

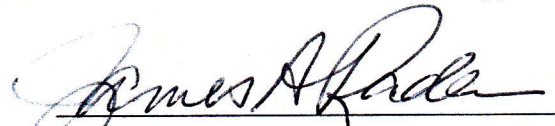
**Department of
Public Health &
Environment**

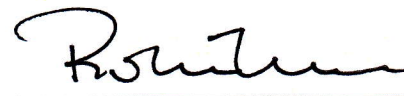
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**Rules and Regulations
Governing Syringe Access and
Treatment Referral Programs**



Approvals


Chair, Board of Public Health and Environment



Executive Director, Department of Public Health and Environment



Attorney for the City & County of Denver

Date of Final Signature / Effective Date: 2/7/19

**RULES AND REGULATIONS GOVERNING
SYRINGE ACCESS AND TREATMENT REFERRAL PROGRAMS (“SAPs”)**

Statement of Basis and Purpose

These rules and regulations (“Rules”) are adopted pursuant to Chapter 24, Article V, Section 24-157 and Section 24-158 of the Denver Revised Municipal Code (“D.R.M.C.”). These rules amend and supersede the Rules and Regulations Governing Needle Exchange and Treatment Referral Programs adopted May 12, 2011.

These Rules are established to regulate hypodermic syringe exchange, hereinafter “syringe” access. Agencies participating in the syringe access program (“SAP”) will provide sterile hypodermic syringes in exchange for used hypodermic syringes, needles or other objects used to inject substances into the body; provide education to participants on the transmission of HIV, hepatitis B, and hepatitis C; and provide referral to HIV and viral hepatitis screening programs and substance use treatment services for participants and their partners.

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SECTION 1.0 DEFINITIONS

- A. “Board” means the Board of Public Health and Environment.
- B. “Commercial Medical Waste Transporter” means a transporter who transports medical waste as a major part of its business and includes companies offering medical waste disposal services that pick up medical waste and transport it to a permitted facility to be treated and disposed of properly.
- C. “Department” means the Department of Public Health and Environment.
- D. “Executive Director” means the Executive Director of the Department of Public Health and Environment or the Executive Director’s representative and otherwise referred to as the Manager under D.R.M.C. §§ 24-157–58.
- E. “High Hazard Body Fluids” means body fluids which constitute a higher risk of containing potential biohazards, such as human blood and blood products; semen and vaginal secretions; vomit; and feces.
- F. “Medical Waste” means used syringes and any other equipment or materials used that is exposed to high hazard body fluids.
- G. “Mobile Exchange” means syringe exchange activities occurring off the premises of an approved fixed-location syringe access program
- H. “Non-Commercial Medical Waste Transporter” means a transporter who transports medical waste generated or managed in the course of its business but does not provide waste transportation as its principal business.
- I. “PWID” means people who inject drugs.
- J. “SAP” means syringe access program.
- K. “Spill” means the unauthorized release or discharge of any amount of medical waste as defined in 6 CCR 1007-2 of the Colorado Regulations Pertaining to Solid Waste Sites and Facilities.
- K. “Staff” means paid and volunteer staff of a SAP.

SECTION 2.0 STANDARDS FOR OPERATION OF REGISTERED SAPS

2.1 Service Population

2.1.1. PWID are the service population to participate in the syringe access program.

2.2. Implementation and General Provisions

2.2.1. All programs must operate in accordance with state and local laws, rules, and regulations.

2.2.2. Providers must demonstrate experience in providing disease prevention services and referrals to health care, social services, and substance use treatment to PWID. Annual training must be provided to staff to keep them current on best practices, harm reduction methods, and service availability. The SAP must maintain a record of this training for each staff member.

2.2.3 Copies of all plans and procedures required to be kept pursuant to these rules shall be reviewed and updated regularly and available for review by the City at all times.

2.2.4. The Department reserves the right to inspect any and all documentation or information concerning the SAP operations.

2.3. Application

2.3.1. All applicants seeking to operate as a SAP must complete and submit to the Department an application with true and accurate information in accordance with the requirements of this section. The registrant must receive a notice of approved registration from the Department prior to the SAP commencing operations. The Department reserves the right to limit the number of SAPs approved to operate in the City and County of Denver.

2.3.2. Applicants shall delineate plans to meet all state and local laws related to syringe exchange, provide supporting evidence of a history of serving the affected population, and outline the details of the proposed program.

2.3.3. The application must include the following information:

2.3.3.1. An assessment of need in the community, which includes the estimated number of PWID to be served in the program;

2.3.3.2. Evidence of the capacity of the applicant to be successful in the development and implementation of a SAP;

2.3.3.3. Evidence of financial resources for successful implementation of a SAP;

2.3.3.4. The proposed location of the syringe access site(s) and the hours of operation. The location choice must show adherence to local laws.

2.3.3.5. The detailed plans, policies and procedures under which the proposed SAP will operate, including solid and biohazard waste disposal.

2.3.3.6. Evidence that the proposed SAP meets requirements of these Rules and other applicable local and state laws;

2.3.3.7. A summary of the paid staff positions to be involved, including a description of job duties and necessary qualifications;

2.3.3.8. A written training and safety plan for the applicant's staff;

2.3.3.9. A written community outreach plan to inform and educate law enforcement, local residents, business owners, organizations, and PWID within the community in which the exchange is to be located must be established, as well as a plan for maintaining that support and utilizing on-going community input and involvement in program implementation, evaluation, and refinement;

2.3.3.10. Description of a referral system for hepatitis and HIV screening, substance use treatment, and other health services.

2.3.4. Complete applications will be reviewed by the Department for conformance with the standards set forth in these Rules. Each applicant shall be notified of registration approval status within 30 days of the Department's receipt of a complete application unless otherwise notified of an extended timeframe needed for review.

2.3.5. The Department reserves the right to request additional information as needed to make an informed decision on the approval.

2.3.6. Applicants will have thirty (30) calendar days from the Department registration decision to contest the Department's decision as an appeal of a notice or order of the Department pursuant to the Regulations Governing Hearings before the Board of Environmental Health.

2.4 Community and Professional Relations

2.4.1. Each SAP shall have a plan in place to facilitate on-going community input and an advisory board that is representative of the community and geographic area established. The advisory board shall further the integration of the program services within the community and provide a forum for input on program operations. The advisory board shall consist, in part, of community residents and program participants. It is recommended that the advisory board also

include representatives of community organizations, substance use professionals, and experts in fields such as medicine and law, and law enforcement agents.

2.4.2. Each SAP shall appoint a program staff person as a liaison that will maintain on-going communication with local police and respond to any issues which may arise with law enforcement. Incidents involving the SAP including law enforcement episodes, violence at program sites, and potential legal action against the program shall be reported in writing to the Department within 72 hours.

2.4.3. The SAP shall inform in writing any other program entities with which they share a facility/location of the implementation of syringe exchange. Ongoing reasonable efforts shall be made to address any complaints regarding the program or its operations raised by clients, staff, other programs, or any person. Documentation regarding any concerns expressed by external parties and the SAP's response shall be maintained on file for five years by the SAP and shall be available for review by the Department immediately upon request.

2.5. Staff and Training

2.5.1. A written, current staff training program for all paid and volunteer staff shall be maintained onsite at all times. Training may differ by position but must address the hazards associated with a position's duties. The training program shall delineate the different training requirements for each position. The curriculum for each training component shall be available in writing.

2.5.2. Training of all staff must include written information regarding laws, regulations, and guidelines relevant to syringe exchange and the possession of drug use equipment, such as injection works.

2.5.3. Training shall include a written confidentiality and information security plan to protect any personally identifiable information.

2.5.4. Staff shall be trained on the program's written needle stick injury plan.

2.5.5. Training shall include written operating procedures, universal precautions training that is in conformance with OSHA standards, the proper handling of potentially infectious injection equipment, waste disposal procedure, and the prevention and handling of needle sticks.

2.5.6. All staff shall be trained on overdose reversal.

2.5.7. Staff responsible for exchanges and/or handling of injection equipment, including injection equipment in enclosed containers, shall be trained in universal precautions with a certificate or other documentation available detailing the type and date of training.

2.5.8. A record of each staff member's training completion, including date of completion, shall be maintained onsite, at all times.

2.5.9. Staff shall not conduct syringe exchanges or handle syringe or drug use equipment unless they have completed all required training.

2.5.10. Staff shall operate in conformance with their training at all times.

2.5.11. All required documentation shall be made available immediately upon request.

2.6 Facility Requirements

2.6.1. All restroom hand washing sinks shall be continuously stocked with water between 100 and 120 F, soap, and single use drying devices.

2.6.2. Stored containers of used syringes and other contaminated waste shall be in an area labeled as "Biohazard Storage Area" and segregated from other supplies and equipment.

2.6.3. The facility shall be maintained in a clean and sanitary manner. All areas of the operation shall be free of visible dirt, debris, rubbish, trash, waste, and free from other uncontained substances, contaminants, materials, or environmental conditions harmful to human health.

2.6.4. All surfaces contaminated by high hazard body fluids shall be promptly cleaned and disinfected using a disinfection product that is EPA approved and specifically intended to address high hazard body fluids and used in compliance with manufacturer's directions.

2.6.5. All other frequently contacted surfaces, including but not limited to work tables, desks, door knobs, hand sinks, must be sanitized prior to program hours of operation. All chemicals used for sanitization shall conform to formulation specifications in the Code of Federal Regulations Sanitizer Standard 21 CFR § 178.1010.

2.6.6. A designated person in charge must be present at all times of operation.

2.6.7. The SAP will maintain written verification of proper disposal of biohazard waste by obtaining documentation after each pick-up and/or drop-off from the disposal company used by the SAP, such as, but not limited to invoices or receipts.

2.6.8. Unless otherwise stated, all required records of the SAP shall be maintained for five years.

2.7. Syringe Exchange Protocol

2.7.1. SAPs shall have written enrollment and complete operating procedures that are followed and available to the Department upon request.

2.7.2. SAPs shall operate on a regular and consistent basis in terms of location and times of operation. They shall be located in areas which are accessible to a large portion of the PWID population and maintain hours of operation that are deemed by its advisory board as most practical to the community being served. The program shall utilize its advisory board in determining the locations and schedule of syringe exchange sessions. Fully trained staff must be present during all operating hours.

2.7.3. The SAP must keep a current file of all staff who work in the SAP, including effective start and end dates, their job duties, training completion dates, records, and certificates, where applicable.

2.7.4. The SAP shall maintain copies of exchange and referral records for at least two years. These documents shall be kept in accordance with security precautions for ensuring the confidentiality of syringe exchange and harm reduction program participants and records.

2.7.5. During each client interaction with the SAP, the SAP may distribute other materials necessary for sterile and safer injection (e.g., cookers, cotton, water), overdose prevention, and harm reduction.

2.8. Education, Services, and Referrals

2.8.1. Program staff shall offer to SAP participants during each exchange or dispensing of substance use, materials with hepatitis and HIV prevention education, including safe sex and safer injection practices. Information shall also be offered regarding the prevention, testing, and treatment of other sexually transmitted diseases, tuberculosis, and other health problems related to drug use. Such information shall be provided verbally or in writing to participants, either on a one-on-one basis or in a group setting.

2.8.2. Referral relationships with other service providers shall be established for services not available on site. All participants shall be informed of such available services and aided in their efforts to access those services. Such services shall include HIV and primary health care; family planning, prenatal, and obstetrical care; substance use treatment; STD screening and treatment; TB screening and treatment; Hepatitis testing and treatment; mental health services; basic needs support (e.g. housing and food); and case management and support services for people living with HIV or AIDS.

2.8.3. Services shall also be made available to people with disabilities in compliance with all applicable laws.

2.8.4. Services shall not discriminate on the basis of race, color, religion, national origin, gender, age, military status, sexual orientation, gender identity, gender expression, marital status, or physical or mental disability

2.9. Staff Safety, Needle Stick Protocol

2.9.1. Programs shall have a written plan in place, available upon request, for protecting the safety of staff which is based, in part, on input from those staff.

2.9.2. There shall be a minimum of two applicant staff members present at the SAP site during hours of operation.

2.9.3. All staff shall have access to working telephones.

2.9.4. Staff may cancel a syringe exchange session in the event of any occurrence that affects the safety, security, confidentiality, or effectiveness of a session.

2.9.5. Program staff must not interfere or obstruct law enforcement personnel who may be involved in a situation with a program participant while performing their duties.

2.9.6. Staff are responsible for adhering to established written procedures during exchange operations.

2.9.7. Staff conducting exchange operations shall not handle or touch used needles without appropriate protective equipment. Appropriate protective equipment and tools for handling exposed, used injection equipment such as tongs and impermeable gloves must be available to staff at all times.

2.9.12. Staff shall wear clothing (such as long pants) and footwear (no open toed shoes) that protect them from possible needle sticks. Feet, ankles, and legs shall be covered by shoes/clothing and shall not be exposed.

2.9.14. All staff shall be informed where they can obtain hepatitis and tetanus vaccinations. If staff decline vaccination, they shall sign and date a waiver specifying that they are declining the vaccination(s). The waiver shall be kept on file for one year beyond the duration of their tenure.

2.9.15. Each SAP shall have a written protocol available upon request for handling needle stick injuries. Immediately following an exposure, needle stick sites shall be washed with soap and warm water. A doctor's advice shall be sought immediately through a local emergency department or the staff member's primary care provider to discuss the possibility of disease post-exposure prophylactic treatment (which should begin within 2 hours) and testing procedures.

2.10 Waste Management and Disposal

2.10.1 The SAP shall have a written on-site medical waste management plan that contains the following information:

2.10.1.1. Identification of the type(s) of medical waste handled or stored at the SAP;

2.10.1.2. Procedures for the handling, treatment, and disposal of medical waste;

2.10.1.3. A contingency plan for spills or loss of containment which includes the following:

2.10.1.3.1. Cleanup procedures that will be followed to contain and cleanup spills or releases of medical waste

2.10.1.3.2. Use of a spill-kit and a list of supplies (e.g. absorbent materials, medical waste bags and containers, and disinfectant) and personal protective equipment (e.g., disposable gloves, face mask, goggles apron) available in the spill-kit;

2.10.1.3.3. Proper disposal of used absorbent materials and personal protective equipment; and

2.10.1.3.4. Clean-up and disinfection of the containment area.

2.10.2 Spills or releases shall be reported to the Department and the Colorado Department of Public Health & Environment and shall be tracked by the SAP, including the date of spill and actions taken by the SAP to address the spill.

2.10.3. All SAP staff shall complete training regarding the medical waste plan prior to receiving or handling medical waste and/or syringe exchange; the date of training shall be documented for each staff member.

2.10.4. The SAP shall designate a person responsible for plan implementation.

2.10.5. SAPs that transport medical waste without using a commercial medical waste transporter shall comply with US Department of Transportation requirements.

2.10.6. All used injection equipment collected by the program shall be placed in approved leak-proof, puncture-resistant containers intended for medical waste. Containers must be collected, handled, stored, and transported in compliance with established medical waste collection procedures, laws, and rules. Containers must bear a label containing the word "Biohazard" and the universal biohazard symbol; and the label should be legible and in good condition. The background of the label must be fluorescent orange or orange-red and the universal biohazard

symbol and “Biohazard” lettering must be of a contrasting color. Secondary containment containers must also be properly labeled as specified in this section.

2.10.7. Any injection equipment that falls outside the sharps container shall be retrieved by the participant whenever possible. When not possible, personal protective equipment and tools shall be used to safely retrieve and discard the injection equipment.

2.10.8. Participants and staff shall not insert their hands into the sharps container or forcibly push used injection equipment down into the container beyond the opening at the top. Sharps containers shall never be filled more than $\frac{3}{4}$ full or, if indicated, beyond the “fill” line marked on the container. Containers shall be placed on a secure surface or on the ground and shall be kept level at all times. Collection containers shall not be emptied or reused onsite.

2.10.9. If syringes are returned in sealed containers or containers that are difficult to empty safely (e.g., bleach bottles), the number being returned should be estimated rather than emptying the container for a more exact count.

2.10.10. Hazardous waste containers shall be properly sealed before transport. Only properly trained staff shall transport hazardous waste, or such waste shall be picked up by a properly licensed medical waste disposal company. Each approved SAP is responsible for the proper and lawful disposal of hazardous waste generated through exchange activities, which is consistent with established procedures, laws, and rules governing such disposal. A formal written agreement with a properly trained medical or hazardous waste company or agency must be established before exchange activities may begin. The written agreement shall be on file at the program site and available for review by the Department.

2.10.11. All medical waste must be maintained and stored in a way that will not produce nuisance conditions. An area in the SAP facility shall be designated for the storage of medical waste while it is waiting for on-site or off-site treatment and disposal. Medical waste shall not be stored in the areas where collected once the bag or container is full or is removed from service for any reason. The storage period begins when the container is full, has been closed or sealed, and/or is no longer being used to collect medical waste. The waste shall be moved to the designated medical waste storage area within 24 hours of being taken out of service.

2.10.12. The designated medical waste storage area can be located inside or outside, but the storage area shall comply with the following:

2.10.12.1. The storage area shall be a secured, enclosed structure or storage unit that is inaccessible to animals and unauthorized personnel. Inside storage areas may require ventilation if nuisance conditions arise.

2.10.12.2. The storage area shall be constructed with smooth, easily cleanable non-porous materials that are impervious to liquids and resistant to corrosion by disinfection agents and hot water. Floors shall have adequate drainage and be free

of standing water. Carpet and floor coverings that have cracks or gaps shall not be used in the storage area.

2.10.12.3. The storage area shall be secured to prevent unauthorized access. Warning signs, on or adjacent to the exterior door(s), shall be marked with the international biohazard symbol (if the medical waste is subject to OSHA's Bloodborne Pathogens Standard) and the words "Caution – Medical Waste Storage Area – Unauthorized Persons Keep Out." Signs shall be legible with lettering at least 2 inches tall.

2.10.12.4. Medical supplies and substances for human consumption shall not be kept in the storage area.

2.10.13. On-site storage of sealed sharps containers may not exceed 90 days. These containers must be maintained in good condition and secured to prevent unauthorized access.

2.10.14. The SAP shall identify and label each medical waste container containing medical waste with a tracking identification number or other identifier. The SAP shall maintain a tracking log identifying the date that use of the container commenced, the date that the container was sealed, and the date that the container was transported offsite to a State-approved commercial medical waste treatment or disposal facility. The SAP shall retain medical waste manifests, shipping papers, or other clear tracking documentation for all containers transported offsite.

2.11. Reporting

2.11.1. SAPs shall submit quarterly reports of services to the Department no later than thirty (30) calendar days following the end of each calendar quarter. These reports shall include, but may not be limited to:

2.11.1.1. Number of new participants enrolled in the quarter;

2.11.1.2. Number of active participants during the quarter;

2.11.1.3. Aggregate demographic information for participants including gender, age, ethnicity;

2.11.1.4. Approximate number of syringes collected in total and the average number per participant per transaction;

2.11.1.5. Number of syringes distributed to participants and the average number per participant per transaction;

2.11.1.6. Number and types of services provided and referrals made;

2.11.1.7. Updates on significant program challenges and developments;

2.11.1.8. Number of people trained on overdose reversal, number of reported reversals, and number of overdose prevention kits distributed; and

2.11.1.9. A description of any deviation(s) from approved plans, policies and procedures required under these Rules during the reporting period.

2.12. Fees

2.12.1. The Department may assess and recover fees to offset actual, direct costs of the program site visits and reviews, as authorized by C.R.S. 25-1-508.

2.13 Mobile Exchange Protocol

2.13.1. SAPs seeking to provide mobile services must submit a written request for Department approval 60 days prior to the expected start date. SAPs already engaging in mobile operations at the time of adoption of these Rules shall submit the written request no later than 60 days after the effective date of these regulations.

2.13.2. All requirements for fixed-site syringe access shall apply unless otherwise indicated in this section.

2.13.3. The SAP shall maintain a log of all mobile exchanges that occur which includes the time and location of the mobile exchange, as well as all other information that is required for fixed-site exchanges.

2.13.4. All SAPs seeking to provide mobile syringe access, shall provide the following information to the Department in their written request:

2.13.4.1. A mobile safety plan and protocol that addresses at a minimum staff and public safety, needlestick protocol, waste disposal, and vehicle cleaning and sanitation;

2.13.4.2. A description of staff qualifications and training to conduct mobile services;

2.13.4.3. A description of how the SAP will maintain confidentiality of participants while providing mobile services;

2.13.4.4. A written plan detailing how, where, and with what frequency mobile exchanges will occur; and

2.13.4.5. A description of how mobile exchange staff can identify themselves as SAP staff.

2.13.5. Additional quarterly reporting requirements for mobile services shall include:

2.13.5.1. The SAP shall provide the Department with dates, times, and locations where mobile syringe access is conducted;

2.13.5.2. Information on the number of newly enrolled participants through mobile syringe access services; and

2.13.5.3. Information regarding any injury, law enforcement, or overdose reversal incidents that occurred during mobile syringe access services.

2.13.6. At any time, the Department may impose conditions and restrictions on proposed or existing mobile exchange locations, times, frequency, and other factors.

SECTION 3.0 SUSPENSION AND REVOCATION PROCEEDINGS

3.1. When the Executive Director determines that grounds exist to suspend or revoke a registration as set forth in D.R.M.C. 24-158, the Executive Director may initiate a show-cause proceeding, including a hearing at which the registrant shall be afforded an opportunity to be heard by the Board.

3.2 A show-cause proceeding shall be initiated by the Executive Director's order allowing the registrant to appear and show cause at a designated date, time, and location. The proceeding shall be governed by the Rules Governing Hearings Before the Board of Environmental Health ("Hearing Rules"). The registrant shall have burden of persuasion as set forth in the Hearing Rules.

3.3. The order shall be served upon such registrant in accordance with the service requirements of Chapter 2, D.R.M.C., at least thirty (30) days before the time designated for the registrant to appear.

3.4. If such registrant fails to appear at the time so designated in the order, and the registrant was properly served with copies of the order pursuant to Chapter 2, D.R.M.C., the registrant shall be in default and the order shall be deemed admitted. At the discretion of the Board, registration may be revoked or suspended, and the SAP barred from operation.

3.5. If the registrant appears at the show cause hearing, the Board shall hear and consider evidence for and against the registrant. The Board may either find the registrant in violation and may order suspension or revocation, or the Board may find in favor of the registrant. The Board shall enter an order in writing stating its finding(s) and, if there is a finding, describing the violation and sanction.

3.6. Any appeal of revocation or suspension of the Board's decision shall be subject to the requirements of C.R.C.P. 106(a)(4).