

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 harm reduction center 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 Harm Reduction Center Director and/or the Medical Director;
 - b. Maintain and control the books and records of the Harm Reduction Center;
 - c. Dispose of assets and incur liabilities on behalf of the Harm Reduction Center; or
 - d. Adopt and enforce policies regarding operation of the Harm Reduction Center.
2. "Case manager" means a person that coordinates and links care across community-based health and social services organizations. A case manager identifies and secures the necessary resources, equipment, and supplies from formal and informal sources including professionals, paraprofessionals, volunteers, family and friends.
3. "Client" means a person who utilizes the services of a Harm Reduction Center.

4. "Department" or "RIDOH" means the Rhode Island Department of Health.
5. "Director" means the Director of the Rhode Island Department of Health or his or her designee.
6. "Drug consumption" means smoking, injecting, snorting, inhaling, swallowing, or otherwise consuming pre-obtained, controlled substances.
7. "Harm reduction center" or "Center" means a community-based resource for health screening, disease prevention, and recovery assistance where persons may consume pre-obtained controlled substances in a non-judgmental, supportive environment.
8. "Harm reduction education" means education on practical strategies aimed to reduce behaviors associated with negative consequences associated with drug use including but not limited to infections, overdose, other illness and death.
9. "Harm reduction services" means practical strategies and evidence-based approaches aimed at reducing behaviors associated with negative consequences associated with drug use, such as: safe smoking practices, safe injection practices, using with others, use of clean needles and syringes, etc.
10. "Licensed capacity" means the number of drug consumption stations a center is licensed to operate within the Center.
11. "Medical director" means a physician licensed to practice medicine in Rhode Island in accordance with R.I. Gen. Laws Chapter 5-37.
12. "Mental health counselor" means a person who has been licensed to provide clinical counseling in accordance with R.I. Gen. Laws Chapter 5-63.2.
13. "Temporary service site" means a non-permanent, temporary location where a Harm Reduction Center operates using a mobile unit or short-term unit.
14. "Mobile unit" means a Harm Reduction Center that can move location, such as a van or a bus.
15. "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 fixed, mobile, or short-term Harm Reduction Center is proposed to be located, which the affirmative vote approves the opening and operation of the Harm Reduction Center.

16. "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.
17. "Opioid" means any opiate, synthetic or natural, or opium derivative, listed in [R.I. Gen. Laws § 21-28-2.08](#).
18. "Opioid antagonist" means a drug used to reverse the effects of opioids, such a naloxone hydrochloride, commonly referred to as naloxone, 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.
19. "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.
20. "Peer" is a person with lived experience with substance use.
21. "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.
22. "Premises" means a tract of land and the buildings thereon where harm reduction services are provided.
23. "Smoking" or "smoke" means inhaling, exhaling, burning, vaporizing, or carrying any lighted or heated cigar, cigarette, pipe, plant, tobacco product, pharmacologically active chemical, or other combustible substance in any manner or in any form. "Smoking" or "smoke" also includes the use of electronic cigarettes, electronic cigars, electronic pipes, and any other electronic vaporization devices.
24. "Short-term unit" (less than one hundred eighty (180) days) means a Harm Reduction Center or component of a Harm Reduction Center thereof that does not have a permanent, fixed location, such as a tent.

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 Chapter 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 licensed 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, an entity licensed as a Harm Reduction Center in Rhode Island, may provide services at other premises or by use of Temporary 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 Temporary Service Site 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 Temporary Service Site on the Harm Reduction Center license and commencement of operations at such location.
- F. Each premises, Mobile Unit, or Short-term 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 center specific electronic mail address (i.e., e-mail address) and physical 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 or physical 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 thirty (30) 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 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 licensee must submit written documentation of municipal authorization and approval in the form of a copy of the affirmative resolution from the municipal vote with the licensure application. An initial license or additional premises or Temporary Service Site approval will not be issued without written documentation of municipal authorization.
 - 1. Mobile routes must have municipal authorization, such authorization shall also include, but not be limited to:
 - a. Specific addresses or blocks where the Mobile Unit or Short-term Unit will be operating with specific schedule outlined.
 - b. If partnering with a property owner, a letter must be obtained agreeing to host the Mobile Unit or Short-term Unit or to operate on their premises, including hours of operation.
 - 2. If the routes/locations change, a municipal designee must be notified prior to the new route/location, and official approval must be obtained as soon as practicable for the new location and/or route. A copy of the affirmative resolution must be submitted to the Department within thirty (30) days.

- C. The licensee must develop, in collaboration with local public safety officials, a plan to address public safety and order for the Center. Such plan must be made available to the Department upon request and submitted to the municipality.
- D. Prior to issuing a license, RIDOH will conduct an inspection of the Center.
- E. A license shall be issued to a specific licensee for a specific premise and/or Temporary 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.
- F. 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.
- B. 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.
- C. 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).

25.3.6 Licensing of Mobile Units & Short-Term Units

- A. A Harm Reduction Center that only provides service through a mobile unit or Short-term Unit must have a physical address, but services are not required to be provided at the physical address. Existing, physical Harm Reduction Centers must receive prior approval of the Department prior to operating a Mobile Unit or Short-Term Unit.
- 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.
 2. The driver of the Mobile Unit shall maintain an appropriate 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. Compliance with the Rhode Island State Fire Safety Code as evidence by inspection report from the State Fire Marshal or designee.
 5. All electrical material and equipment shall be installed with applicable sections of RISBC-5, Rhode Island Electrical Code ([510-RICR-00-00-5](#)).
- C. Short-term units must comply with Rhode Island State Fire Safety Code as evidence by inspection report from the State Fire Marshal or designee.
- D. All electrical material and equipment within short-term units shall be installed with applicable sections of RISBC-5, Rhode Island Electrical Code ([510-RICR-00-00-5](#)).

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;
 - 2. A statement of the responsibilities of the Center Director;
 - 3. A statement of the governing body's responsibility for the quality care and services;

4. 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;
 5. A statement relating to development and implementation of long and short-range plans;
 6. A statement relating to conflict of interest on the part of the governing body and staff;
 7. 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;
 8. A statement relating to confidentiality of information and right to anonymity of clients using the Center;
 9. A policy statement concerning the publication of an annual report; and
 10. 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. Harm reduction services to be provided;
 2. Client consent for the provision of services;
 3. Referrals to community providers and organizations 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. All staff shall be trained in:
1. Cardiopulmonary resuscitation from a recognized program such as the American Heart Association or the Red Cross;
 2. Overdose response;

3. Opioid antagonist administration;
 4. Disposal and transportation of sharps and hazardous medical waste; and
 5. Confidentiality of medical information and anonymity for Harm Reduction Center clients.
- B. Harm Reduction Centers must have appropriately qualified personnel to provide Center services. Such personnel may include, but are not limited to, the following:
1. Peers;
 2. Case managers;
 3. Nurses; and
 4. Mental health counselors.
- C. Each Center shall establish a job description for each classification of all positions, whether paid or volunteer, which clearly delineates qualifications, duties, authority and responsibilities inherent in each position.
- D. 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 a State criminal background check obtained upon hire and prior to delivering services 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 or observe 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.
- E. 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 Part [20-15-7](#) of this Title, Immunization, Testing, and Health Screening for Health Care Workers. Each Center shall also assure that staff members are in compliance with all applicable laws and Regulations.

- F. Each Center must ensure that staff competence to perform job responsibilities is assessed, demonstrated, maintained, and documented in a training file.
 - 1. Each Center must conduct staff performance evaluations no less than once annually per staff member and retain a copy of the evaluation in a personnel file for paid staff.
- G. Each Center must develop and implement employee wellness policies and practices that are reflective of working in a potentially traumatic setting. Staff must be made aware of these policies and practices upon hire, and policies must be posted in an area regularly accessed by staff.

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 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 its 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 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); and
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 Rights of Clients & Code of Conduct

- A. Each Harm Reduction Center shall develop a Code of Client Rights & Responsibilities for Harm Reduction Services 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 their 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. Language assistance must be provided for clients who do not communicate using English.

25.4.6 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 and regulatory requirements.

25.4.7 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 Center'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 401-222-5200 or 401-276-8046. All reports, as required by this Part, shall be provided to the licensing agency in writing via facsimile or electronic transmission to doh.ofr@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 Part [20-20-5](#) of this Title, Opioid Overdose Prevention and Reporting.

25.4.8 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, including
 - (1) Total visits; and
 - (2) Unique client visits.
 - b. Number and type of services utilized, including stratification of consumption service by method of consumption (e.g., smoking);
 - c. Time of visit;
 - d. Number of overdoses (fatal & non-fatal), including stratification of location of overdose (e.g., smoking space, other consumption space, etc.);
 - e. Use of an opioid antagonist or other opioid resuscitation method, including stratifying by location and method (e.g., smoking space, other consumption space, etc.); and
 - f. 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, by such dates, and in a format 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 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 shall not be asked to present identification to utilize Center drug consumption services.
- C. Clients are only permitted to consume drugs they have brought to the Center. Clients are prohibited from sharing, exchanging, or selling drugs at the Center.
- D. Staff are prohibited from assisting clients with consumption of drugs that the client has brought into the Center. Clients are prohibited from assisting other clients with drug consumption.

25.5.2 Client Orientation

- A. The Center must have a process to ensure each person using the Center has 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 and sharing policy;
 - b. Disposal of paraphernalia;
 - c. Confidentiality and anonymity; and
 - d. Client termination criteria and process.
 - 5. Client denial of services criteria.

25.5.3 Services & Referrals

- A. The Harm Reduction Center must provide at a minimum the following services:
 - 1. Drug consumption;
 - 2. Harm reduction education/training and supplies; and

3. Needle exchange.
- B. The Harm Reduction Center must provide referrals for counseling or other medical treatment that may be appropriate for clients utilizing the Harm Reduction Center.
 - C. Harm Reduction Centers must make available additional referrals and information to serve the needs of their client population, such as, but not limited to, the following:
 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.

25.5.4 Drug Checking

- A. Harm Reduction Centers are permitted to offer drug checking/testing of client's pre-acquired substances. Drug checking/testing includes the use of fentanyl test strips or other means of drug testing as available. Clients are permitted to utilize their own drug checking/testing supplies, and Center staff may assist as needed.
 1. Unless using tests that have been approved to detect quantity and potency, clients utilizing the Center's drug checking resource must 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.

25.5.5 Client Records

Clients shall be anonymous for Harm Reduction Center Services. Centers are required to assign a non-identifying ID to allow for population-level tracking and reporting of service utilization as prescribed by the Department.

25.5.6 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 Part [30-05-1](#) of this Title, Reporting and Testing of Infectious, Environmental, and Occupational Diseases.

25.5.7 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.
1. In the event of a life-threatening emergency or death the Center must call 911.
- B. The Harm Reduction Center Director must develop rapid response protocols for addressing community/neighborhood concerns and must have designated community liaison representatives.

25.6 Environmental Management

- 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 Center

- A. Each Center shall be 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 the following areas:
 - 1. An intake space where potential clients can learn about the Harm Reduction Center services and its operation;
 - 2. Smoking drug consumption area;
 - 3. Drug consumption areas for other consumption methods; and
 - 4. An aftercare area where clients receive referrals, education, and counseling, as applicable.
- 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(s) 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. 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. Smoking areas shall be ventilated in such a way that the air from that area shall not enter any other areas of the center.
 - e. The exhaust system shall run at all times that the smoking area is occupied and for at least one (1) hour afterwards.
 - f. Air from smoking areas shall be exhausted outdoors to a location secure from public access, such as the roof.
- 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. Secure 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. Heating and ventilation systems shall be capable of maintaining comfortable temperatures.
- I. Each Harm Reduction Center shall be adequately lighted with appropriate lighting in the drug consumption area(s).
 - 1. An emergency source of electrical lighting shall be available 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.

- J. 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. 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. Oxygen and AMBU-bags;
 - 5. Automated External Defibrillator (AED);
 - 6. Opioid Antagonist; and
 - 7. 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. Safe injection supplies;
 - 4. Safe snorting supplies; and

5. Safe smoking supplies.
- C. Any Harm Reduction Center that utilizes latex gloves shall do so in accordance with the provisions of Part [20-15-3](#) of this Title, 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.
 - 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 Center.
 - F. Each Center must ensure that all equipment is maintained appropriately and in proper working condition.

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 Center 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 Part [20-20-1](#) of this Title, Disposal of Drugs.

25.7.7 Design and Layout of Mobile Units and Short-term Units

- A. Each mobile unit or short-term unit 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 or Short-Term Unit 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.

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 center 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 center of violations of individual standards through a notice of deficiencies which shall be forwarded to the Center 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 23-12.10 shall be held in accordance with Part [10-05-4](#) of this Title, Practices and Procedures Before the Rhode Island Department of Health.

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.

216-RICR-40-10-25

TITLE 216 - DEPARTMENT OF HEALTH

CHAPTER 40 - PROFESSIONAL LICENSING AND FACILITY REGULATION

SUBCHAPTER 10 - FACILITIES REGULATION

PART 25 - HARM REDUCTION CENTERS (216-RICR-40-10-25)

Type of Filing: Adoption

Agency Signature

Agency Head Signature

Agency Signing Date

Department of State

Regulation Effective Date

Department of State Initials

Department of State Date