

CONCISE EXPLANATORY STATEMENT

In accordance with the Administrative Procedures Act, R.I. Gen. Laws § 42-35-2.6, the following is a concise explanatory statement:

AGENCY: Rhode Island Department of Health (the Department)

DIVISION: N/A

RULE IDENTIFIER: 216-RICR-40-10-25

RULE TITLE: Harm Reduction Centers

REASON FOR RULEMAKING: The Rhode Island Department of Health is proposing a new regulation to permit the operation of Harm Reduction Centers. The proposed regulation includes rules and regulations on how Harm Reduction Centers are to be licensed, organized and managed, confidentiality, reporting, including client deaths and overdoses, management of services including infection control and handling of emergencies, environmental management, physical plant and equipment required at the center, and variances and plans of correction in the event of deficiencies.

ANY FINDINGS REQUIRED BY LAW AS A PREEQUISITE TO THE EFFECTIVENESS OF THE RULE: N/A

TESTIMONY AND COMMENTS:

Numerous public comments were received in support of these regulations. RIDOH is appreciative of this support and thanks all individuals who wrote in with their support.

A comment was received requesting that language be added to require development of a public safety plan, in consultation of local public safety officials, where a harm reduction center is to be established. The Department agrees that a successful harm reduction center will need to provide a safe environment for all their clients. Staff must determine how to maintain a calm and welcoming environment. The Department has added language in § 25.3.3 to this effect. Thank you for this comment.

A comment was received requesting that public safety officers be consulted on the location of the harm reduction center. The statute already requires municipality approval prior to the harm reduction center being licensed. The municipality can choose to have local public safety officials weigh in on the site selection during the review process. This comment will not be accepted at this time.

A comment was received requesting additional language in § 25.4.6 regarding confidentiality of records that would further prohibit disclosure of health records to law enforcement unless required by the referenced statutes. Harm reduction centers are not health care facilities and the center will not be collecting health care records. As such, the requested language is unnecessary and does not provide any additional confidentiality protections. This comment will not be accepted at this time.

A comment was received to add language in § 25.4.1 to prohibit the center from admitting law enforcement without a warrant or exigent circumstances. The harm reduction center will need to build relationships with the community it resides in – including local law enforcement and other public safety officials. Per the required public safety plan, the center and local public safety officials will work together to develop an approach on how they work together. Furthermore, the Department does not want to be the arbitrator for what constitutes an “exigent circumstance” that would require law enforcement entry into the center. This comment will not be accepted at this time.

A comment was received requesting that language be added in § 25.5.2(A) to require that harm reduction centers provide information on “know your rights laws.” The objective of the harm reduction center, as stated in R.I. Gen. Laws § 23-12.10-1 is to provide “...[a] community-based resource for health screening, disease prevention and recovery assistance where persons may safely consume pre-obtained substances.” Including mandatory education on interactions with police are not part of the mission of harm reduction centers. Additionally, not including such language does not mean a harm reduction center cannot provide it – the Department simply will not require it. This comment will not be accepted at this time.

A comment was received noting that harm reduction centers are similar environments to needle exchange programs and recovery community center workplaces which can be traumatic environments and negatively impact employee’s mental health. The comment suggested requiring wellness policies and procedures for staff and making them readily available. The Department recognizes that a harm reduction center environment can be taxing on employees. The Department has added language in § 25.4.2(G) to this effect. The Department thanks you for this comment.

A comment was received asking if the center will permit clients assisting one another with consumption services or if staff will be able to assist with consumption. It is not the Department’s intent to permit assisting of consumption; language has been added in § 25.5.1. The Department thanks you for this comment.

A comment was received asking which room a client who insufflates (snorts) his or her drug would use. Harm reduction centers are required to have an area where someone can inhale their substance separate from other consumption spaces, and will develop their own policies for the use of these spaces. The Department thanks you for this comment.

A comment was received suggesting stratified data for clients who use a smoking room and non-smoking room. The Department agrees that non aggregate data would be useful and has added language to require stratification in §25.4.8. The Department thanks you for this comment.

A comment was received regarding concerns for cost and effectiveness of a smoking room for clients to use and suggested this requirement to provide smoking rooms be optional and not mandatory. Providing a safe space for all methods of consumption

ensures that the harm reduction is providing services in an equitable manner for persons with a substance use disorder, and not creating further disparities in the overdose epidemic.

The Department recognizes the potential cost for implementing such a requirement and worked with several subject matter experts to include the most cost-effective ventilation requirements for harm reduction centers. If such requirements are too burdensome for a harm reduction center, the center can apply for a variance and the Department will review the request. The Department will continue to require smoking rooms and this comment will not be accepted at this time.

A comment was received to request the delineation between the role of case managers and peer recovery specialists. The comment also requests that substance abuse counselors with motivational interviewing should be designated as special staff. Each harm reduction center will be different based on the population it serves. The Department is not requiring any type of licensee other than a medical director. The Department will allow the harm reduction center to determine the required staff necessary in order to address the needs of the population. This comment will not be accepted at this time.

A comment was received noting that in order to effectively address the overdose epidemic and to help gain back drug users' trust in the medical system, Rhode Island needs a safe, regulated drug supply. Regulating the drug supply is beyond the scope of the Department's authority. This comment will not be accepted at this time.

A comment was received stating that total anonymity will prevent the staff from working effectively together. There is a precedent for anonymity when receiving harm reduction services (i.e., syringe service programs), and harm reduction staff in Rhode Island have been able to work together effectively to serve the client population without using identifiers. The Department is continuing this approach in regulating harm reduction services and is requiring anonymity within the Center. This comment will not be accepted at this time.

A comment was received requesting that the definition of "change in owner" is amended to not include changes to board of directors and remove the term operator from the definition. The definition of "change in owner" is from R.I. Gen. Laws § 23-17-2. Having a definition that is different from statute can be confusing and have the regulation not in synch with the law. This comment will not be accepted at this time.

A comment was received asking to amend the definition of "medical director" to include physician, certified nurse practitioner, or certified clinical nurse specialist as each of those professions are qualified to do the work required of a harm reduction center. The Harm Reduction Center Advisory Committee, established by R.I. Gen. Laws § 23-12.10-2, recommended that only physicians be appointed as medical directors. As the establishment of a harm reduction center is only a two-year pilot program, the Advisory

Committee thought it best to start with a medical director as a physician and then perhaps revisit expanding the medical director to include other qualified professionals. This comment will not be accepted at this time.

A comment was received requesting that the definition of “nurse” be modified to include all advance practices registered nurses (APRN). APRNs are considered registered nurses and are included within the definition. This comment will not be accepted at this time.

A comment was received asking that the requirement of addresses for all owners of the harm reduction center be removed and that such information not be posted publicly or discoverable via a public record request. The collection of addresses is standard practice for the Department. Having two pieces of identifiable information ensures the Department can confirm who a true owner(s) of the harm reduction center. Public record requests are governed by statute which the Department has no discretion of what is and is not shared as a result of the request. This comment will not be accepted at this time.

A comment was received stating that § 25.3.2(C) is permissively vague. This language is standard practice for the Department and appears in other facility regulations. The Department maintains a policy of open communication between the entities we regulate. Any questions regarding change in ownership, locations or contemplated changes should be directed to the Department. This comment will not be accepted at this time.

A comment was received opposing § 25.3.2(D) through (F) and that the language be modified so that a six-week transition period is the default. These requirements are standard for all licensees. This comment will not be accepted at this time.

A comment was received opposing the language of § 25.3.4(C) regarding the Department’s authority to inspect without notice. The Department generally only inspects facilities on one of the following occasions: 1) prior to licensure; 2) when an adverse event occurs; 3) when an allegation of non-compliance is received (e.g., a complaint) and 4) routine inspection. The Department reserves the right to inspect without notice to ensure proper compliance with applicable statutes and regulations. This comment will not be accepted at this time.

A comment was received requesting that a harm reduction center has the discretion to conduct a criminal record check on potential employees. There are certain crimes, such as violent crimes, that may prohibit a person from being hired at a harm reduction center. A failure to conduct a criminal record check could potentially put clients at risk of harm with staff members. This comment will not be accepted at this time.

A comment was received that § 25.4.2(F) be removed as staff evaluations should be determined by the harm reduction center director and/or management. The harm reduction center will be working with a vulnerable population and it is imperative that staff are qualified to perform tasks and are evaluated regularly. This comment will not be accepted at this time.

A comment was received requesting that the number of times oxygen is administered be required to be recorded. The Department has added language in § 25.4.8 to require recording of opioid antagonist or other opioid resuscitation administration. The Department thanks you for this comment.

A comment was received regarding concerns that the harm reduction center has discretion to decide what clients to accept and requested that a harm reduction center be required to accept everyone. There are certain clients, such as minors or pregnant individuals, that a harm reduction center may not be able to adequately serve. The Department prefers to allow the center to decide if it has the capacity to handle the client's needs. This comment will not be accepted at this time.

A comment was received requesting changing "needle exchange" to "sterile syringe access." The Department uses the term needle exchange in all other programming. To be consistent, the Department will continue to use the term "needle exchange." This comment will not be accepted at this time.

A comment was received requesting that smoking spaces be optional instead of required. Providing a safe space for all methods of consumption ensures that the harm reduction is providing services in an equitable manner for persons with a substance use disorder, and not creating further disparities in the overdose epidemic.

The Department recognizes the potential cost for implementing such a requirement and worked with several subject matter experts to include the most cost-effective ventilation requirements for harm reduction centers. If such requirements are too burdensome for a harm reduction center, the center can apply for a variance and the Department will review the request. The Department will continue to require smoking rooms and this comment will not be accepted at this time.

A comment was received in support of the variance procedure of the regulation. The Department thanks you for the comment.

Testimony was received during the hearing to request the addition of trainings for staff members to include stigma training and de-escalation trainings. As the harm reduction center is going to start out as a pilot program, the Department does not want to overburden centers with mandatory trainings and would consider this change after the pilot program. Furthermore, a separate comment requested a safety plan be implemented in the center, in coordination with local public safety officials. This change was accepted, and the Department would assume that such safety plan would first include de-escalation of any unsafe situations that may arise in the center. This comment will not be accepted at this time.

Testimony was received during a hearing to request referrals to general health care, human immunodeficiency virus (HIV) and Hepatitis C testing. The proposed regulations already require referrals to appropriate medical treatment that a client may need, which

may include general health care, HIV or Hepatitis C testing. This comment will not be accepted at this time.

CHANGES TO THE TEXT OF THE RULE:

§ 25.3.3(C) requires the center to develop a public safety plan in collaboration with local public safety officials.

§ 25.4.2(G) requires the center to develop wellness policies and practices for employees.

§ 25.4.8(A)(1)(b) requires stratification of services used

§ 25.4.8(A)(1)(d) requires stratification of overdoses by location

§ 25.4.8(A)(1)(e) requires stratification of use of an opioid antagonist by location and method.

§ 25.5.1(D) prohibits staff from assisting clients with consumption. Prohibits clients assisting one another with consumption.

REGULATORY ANALYSIS:

In development of this rule, consideration was given to:

- 1) Alternative approaches;
- 2) Overlap or duplication with other statutory and regulatory provisions; and
- 3) Significant economic impact on small business

No alternative approach, duplication or overlap was identified based on available information. RIDOH has determined that the benefits of the rule justify its costs.