

Environmental

Health

RULES & REGULATIONS

GOVERNING
NEEDLE
EXCHANGE AND
TREATMENT
REFERRAL
PROGRAMS



Approved, as Amended
Patty Switzer
Chair, Board of Environmental Health

**BOARD OF ENVIRONMENTAL HEALTH
RULES AND REGULATIONS GOVERNING
NEEDLE EXCHANGE AND TREATMENT REFERRAL PROGRAMS (“NEPs”)**

Adopted by the Board of Environmental Health on May 12, 2011
Denver Department of Environmental Health
Community Health & Decision Support Division
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SECTION 1.0 INTRODUCTION

As a result of recent amendments to State law and City ordinance, the Board of Environmental Health in Denver may establish and administer a Needle Exchange Program (NEP) within the City and County of Denver for the purpose of sterile hypodermic syringe and needle exchange, hereinafter “needle” or “syringe” exchange. Agencies participating in the NEP will provide sterile hypodermic syringes and needles in exchange for used hypodermic syringes, needles or other objects used to inject controlled substances or controlled substance analogs into the human body; provide education to participants on the transmission of HIV, hepatitis B, and hepatitis C; and provide referral to HIV and Hepatitis screening programs and substance abuse treatment services for participants and their partners.

These rules and regulations (Rules) implement the needle exchange and treatment referral program provisions (NEP) of Section 24-157 to 8 of the Denver Revised Municipal Code (DRMC) and C.R.S. 18-18-430.5, 25-1-508, and 25-1-520.

SECTION 2.0 CODE CHAPTERS AND SECTIONS

To the extent established by the Charter and Ordinances of the City and County of Denver, including but not limited, to the generally applicable enforcement provisions of Title II Chapter 1 and DRMC 24-157-8, the Manager may set standards and procedures for the selection, registration and regulation of qualified NEPs. This regulation governs the selection, registration and regulation of qualified NEPs.

SECTION 3.0 STANDARDS FOR OPERATION OF REGISTERED NEPS

3.1. Service Population

3.1.1. The populations that will be actively recruited for the needle exchange project are active, or former users of illicit intravenous drugs.

3.2. Implementation and General Provisions

3.2.1. All programs must operate in accordance with federal, state, and local law, rules, and regulations.

3.2.2. Providers must demonstrate relevant experience in providing disease prevention services, health care, social services or substance use treatment services to injection drug users. Annual training must be provided to staff to keep them current on best practices and harm reduction methods.

3.3. Application

3.3.1. A request for application for certification to establish a needle exchange program will be publicized by the Department of Environmental Health. All organizations seeking certification must complete an application and return it by the deadline publicized by the Department, in accordance with the instructions.

3.3.2. Applicants will be required to delineate plans to successfully meet both State Law and City ordinance related to needle exchange, provide supporting evidence of a history of serving the affected population, and outline the details of their proposed program.

3.3.2.1. The application must include a program implementation plan submitted to the Denver Board of Environmental Health, or its designee, and should include the following information:

3.3.2.2 An assessment of need in the community, which includes the estimated number of injection drug users to be served in the program;

3.3.2.3. Evidence of the capacity of the agency to be successful in the development and implementation of an exchange program;

3.3.2.4. Evidence of financial resources for successful implementation of an exchange program;

3.3.2.5. The proposed location of the syringe exchange site(s) and the hours of operation. The location choice must show adherence to local laws, and not be situated close to any locations that are deemed inappropriate by the local governing entity (e.g., schools, playgrounds, residences, or drug treatment centers);

3.3.2.6. The detailed policies and procedures under which the exchange program will operate.

3.3.2.7. Evidence that the proposed program meets requirements of the City ordinance, these rules, and Colorado State law;

3.3.2.8. A summary of the staff and volunteers to be involved, including a description of their job duties, experience, and general qualifications to work effectively with injection drug users;

3.3.2.9. The training and safety plan for staff and volunteers;

3.3.2.10. A community outreach plan to inform and educate law enforcement, local residents, business owners, organizations, and injection drug users 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;

3.3.2.11. Description of referral system for hepatitis and HIV screening, substance abuse treatment referrals, and other preventative health services.

3.3.3. Complete applications will be reviewed by a volunteer review committee recruited by the Department of Environmental Health. The committee's recommendation will be forwarded to the Manager of Environmental Health. The Manager will review the committee's recommendation, reserving the right to differ from the review committee. A written recommendation and any justification for deviation from the review panel's recommendation will be forwarded to the Denver Board of Environmental Health for final determination. The Board will make the final decision on agencies selected for certification.

3.3.4. Agencies will have 30 calendar days from the final Board decision to submit written grievances to the Manager of Environmental Health. The Manager will meet with grieving agencies to attempt resolution to the grievance. If an agreement is not reached, the agency may submit a written appeal to the Board. This appeal must be received no later than 14 calendar days following the meeting with the Manager of Environmental Health. The Board will have the opportunity to hear from both the agency and the Manager. The Board decision on the appeal will be final.

3.4. Community and Professional Relations

3.4.1. A syringe exchange program should have a plan in place to facilitate on-going community input. It is recommended that an advisory board that is representative of the community and geographic area be established. The advisory board's role will be to further the integration of program services within the community and provide a forum for input on program operations. The board should consist, in part, of community residents and program participants. It is recommended that the board also include representatives of community organizations, substance abuse professionals, and experts in fields such as medicine and law, and law enforcement agents.

3.4.2. A needle exchange program staff person should be appointed 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 needle exchange program including law enforcement episodes, violence at program sites, and potential legal action against the program must be reported to the DEH within 72 hours.

3.4.3. The needle exchange program or office must inform any other program entities with which they share a facility or location of the implementation of needle exchange. Ongoing reasonable efforts should be made to prevent, and/or to overcome concerns or objections raised by other staff or programs, or local governments.

3.5. Staff and Training

8.5.1. All needle exchange program staff and volunteers who collect hypodermic needles and syringes, or who distribute hypodermic needles and syringes must complete a proper course of training as appropriate to their level of involvement in program activities. Supervisors must oversee and ensure the quality of staff and volunteer performance, which must include periodic on-the-job supervision. Training of staff and volunteers shall include laws, regulations, and guidelines relevant to needle exchange and the possession of paraphernalia.

3.6. Syringe Exchange Protocol

3.6.1. Needle exchange programs shall have enrollment procedures in place and available to the Department of Environmental Health upon request.

3.6.2. Needle exchange programs should operate on a regular and consistent basis in terms of location and times of operation. They should be discrete, located in areas which are accessible to a large portion of the injection drug using population, and maintain hours of operation that are deemed most practical to the community being served. The program should utilize their advisory board in determining the locations and schedule of syringe exchange sessions. The program should strive for consistency in staffing, in order to develop and foster more constructive relationships with participants. Fully trained staff or volunteers must be present during all operating hours.

3.6.3. The needle exchange program must keep a running log/file of ID codes of all staff and volunteers who work in the needle exchange program.

3.6.4. The needle exchange program must make available copies of utilization log forms to the Department of Environmental Health upon request. It is recommended that a program or office maintain copies of these documents on file for at least 5 years. These documents should be kept in accordance with security precautions for ensuring the confidentiality of syringe exchange and harm reduction program participants and records. A written confidentiality and security protocol must be followed and available to staff.

3.6.5. At each visit, programs may distribute condoms as well as other materials necessary for sterile and safer injection (e.g., cookers, cotton, water).

3.6.6. Clients should always be treated in a respectful and non-judgmental manner by staff and volunteers of the exchange.

3.6.7. Programs must establish policies and procedures for the maintenance of confidentiality which are consistent with state and federal laws.

3.7. Education, Services, and Referrals

3.7.1. Program staff and volunteers must provide all needle exchange participants with hepatitis and HIV prevention education including safer sex and safer injection practices. Information should also be available on the prevention, testing, and treatment of other sexually transmitted diseases, tuberculosis, and other health problems related to drug use. Such information should be provided through both direct verbal exchanges with participants, either on a one-on-one basis or in groups, as well as through the distribution of culturally sensitive and appropriate printed materials.

3.7.2. Formal referral relationships with other service providers must be established for services not available on site. All participants should be informed of such available services and aided in their efforts to access those services. Such services should include: HIV and general primary health care; family planning, prenatal, and obstetrical care; substance abuse 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 HIV-infected people.

3.7.3. Services must also be made available to people with disabilities in compliance with all applicable laws.

3.8. Staff Safety, Needle Stick Protocol, and Waste Disposal

3.8.1. Programs must have a plan in place for protecting the safety of staff and volunteers which is based, in part, on input from those staff and volunteers.

3.8.2. There should be a minimum of two, but preferably more than two, staff members present at an exchange program site during hours of operation.

3.8.3. All staff should have access to working telephones.

3.8.4. Staff have the prerogative to cancel a needle exchange session in the event of any occurrence that affects the safety, security, confidentiality or effectiveness of a session.

3.8.5. Staff have the option to summon the police in the event of an occurrence that raises security concerns. Program staff and volunteers must not interfere or obstruct law enforcement personnel who may be involved in a situation with a program participant while performing their duties.

3.8.6. All staff and volunteers who will be present during exchange operations must receive training in universal precautions, the proper handling of potentially infectious injection equipment, waste disposal procedures, and the prevention and handling of

needle sticks. These staff and volunteers are responsible for observing proper safety and security precautions during exchange operations.

3.8.7. Staff and volunteers conducting exchange operations should never handle or touch used needles. Appropriate equipment – tongs, impermeable gloves, etc – must be available to staff at all times.

3.8.8. All used injection equipment collected by the program must be placed in approved leak-proof, puncture-resistant containers that are conspicuously labeled as "Infectious Waste" and consistent with established medical waste collection procedures, laws and rules. Whenever possible, the container should be placed on a secure table or on the ground and should be kept level at all times; they should never be filled beyond the manufacturer's fill line, and they should not be held during an exchange.

3.8.9. Any injection equipment that falls outside the sharps container should be retrieved by the participant whenever possible.

3.8.10. Participants, staff and volunteers should never insert their hands into the sharps container or forcibly push used injection equipment down into the container beyond the opening at the top.

3.8.11. 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.

3.8.12. Staff and volunteers must wear clothing (such as long pants) and footwear (no open toed shoes) that protects them from possible needle sticks.

3.8.13. Hazardous waste containers must be properly sealed before transport. Only trained staff and volunteers should transport hazardous waste, or such waste should be picked up by a properly licensed medical waste disposal company. Each program is responsible for the proper and lawful disposal of any hazardous waste generated through exchange activities, which is consistent with established procedures, laws and rules governing such disposal. A formal agreement with an appropriate company or agency must be established before exchange activities may begin.

3.8.14. All staff and volunteers who have not previously been vaccinated for hepatitis and/or currently vaccinated for tetanus should be offered these vaccinations.

3.8.15. Each syringe exchange program must establish a protocol for handling any needle stick injuries that may occur. Immediately following an exposure, needle sticks should be washed with soap and water. A doctor's advice should be sought immediately through a local emergency department or the staff/volunteer's primary care provider to discuss the possibility of HIV or other disease post-exposure prophylactic treatment (which should begin within 2 hours) and testing procedures, as well as hepatitis B prophylaxis.

3.9. Reporting

3.9.1. Exchange programs must submit quarterly reports of services to the Department of Environmental Health no later than 15 days following the end of each calendar quarter. These reports will include, but may not be limited to:

- 3.9.1.1. Number of participants enrolled in that quarter;
- 3.9.1.2. Aggregate demographic data for participants: gender, age, ethnicity;
- 3.9.1.3. Number of syringes collected in total and the average number per participant per transaction;
- 3.9.1.4. Number of syringes distributed to participants and the average number per participant per transaction;
- 3.9.1.5. Number and types of services provided or referrals made;
- 3.9.1.6. Significant barriers, significant program changes, and significant program milestones achieved.
- 3.9.1.7. Number of condoms and safer injection materials distributed

3.10 Fees

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

SECTION 4.0 SUSPENSION OR REVOCATION OF REGISTRATION PROCEEDINGS

4.1. When it appears to the Manager (on her/his own motion or upon complaint) and after investigation, that there are grounds to suspend or revoke a previously allowed registration, then the Manager shall initiate a show cause proceeding, including a hearing at which the registrant shall be afforded an opportunity to be heard by the Board.

4.2. A show cause proceeding shall be initiated by the Manager's ex parte order for a citation to issue to the registrant to appear and show cause at a date, time and place designated why the registrant's authorization to operate a Needle Exchange and Treatment Referral Program should not be suspended or revoked. The nature of the sanctions that may be imposed shall be described in the citation.

4.3. The citation and a copy of the motion or complaint, and order shall be served directly upon such registrant at least twenty (20) days before the time designated for the registrant to appear by any of the following methods:

4.3.1. In person. A DEH official shall attempt to deliver the Citation and a copy of the motion or complaint and order, to the registrant at the registrant's site or at the registrant's business or personal address, or other form of service generally provided by Rule 4, Colorado Rules of Civil Procedure (C.R.C.P.) and authorized by the Manager. A DEH official shall attempt to obtain the signature of the registrant's representative at the time of personal service of the citation and a copy of the motion or complaint and order. If the registrant's representative refuses or fails to sign the citation with the motion or complaint and order, the

failure or refusal to sign shall not affect the validity of service, the citation and motion or complaint and order, or subsequent proceedings related to the citation them.

4.3.2. By registered mail. Service by registered mail to a registrant is authorized for the citation and copy of the motion or complaint and order.

4.3.3. By regular mail. Service by regular mail to a registrant is authorized for all other matters following service of the citation and copy of the motion or complaint and order.

4.3.4. Service shall be effective on the date of receipt by the registrant if personally served. Where service is by registered or regular mailing, service shall be effective on the date of mailing unless returned as undeliverable by the U.S. Postal Service. Unclaimed or refused mail is not considered to be an undeliverable mailing.

4.4. If such registrant fails to appear at the time so designated, and it is evident that the registrant was properly served with copies of the motion, order, and citation, or at any time to which the hearing may be continued, the registrant shall be in default and the motion or complaint and citation shall be deemed admitted and the registration shall be revoked and the formerly approved registrant shall be barred from operating a Needle Exchange and Treatment Referral Program.

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

4.6. Any appeal of revocation or suspension of NEP registration shall be subject to the requirements of Rule 106(a)(4), of the Colorado Rules of Civil Procedure.

4.7. These provisions shall only apply to proceedings for revocation and suspension of registration of NEPs. All other NEP matters shall be determined in accordance with other applicable rules.

SECTION 5.0 GROUNDS FOR SUSPENSION OR REVOCATION OF REGISTRATION

5.1. The grounds for suspension or revocation of NEP registration shall include the following:

5.1.1. The registrant has made false statements in the application for registration as to any of the facts required to be stated in such application;

5.1.2. The registrant has failed either to file the required reports or to furnish such information as may be reasonably required by the Manager under the authority vested in the Manager;

5.1.3. The registrant, either knowingly or without the exercise of due care to prevent the same, has violated any program provision, law, rule, contract, or other standard of care;

5.1.4. Any fact or condition exists which, if it had existed or had been known to exist at the time of the application for such registration, would have warranted the Manager in refusing originally to issue such registration;

5.1.5. The registrant, or any of the agents, volunteers, or employees of the registrant, have violated any rule promulgated by the Board and the Manager or any provision of the Denver Revised Municipal Code;

5.1.6. The registrant has failed to maintain the premises in compliance with the requirements of the building inspection division of the department of public works or the fire or environmental health departments, or any other applicable regulatory entity;

5.1.7. The registrant, or any of the agents, volunteers or employees of the registrant, have violated any ordinance of the city or any state or federal law on the premises or have permitted such a violation on the premises by any other person.

SECTION 6.0 EFFECTIVE DATE

These Rules and Regulations Governing Needle Exchange and Treatment Referral Programs shall be effective on the date of signature by the Manager of the Department of Environmental Health.

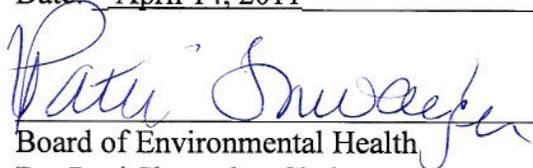
Approved for Publication:



Board of Environmental Health
By: Chris J. Wiant, MPH, Ph.D, Temporary Chair

Date: April 14, 2011

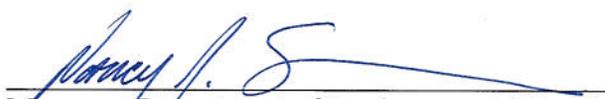
Approved as Adopted:



Board of Environmental Health
By: Patti Shwayder, Chair

Date: May 12, 2011

Adopted:



Manager, Department of Environmental Health

Date: May 12, 2011

Approved As To Form:



City Attorney

Date: 6/17/11

