.I. Gen. Laws § 23-1-21.
- B. A Harm Reduction Center that received a notice of deficiencies must submit a plan of correction to the Department within fifteen (15) days of the date of the

notice of deficiencies. The plan of correction shall detail any requests for variances as well as document the reasons therefor.

- C. The Department will be required to approve or reject the plan of correction submitted by a Harm Reduction Center in accordance with § 25.8.2(B) of this Part within fifteen (15) days of receipt of the plan of correction.
- D. If the Department rejects the plan of correction, or if the Harm Reduction Center does not provide a plan of correction within the fifteen (15) day period stipulated in § 25.8.2(B) of this Part, or if a Harm Reduction Center whose plan of correction has been approved by the Department fails to execute its plan within a reasonable time, the Department may invoke the sanctions enumerated in § 25.3.5 of this Part. If the Harm Reduction Center is aggrieved by the sanctions of the Department, the Harm Reduction Center may appeal the decision and request a hearing in accordance with R.I. Gen. Laws Chapter 42-35.
- E. The notice of the hearing to be given by the Department shall comply in all respects with the provisions of R.I. Gen. Laws Chapter 42-35. The hearing in all respects shall comply with all provisions therein.

### **25.8.3 Rules Governing Practices and Procedures**

All hearings and reviews required under the provisions of R.I. Gen. Laws Chapter 23-12 shall be held in accordance with Practices and Procedures Before the Rhode Island Department of Health (Part 10-05-4 of this Title).

### **25.9 Severability**

If any provisions of these Regulations or the application thereof to any person or circumstance shall be held invalid, such invalidity shall not affect the provisions or application of these Regulations which can be given effect, and to this end the provisions of these Regulations are declared severable.