WEST VIRGINIA SECRETARY OF STATE
KRIS WARNER
ADMINISTRATIVE LAW DIVISION

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Office of West Virginia
Secretary Of State

NOTICE OF FINAL FILING AND ADOPTION OF A LEGISLATIVE RULE AUTHORIZED BY THE WEST VIRGINIA LEGISLATURE

AGENCY: Office of the Inspector General TITLE-SERIES: 71-24

RULE TYPE: Legislative Amendment to Existing Rule: Yes Repeal of existing rule: No

RULE NAME: Syringe Services Program Licensure

CITE STATUTORY AUTHORITY: W. Va. Code 16-64-7

The above rule has been authorized by the West Virginia Legislature.

Authorization is cited in (house or senate bill number) HB4215

Section W. Va. Code 64-5B-1(d) Passed On 2/27/2026 12:00:00 AM

This rule is filed with the Secretary of State. This rule becomes effective on the following date:

May 1, 2026

This rule shall terminate and have no further force or effect from the following date:

August 01, 2031

BY CHOOSING 'YES', I ATTEST THAT THE PREVIOUS STATEMENT IS TRUE AND CORRECT.

Yes

Jessica Y Whitmore -- By my signature, I certify that I am the person authorized to file legislative rules, in accordance with West Virginia Code §29A-3-11 and §39A-3-2.

TITLE 71
LEGISLATIVE RULE
OFFICE OF INSPECTOR GENERAL

SERIES 24
SYRINGE SERVICES PROGRAM LICENSURE

§71-24-1. General.

1.1. Scope. - This legislative rule establishes standards and procedures for the licensure and regulation of syringe services programs in the state of West Virginia.

1.2. Authority. - W. Va. Code §16-64-7.

1.3. Filing Date. - April 8, 2026.

1.4. Effective Date. - May 1, 2026.

1.5. Sunset Provision. - This rule shall terminate and have no further force or effect upon August 1, 2031.

1.6. Applicability - This rule applies to any person, partnership, association, or corporation that operates a syringe services program as part of a harm reduction program. This rule does not apply to any person, partnership, association, or corporation that operates a harm reduction program that does not provide syringe services program.

1.7. Purpose. - The purpose of this rule is to ensure that all West Virginia syringe services programs conform to a common set of minimum standards and procedures to ensure the care, service, safety, and welfare of participants therein.

1.8. Enforcement. - This rule is enforced by the Inspector General. The Inspector General designates the Director of the Office of Health Facility Licensure and Certification to enforce the provisions of W. Va. Code §§16-64-1, *et seq*., and this rule, except where otherwise stated.

§71-24-2. Definitions.

2.1. Definitions incorporated by reference. - Those terms defined in W. Va. Code §§16-64-1, *et seq*., are incorporated herein by reference.

2.2. 1:1 Exchange Model -- A practice of restricting syringe access by providing a participant only the number of syringes that the participant returns to the syringe services program for disposal either by counting or by weight.

2.3. Adverse Event or Incident -- An event involving an immediate threat to the care or safety of an individual, either program staff member, contracted individual, volunteer, or participant; the possibility of serious operational or personnel problems within the syringe services program; or the potential to undermine public confidence in the syringe services program.

2.4. Bloodborne pathogens -- Pathogenic microorganisms that are present in human blood and can cause disease in humans; including, but not limited to, hepatitis B virus, hepatitis C virus, and human immunodeficiency virus.

2.5. Bureau for Public Health -- The West Virginia Bureau for Public Health within the West Virginia Department of Health.

2.6. Director – The Director of the Office of Health Facility Licensure and Certification.

2.7. Full Array of Harm Reduction Services -- As used in this rule and in W. Va. Code §16-64-10(d), "full array of harm reduction services" means those harm reduction services stated in W. Va. Code §16-64-3(a).

2.8. Injection Equipment -- Equipment is limited to cottons, water, and alcohol wipes.

2.9. Inspector General – The Inspector General of the Office of Inspector General as described in W. Va. Code §16B-2-1, or his or her designee.

2.10. Office of Health Facility Licensure and Certification – The West Virginia Office of Health Facility Licensure and Certification within the Office of Inspector General.

2.11. Opioid Antagonist -- A drug that blocks opioids' reception by attaching to the opioid receptors without activating them thereby causing no opioid effect and blocking full agonist opioids.

2.12. Participant -- An individual who receives services or supports, or both, from a syringe services program or harm reduction program, or both, under this rule.

2.13. Participant Confidentiality Protocols -- Written protocols that strictly limit the disclosure of participant identification information.

2.14. Plan of Correction -- A written description of the actions the syringe services program intends to take to correct and prevent the reoccurrence of violations of a rule or policy identified by the Office of Health Facility Licensure and Certification during an investigation, inspection, or survey.

2.15. Viral Hepatitis -- Any of the forms of hepatitis caused by a virus, including hepatitis A virus, hepatitis B virus (HBV), and hepatitis C virus (HCV).

§71-24-3. Licensure.

3.1. General Licensure Provisions.

3.1.1. No person, partnership, association, or corporation may operate a syringe services program in the state of West Virginia without first obtaining a license.

3.1.2. A license is valid only for the location and persons named and described in the application. Mobile site applications shall list all places the mobile site locates itself.

3.1.3. Each syringe services program shall be licensed separately, regardless of whether the program is operated under the same business name or management as another syringe services program.

3.1.3.a. Each fixed site location shall be licensed separately.

3.1.3.b. Each mobile site shall be licensed separately. Each mobile site may encompass multiple places within the program's service area.

3.1.4. A license is not transferable or assignable.

3.1.5. If the ownership of a syringe services program changes, the new owner shall notify the Director within 10 days and immediately apply for a new license. The new owner's application for a license has the effect of a valid license for three months from the date the application is received by the Director.

3.1.6. The syringe services program shall notify the Director in writing 30 days prior to a change in the name or location of the program and submit an application form for a license amendment.

3.1.7. In the event a public health emergency or emergency community need is identified by a currently licensed syringe services program, the program shall immediately contact the Office of Health Facility Licensure and Certification. The Office of Health Facility Licensure and Certification shall develop a policy for such emergency situations. This process shall not be used in lieu of licensing each location separately and is not a substitute for a syringe services program creating an emergency plan as described in section 5.3.

3.1.8. A licensure survey may be conducted periodically during the course of the annual licensing term.

3.1.9. The Director or his or her designee may enter the premises of any practice, office, or facility if the Director has reasonable belief that it is being operated and maintained as a syringe services program without a license.

3.1.10. If the owner or operator, or program administrator of a licensed syringe services program or of any other unlicensed practice, office, or facility which the Director has reasonable belief that it is being operated as a syringe services program refuses entry pursuant to this rule, the Inspector General shall petition the Circuit Court of Kanawha County for an inspection warrant.

3.1.11. If the Director finds on the basis of an inspection that any person, partnership, association, or corporation is operating as a syringe services program without a license, the syringe services program shall apply for a license within 14 days of the date of notice from the Director.

3.1.12. A syringe services program that fails to apply for a license is subject to the penalties established by sections 13 and 14 of this rule.

3.1.13. A syringe services program shall surrender an expired, revoked, or otherwise invalid license to the Director upon written demand.

3.2. Initial License.

3.2.1. An applicant shall submit a completed application to the Director, on a form prescribed by the Director. A non-refundable fee required by section 3 of this rule shall be submitted with the application.

3.2.1.a. Any existing syringe services program, as of the effective date of W. Va. Code §§16-64-1, *et seq.*, which offers or refers for the full array of harm reduction services may continue operation and shall have until January 1, 2022, to come into compliance with the provisions of W. Va. Code §§16-64-1, *et seq.*, and this rule and apply for licensure.

3.2.1.b. Any existing syringe services program, as of July 9, 2021, which does not offer or refer for the full array of harm reduction services must cease and desist from offering all syringe services and operating as a syringe services program. These syringe service programs may continue in operation for the sole purpose of referring current participants to other syringe services programs.

3.2.1.c. Any new syringe services program shall apply for an initial license not less than 30 days and not more than 60 days before the syringe services program begins operation as part of a harm reduction program.

3.2.2. The initial application shall include:

3.2.2.a. The name of the program;

3.2.2.b. A description of the harm reduction program the syringe services program is associated with and the full array of harm reduction services being provided in accordance with W. Va. Code §16-64-3(a);

3.2.2.c. Contact information for the program administrator of the harm reduction program, including an email address;

3.2.2.d. Description of the hours of operation, including the specific days the syringe services program is open, opening and closing times, and the frequency of syringe exchange services;

3.2.2.e. Description of staffing, including the number of staff, titles of positions, and basic description of each position's functions;

3.2.2.f. Location of the syringe services program;

3.2.2.g. Specific description of the applicant's ability to refer to or facilitate entry into substance use disorder treatment;

3.2.2.h. Specific description of the applicant's ability to encourage usage of medical care and mental health services as well as social welfare and health promotion; and

3.2.2.i. Written statement of support from a majority of the members of the county commission and a majority of the members of a governing body of a municipality in which it is located or is proposing to locate.

3.2.3. The syringe services program shall update program administrator contact information if any changes occur by contacting the Office of Health Facility Licensure and Certification.

3.2.4. The Director shall issue an initial license only after a review of the application and required policies and procedures is completed which finds the syringe services program complies with those requirements.

3.2.5. If the application is incomplete in required information or documentation, the application shall be denied and returned to the applicant.

3.2.6. If the applicant fails to comply with the program requirements specified in W. Va. Code §16-64-3, the application shall be denied and returned to the applicant.

3.2.7. If an application is denied, the syringe services program may reapply for an initial license by submitting a new application together with the applicable fee.

3.2.8. An initial license for a syringe services program is valid for one year.

3.3. Renewal License.

3.3.1. An applicant shall submit a completed application to the Director, on a form prescribed by the Director, 60 days prior to the expiration date of the current license. The renewal application shall contain updated information and attachments as were required in the initial application. A non-refundable fee required by section 3 of this rule shall be submitted with the application.

3.3.2. The Director shall issue a renewal license when it is found after a review of the application and required policies and procedures is completed which finds the syringe services program complies with those requirements.

3.3.3. A renewal license for a syringe services program is valid for one year.

3.4. License Fees and Inspection Costs.

3.4.1. All applications for an initial or renewal syringe services program license shall be accompanied by a non-refundable license fee. The amounts for the initial and renewal fees are as follows:

3.4.1.a. Initial license fee - $250; and

3.4.1.b. Renewal license fee - $50.

3.5. Denial of License.

3.5.1. The Director may deny an application for an initial or renewal license if:

3.5.1.a. The applicant does not submit all information and documentation required in W. Va. Code §16-64-2;

3.5.1.b. The applicant does not comply with the syringe services program requirements;

3.5.1.c. The syringe services program will not permit an inspection or survey to proceed or will not permit in a timely manner access to records or information deemed relevant by the Director; or

3.5.1.d. The syringe services program has made misrepresentations in obtaining a license.

3.5.2. If the Director determines not to issue a license, the Director shall notify the applicant in writing of the denial and the basis for the decision. Following the denial, the syringe services program must follow closure procedures in section 13 of this rule.

§71-24-4. Inspections and Plans of Correction.

4.1. The Director or his or her designee shall conduct unannounced inspections of a syringe services program for cause if the Director has received a complaint about the program or has reason to believe that the program may be operating in violation of federal or state statutes, rules, or regulations.

4.2. Inspections may include interviews with owners and staff; interviews of participants with participant's consent; review of program records; observation of service delivery; review of program documents and policies; and review of any other documents necessary for the determination of compliance with this rule and W. Va. Code §§16-64-1, *et seq.*

4.3. The syringe services program shall ensure immediate access to all participant and program records upon request of the Director or his or her designee. If access is denied, a judge of any court of record in this state having criminal jurisdiction, and upon proper oath or affirmation showing probable cause, may issue administrative or inspection warrants for the purpose of conducting inspections and seizures of property appropriate to the inspections.

4.4. At the time of any onsite investigation activities, the investigator shall notify the syringe services program administrator at the syringe services program of the general reason for the investigation.

4.5. The Director, in consultation with the Inspector General, has the power to subpoena documents, when the Director has any cause to believe that any provision of this rule or West Virginia Code §§16-64-1, *et seq*., has been violated, and

4.5.1. That such violation may have resulted in harm to a known person; or

4.5.2. That such violation or pattern of violations may endanger the health, safety, or welfare or any person.

4.5.3. Upon a finding of the requisite cause, the subpoena may be issued against any licensee or permittee under the jurisdiction of the Director, even if said licensee or permittee is not suspected of the violation being investigated.

4.5.4. Upon failure of a person without lawful excuse to obey a subpoena to provide documents, and upon reasonable notice to all persons affected thereby, the Director, in consultation with the Inspector General, may apply to Circuit Court of Kanawha County or the county where the documents are located for an order compelling compliance.

4.6. Within 15 working days of the investigation, the Director shall provide to the program administrator at a syringe services program a written report of the results of the investigation. The report shall specify any deficiency found and the statute or rule that forms the basis for each deficiency.

4.7. Within 10 working days after receipt of the inspection report, the program administrator of a syringe services program shall submit to the Director for approval a written plan to correct all deficiencies that are in violation of this rule or statute. The plan of correction shall specify:

4.7.1. Any action taken or procedures proposed to correct the deficiencies, and prevent their reoccurrence;

4.7.2. The date of completion of each action taken or to be taken; and

4.7.3. The signature of the program administrator, or his or her designee, or other executive officer of the syringe services program.

4.8. The proposed plan of correction shall be approved, modified, or rejected by the Director in writing.

4.9. The Director shall state the reasons for modification or rejection of any plan of correction.

4.10. The program administrator shall submit a revised plan of correction to the Director within 10 working days of receipt of a rejection by the Director.

4.11. The syringe services program shall immediately correct a violation that severely risks the health or safety of a participant, program staff member, contracted individual, or volunteer.

4.12. The Director shall determine if satisfactory corrections have been made and advise the program administrator of any compliance or continued deficiencies in writing.

4.13. The Director, in consultation with the Inspector General, may impose a civil money penalty, suspend, limit, or revoke a license or take such other action as deemed appropriate to address any violations or deficiencies. In the event the Director determines that the continued operation of the syringe services program is a threat to the health, welfare, and safety of its participants, the Director, in consultation with the Inspector General, may issue an order immediately closing a syringe services program pursuant to applicable administrative procedures.

4.14. Any person may file a complaint with the Director alleging violation of applicable laws, rules, or policies by a syringe services program. A complaint shall identify the syringe services program by name and state in detail the nature of the complaint.

4.15. If and upon completion of the investigation and approved plan of correction, the Director shall notify the complainant whether the allegations have been substantiated and how to obtain a copy of the report.

4.16. Nothing contained in this section or rule shall be construed to require or permit the public disclosure of confidential medical, social, personal, or financial records of any participant or program, nor any information required to be kept confidential by state or federal law.

§71-24-5. Organization and Management.

5.1. Each syringe services program shall identify a program administrator and disclose other employees and their duties.

5.2. Program Administrator.

5.2.1. The administrator of a syringe services program shall have at a minimum one of the following:

5.2.1.a. Any degree in an appropriate area of study and a minimum of one year of experience in the fields of public health, substance use disorders, behavioral health, health care administration, peer recovery programs, nursing, or harm reduction; or

5.2.1.b. Four years of experience in the fields of public health, substance use disorders, behavioral health, health care administration, peer recovery programs, nursing, or harm reduction.

5.2.2. The administrator is responsible for the day-to-day operation of the syringe services program in a manner consistent with the laws and regulations of the United States Department of Health and Human Services and the laws and rules of the state of West Virginia.

5.2.3. Duties of the administrator include:

5.2.3.a. Contribution to the development of policies and procedures for operation of the program;

5.2.3.b. Maintenance and security of the facility;

5.2.3.c. Employment, credentialing, evaluation, scheduling, training, and management of staff;

5.2.3.d. Protection of participant rights;

5.2.3.e. Responsible for compliance with all requirements related to the licensing and operation of the syringe services program;

5.2.3.f. Security and safe handling of sterile and non-sterile syringes and injection equipment;

5.2.3.g. Contribution to the management of the program budget; and

5.2.3.h. Implementation of program policies and procedures.

5.2.4. Within 90 days after the withdrawal or termination of the program administrator, the owner or owners of the syringe services program shall notify the Director of the identity of another program administrator for the syringe services program. An interim program administrator shall assume the duties of the program administrator on a temporary basis, not to exceed 120 days, until a new program administrator is identified and begins work at the syringe services program.

5.3. Emergency Planning and Response.

5.3.1. The syringe services program shall have procedures in place for responding to accidents, serious illness, fire, medical emergencies, floods, natural disasters, and other life-threatening situations that:

5.3.1.a. Address the needs of any special population served by the syringe services program;

5.3.1.b. Specify evacuation procedures including an evacuation site, parties to notify, and emergency items to take when evacuating;

5.3.1.c. Describe relocation plans for the syringe services program if it becomes necessary; and

5.3.1.d. Specify appropriate responses to medical emergencies.

§71-24-6. Service Environment and Operation.

6.1. Each syringe services program shall have:

6.1.1. Programmatic guidelines including a sharps disposal plan, a staff training plan, data collection and program evaluation plan, and a community relations plan;

6.1.2. Sufficient space and adequate equipment for the provision of or referral for all services specified in the syringe services program's description of harm reduction services offered pursuant to W. Va. Code §16-64-3;

6.1.3. Clean and safe participant treatment areas;

6.1.4. A secure room and lockable equipment for physical participant records or appropriate security mechanisms for electronic records, or both;

6.1.5. Policies and procedures regarding the confidentiality of all information in participant records which specify the requirements for access to the secure room and to electronic records, including levels of access; and

6.1.6. Sanitary and secure disposal areas.

6.2. Participant records may be stored offsite. However, participant records must be readily available upon request from the Director, or his or her designee.

6.3. Service Delivery Plan. Each syringe services program shall have a service delivery plan that shall include:

6.3.1. Sterile syringes and harm reduction services for participants;

6.3.2. HIV and viral hepatitis prevention education services for participants;

6.3.3. Safe recovery and disposal of non-sterile syringes and sharps waste from participants;

6.3.4. HIV and hepatitis screening;

6.3.5. Participant confidentiality protocol;

6.3.6. Screening for sexually transmitted infections; and

6.3.7. Education and supplies for safer sex practices.

6.4. All syringe services programs must meet all requirements of applicable federal, state, and local regulatory or oversight agencies. All syringe services programs must comply with its own policies and procedures.

6.5. Participants Accompanied by Minor Children.

6.5.1. Minor children should not be present during the syringe exchange and shall be left in the care of another responsible adult during the syringe exchange portion of the participant's visit.

6.5.2. Program staff members or contracted individuals shall at no time be responsible for a participant's minor child.

6.6. Data Collection and Program Evaluation Plan. Each syringe services program shall develop and implement a data collection program evaluation plan that:

6.6.1. Incorporates evaluation data into program design;

6.6.2. Specifically outlines the method and process for collecting and documenting data elements;

6.6.3. Uses the Bureau for Public Health's designated data reporting tool to provide required data elements;

6.6.4. Outlines the method and process for quantitative assessment of participants; and

6.6.5. Outlines the method and process for quality improvement.

6.7. Community Relations Plan. Each syringe services program shall have a community relations plan that:

6.7.1. Records adverse incidents and positive interactions between local law enforcement or first responders and program staff members, contracted individuals, volunteers, and participants in their role as program participants;

6.7.2. Documents concerns and positive feedback expressed by participants, community members, neighborhood associations, or local law enforcement officials; and

6.7.3. Documents steps the syringe services program and harm reduction program have taken to address any reasonable concerns.

§71-24-7. Staff; Training and Credentialing of Staff.

7.1. All employees, volunteers, contracted individuals, and associates of a syringe services program are subject to the restrictions, prohibitions, and requirements established in this rule.

7.2. Professional Medical Staff.

7.2.1. The syringe services program may employ, contract with, and use physicians and other licensed health care professionals working within their scope of practice who have received sufficient training and experience in accordance with program policies and procedures developed by the syringe services program.

7.2.2. All physicians and licensed health care professionals employed or contracted by the syringe services program shall be actively licensed in West Virginia.

7.2.3. The syringe services program must ensure that there is trained staff on duty at all times who are proficient in cardiopulmonary resuscitation and administration of opioid antagonist.

7.3. Unlicensed Program Staff, Contracted Individuals, and Volunteers.

7.3.1. A syringe services program may employ or utilize unlicensed staff members, contracted individuals, and volunteers to assist in the operation of the program.

7.3.2. The syringe services program policies and procedures shall specify the job descriptions and responsibilities of unlicensed staff members, contracted individuals, and volunteers. Documentation of the responsibilities, training, and other obligations of unlicensed staff members, contracted individuals, or volunteers shall be included in the personnel file of the staff members or volunteers.

7.3.3. All unlicensed staff members, contracted individuals, and volunteers shall receive appropriate supervision and shall be provided assistance and directions as to their responsibilities and duties.

7.4. Staff Training and Credentialing.

7.4.1. The syringe services program shall ensure that all physician assistants, advanced practice registered nurses, contracted individuals, and all other licensed or certified professional care providers comply with the credentialing requirements of their respective professions, obtain and maintain current licenses, and complete all continuing education requirements of their respective licensing boards and this rule.

7.4.2. All program staff members, contracted individuals, and volunteers shall complete initial and continuing education and training that is specific to their job function and is consistent with the requirements of applicable federal and state laws, rules, regulations, and guidelines. Documentation of all completed education and training courses or programs shall be maintained in the personnel file of each staff member or volunteer. Training of volunteers shall be specific to their job function. Training of program staff members and contracted individuals shall include, at a minimum:

7.4.2.a. The services and eligibility requirements of the syringe services program and the harm reduction program;

7.4.2.b. Overview of harm reduction philosophy and harm reduction model used the by the harm reduction program and syringe services program;

7.4.2.c. The services provided by the syringe services program and the harm reduction program;

7.4.2.d. The syringe services program's policies and procedures concerning syringe exchange transactions and other operating policies and procedures;

7.4.2.e. Disposal of infectious waste and syringe safety;

7.4.2.f. Sharps waste disposal education that ensures familiarity with state law regulating proper disposal of home-generated sharps waste;

7.4.2.g. Procedures for obtaining or making referrals for participants;

7.4.2.h. Hierarchy of risks associated with sexual and drug-using behaviors and risk reduction practices for those behaviors;

7.4.2.i. Education and demonstration of safer injection practices;

7.4.2.j. Opioid antagonist administration;

7.4.2.k. Overdose prevention and recognition and response for all program staff members, contracted individuals, and volunteers;

7.4.2.l. Overview of community concerns and outreach strategies;

7.4.2.m. Cultural diversity and sensitivity to protected classes under state and federal law; and

7.4.2.n. Completion of attendance logs for participation in mandatory trainings.

7.4.3. Program staff members, contracted individuals, and volunteers shall be trained annually on infection control procedures and the importance of reporting occupational exposure.

7.4.4. The syringe services program shall develop detailed job descriptions for each program staff member, including contracted individuals, that clearly define the education, training, qualifications, and competencies needed to provide specific service.

7.4.5. Upon hire of any new clinical staff member or contracted individual, the syringe services program shall provide orientation as to the person's primary job responsibilities, including, but not limited to, confidentiality requirements, on the first day of employment. Documentation of the completed orientation shall be included in the personnel file of each staff member.

7.4.6. The syringe services program shall maintain confidential individual personnel files for every staff member, including contracted individuals. Personnel files shall contain, at a minimum:

7.4.6.a. The application for employment, contract, or request to work as a volunteer;

7.4.6.b. Documentation of the date of employment;

7.4.6.c. Identifying information and emergency contacts;

7.4.6.d. Documentation of completion of orientation, trainings, and continuing education;

7.4.6.e. Documentation of all licenses, certifications, or other credentials;

7.4.6.f. Documentation relating to performance, supervision, disciplinary actions, and termination summaries; and

7.4.6.g. Detailed job descriptions.

§71-24-8. Participant Rights.

8.1. Each syringe services program shall have policies and procedures that guarantee the following rights to participants:

8.1.1. To be informed, both verbally and in writing, of program rules and regulations and participant's rights and responsibilities;

8.1.2. To receive services provided in a fair and impartial manner free from unlawful discriminatory practices pursuant to W. Va. Code §16B-17-9;

8.1.3. To be informed about the financial aspects of any services provided by the harm reduction program and the syringe services program;

8.1.4. To ensure confidentiality in accordance with federal regulations, 42 C.F.R. Part 2, and the Health Insurance Portability and Accountability Act of 1996, as amended;

8.1.5. To be informed of the extent of confidentiality, including the conditions under which information can be released without consent, the use of identifying information for the purpose of program evaluation and statutory requirements for reporting abuse;

8.1.6. To give informed consent prior to being involved in research projects and the right to retain a copy of the informed consent form; and

8.1.7. To inform each participant about all service procedures, services, and other policies and procedures throughout the course of treatment.

8.2. The syringe services program shall notify participants at least 30 days in advance of its intent to permanently change service hours.

8.3. The syringe services program shall provide notice of how to file a complaint with the Office of Health Facility Licensure and Certification, which shall be displayed in the participant service area in a conspicuous place and easily available to participants. The notice shall include the Office of Health Facility Licensure and Certification's telephone number and website.

8.4. The syringe services program shall have policies and procedures that address safety and security issues for participants and staff, including training staff to handle physical or verbal threats, acts of violence, and inappropriate behavior or other escalating and potentially dangerous situations, with emphasis on when assistance needs to be summoned.

§71-24-9. Provision of Services.

9.1. Participant Requirements.

9.1.1. Participants in the syringe services program must be at least 18 years old. Other harm reduction services may be offered to individuals under 18 years old where permitted and appropriate.

9.1.2. Participants in the syringe services program must present proof of West Virginia identification upon dispensing syringes and injection equipment.

9.1.3. Proof of West Virginia identification accepted by the syringe services program at each visit shall include one of the following forms of identification:

9.1.3.a. West Virginia Division of Motor Vehicles-issued driver's license;

9.1.3.b. West Virginia Division of Motor Vehicles-issued learner's/instruction permit;

9.1.3.c. West Virginia Division of Motor Vehicles-issued photo identification card;

9.1.3.d. Photo identification card from a West Virginia school or employer;

9.1.3.e. United States Military identification card of an active duty or retired member;

9.1.3.f. United States passport; or

9.1.3.g. West Virginia Division of Corrections and Rehabilitation identification card.

9.1.3.h. If a participant does not have a West Virginia identification listed in subdivision 9.1.3.a. to 9.1.3.g. of this rule, a participant shall provide two of the following forms of identification:

9.1.3.h.1. United States social security card;

9.1.3.h.2. A utility bill, which include phone, cell phone, electric, gas, or water, with the participants name and current address;

9.1.3.h.3. Automobile registration with the participant's name and current address;

9.1.3.h.4. Automobile insurance card with the participant's name and current address;

9.1.3.h.5. West Virginia voter's registration card with the participant's name and current address;

9.1.3.h.6. Checking account deposit slip or bank statement with the participant's name and current address;

9.1.3.h.7. Paycheck stub or W-2 form with the participant's and current address;

9.1.3.h.8. Health care insurance card with the participant's name;

9.1.3.h.9. Social services benefits identification card with photo issued by a West Virginia governmental agency;

9.1.3.h.10. Weapons or gun permit issued by a federal or state governmental agency; or

9.1.3.h.11. Veterans' Universal Access Identification Card.

9.1.4. A syringe services program may create a program specific identification card which shall include a photograph of the participant to be used for proof of West Virginia identification after the initial enrollment with the program. Initial enrollment with the program shall include verification of West Virginia identification as specified in subsection 9.1.3. of this rule.

9.2. Program Enrollment.

9.2.1. A syringe services program shall develop and implement an enrollment procedure for participants.

9.2.2. Initial enrollment in a syringe services program may occur by an individual participant one time in a 12 month consecutive period. During the initial enrollment, a syringe services program may provide up to 10 syringes if the participant has none. This shall be tracked and reported separately on the program's annual report. This number will not count towards the program's goal of a 1:1 exchange model. If the participant has syringes to exchange at the initial enrollment, the program shall follow the 1:1 exchange model.

9.2.3. Each participant shall be assigned a unique participant code that cannot be duplicated.

9.2.4. Information to be requested during enrollment into the syringe services program includes, at a minimum:

9.2.4.a. Participant initials;

9.2.4.b. Birth year;

9.2.4.c. Zip code or area of current residence

9.2.4.d. Sex or gender;

9.2.4.e. Race or ethnicity;

9.2.4.f. Preferred language;

9.2.4.g. Pregnancy status;

9.2.4.h. Information related to access to other services; and

9.2.4.i. Information related to social determinants of health.

9.2.5. During enrollment, syringe services policies and procedures should be reviewed with the participant.

9.3. Harm Reduction Services.

9.3.1. A syringe services program shall be part of a harm reduction program and offer or refer for the harm reduction services described herein. A syringe services program shall not offer syringe services only.

9.3.2. Harm reductions services that must be offered, at a minimum, include:

9.3.2.a. HIV, hepatitis, and sexually transmitted diseases screening;

9.3.2.b. Vaccinations;

9.3.2.c. Birth control and long-term birth control;

9.3.2.d. Behavioral health services;

9.3.2.e. Overdose prevention supplies and education;

9.3.2.f. Syringe collection and sharps disposal;

9.3.2.g. Educational services related to disease transmission;

9.3.2.h. Assistance or referral of a participant to a substance use disorder treatment program;

9.3.2.i. Referral to a health care practitioner for treatment of medical conditions; and

9.3.2.j. Programmatic guidelines including a sharps disposal plan, staff training plan, data collection and program evaluation plans, and community relations plan.

9.4. Syringes Services.

9.4.1. Each visit at the syringe services program shall include an offer for the provision of or referral for harm reduction services from a qualified, licensed health care provider.

9.4.2. A syringe services program shall ensure that a syringe is unique to the syringe services program. Acceptable means for uniquely identifying the syringe to the syringe services program may include, but is not limited to, color codes, labels, or serial numbers or codes. Each program must have a policy identifying what measures are used to uniquely distinguish that program's syringes.

9.4.3. A syringe services program shall dispense syringes with a goal of a 1:1 exchange model. A syringe services program does not meet the goal of a 1:1 exchange model if their annual report reflects a ratio of 2:1 or higher. Initial enrollment, as described in subsection 9.2.2. of this rule, or community cleanup activity do not count towards this ratio. A syringe services program may substitute weighing the volume of returned syringes rather than a 1:1 exchange model. Weighing returned needles is only permissible if it can be done accurately and in the following manner:

9.4.3.a. Returned syringes shall be contained in a see-through container; and

9.4.3.b. A visual inspection of the see-through container shall take place prior to the returned syringes being weighed.

9.4.4. Syringe Dispensing Plan. A syringe services program shall have a syringe dispensing plan which includes, but is not limited to, the following:

9.4.4.a. Maintaining records of returned syringes by participants for two years;

9.4.4.b. Preventing syringe stick injuries;

9.4.4.c. Tracking the number of syringes dispensed and collected at the syringe services program;

9.4.4.d. Tracking the number of syringes collected as a result of community reports of syringe litter;

9.4.4.e. Eliminating direct handling of sharps waste;

9.4.4.f. Following a syringe stick injury protocol and plan;

9.4.4.g. Dispensing syringes in person to a participant and not via proxy;

9.4.4.h. Maintaining a budget for sharps waste disposal or an explanation if no cost is associated with sharps waste disposal; and

9.4.4.i. Implementing a plan to coordinate with the continuum of care, including requirements set forth in W. Va. Code §16-64-3.

9.5. Syringe Disposal Plan.

9.5.1. The syringe services program shall have policies and procedures governing the disposal of syringes and other medical waste which are designed to maximize the return of non-sterile syringes without increasing the risk of syringe stick injury to program staff members, contracted individuals, volunteers, and participants.

9.5.2. The syringe disposal plan shall include a method to track the number of syringes returned in a manner that eliminates the direct handling of sharps waste and does not interfere with service provision.

9.5.3. The syringe disposal plan shall include a syringe stick injury protocol and plan to ensure that program staff members, contracted individuals, and volunteers are familiar with the protocol.

9.5.4. The syringe disposal plan shall include sharps waste disposal education that ensures program staff members, contracted individuals, volunteers, and participants are familiar with state law regulating the proper disposal of home-generated sharps waste.

9.5.5. The syringe disposal plan shall also include and address a plan for retrieving and the safe disposal of syringe litter found in the community.

9.6. Syringe Litter. A syringe services program shall maintain a program for the public to report syringe litter and shall endeavor to collect all syringe litter in the community.

§71-24-10. Reports and Records.

10.1. Inspection Reports and Records.

10.1.1. The Director shall keep on file a report of any inspection, survey, or investigation of a syringe services program.

10.1.2. Information in reports or records shall be available to the public except for the following:

10.1.2.a. Information regarding complaints and subsequent investigations that is deemed confidential by any provision of this rule or applicable state or federal law;

10.1.2.b. Information of a personal nature from a participant or personnel file; or

10.1.2.c. Information required to be kept confidential by state or federal law.

10.1.3. The Director will not make a report of any investigation public until the syringe services program has the opportunity to review the report, submit a plan of correction, and obtain an approved plan of correction.

10.2. Statistical Reports and Records.

10.2.1. The syringe services program shall file an annual report with the Director on a form prescribed by the Director, which includes, but is not limited to, the following information:

10.2.1.a. The total number of participants served by the syringe services program and the total number of visits;

10.2.1.b. The total number of syringes that were dispensed, collected, and disposed of by the syringe services program and the type of syringes that were dispensed;

10.2.1.c. The total number of syringe stick injuries to non-participants;

10.2.1.d. Statistics regarding the number of individuals entering substance use disorder treatment; and

10.2.1.e. The total number and types of referrals made to substance use disorder treatment and other harm reduction services.

10.3. Incident Reporting and Adverse Events.

10.3.1. Each syringe services program shall develop and implement policies and procedures for documenting, investigating, taking corrective action, and tracking instances of known adverse events or incidents.

10.3.2. If a syringe services program employee, contracted individual, or volunteer has a concern about a participant's or accompanying minor child's safety, the syringe services program employee, contracted individual, or volunteer shall follow the policy and procedure of the syringe services program regarding safety concerns and take appropriate action, including, but not limited to, reporting to the appropriate protective services agency.

10.3.3. Incidents or adverse events may include:

10.3.3.a. Known completed participant suicide and suicide attempts;

10.3.3.b. Known participant death or serious injury due to trauma, suicide, or unusual circumstances;

10.3.3.c. Selling drugs or substances on the premises;

10.3.3.d. Harassment or abuse, including physical, verbal, sexual, and emotional, of participants by staff;

10.3.3.e. Theft, burglary, break-in, or similar incident at the syringe services program;

10.3.3.f. Physical violence leading to injury; and

10.3.3.g. Significant disruption of services due to disaster such as fire, storm, flood, or another occurrence.

10.3.4. Incidents or adverse events shall be reviewed on a quarterly basis by the program administrator who may choose to make recommendations and implement changes regarding improvements in the process to prevent further incidents.

10.3.5. The syringe services program shall ensure in the event of an incident or adverse event that:

10.3.5.a. The incident or adverse event is fully documented and appropriately reported to the correct state agencies as necessary;

10.3.5.b. There is prompt investigation and review of the situation surrounding the incident or adverse event;

10.3.5.c. Timely and appropriate corrective action is taken; and

10.3.5.d. Ongoing monitoring of any corrective action takes place until effectiveness of the action is established.

10.3.6. Within seven days of an incident or adverse event, the program shall file a report with the Director consisting of the following:

10.3.6.a. The action or actions implemented to prevent the reoccurrence of the incident or adverse event;

10.3.6.b. The time frames for the action or actions to be implemented;

10.3.6.c. The person or persons designated to implement and monitor the action or actions; and

10.3.6.d. The strategies for the measurements of effectiveness to be established.

§71-24-11. Quality Assurance and Performance Improvement.

11.1. The program administrator is responsible for and shall review at least annually the development, implementation, maintenance, and effective evaluation of quality assessments for performance improvement and effectiveness. This process systematically collects, measures, analyzes, and tracks objective indicators of participant care and services and program operations. This evaluation plan should review whether the syringe services goals are being met and, if goals are not being met, decide if and how to change services to better meet the syringe services program's goals.

11.2. The syringe services program shall maintain current quality assessment and performance improvement policies that objectively and systematically monitor and evaluate the quality and appropriateness of participant service, evaluate the methods to improve participant service, identify and correct deficiencies within the program, and provide for opportunities to improve the program's performance and quality of service.

11.3. The syringe services program shall make available to the Director the results of quality assessment and performance improvement information upon request.

11.4. Quality assessment and performance improvement policies and areas of measurement shall include, but not be limited to:

11.4.1. Staff, administrative, and practitioner performance;

11.4.2. Evaluation of services provided;

11.4.3. Incidents and adverse events;

11.4.4. Evaluation of all services provided to participants by the syringe services program and harm reduction program;

11.4.5. Review and verification of staff credentials, training, periodic evaluations, and licensure;

11.4.6. Review of syringe services program policies and procedures;

11.4.7. Infection control issues in regard to universal infection control guidelines set forth by the Centers for Disease Control and Prevention; and

11.4.8. Review of participant outcomes and service outcomes.

§71-24-12. Infection Control.

12.1. The syringe services program shall maintain an effective infection control program that protects the participants and program personnel and volunteers by preventing and controlling infections and communicable diseases.

12.2. The syringe services program shall include the implementation of a nationally recognized system of infection control guidelines.

12.3. The syringe services program shall have an active surveillance and education program for the prevention, early detection, control, and investigation of infections and communicable diseases.

12.4. The syringe services program shall designate a person or persons, with appropriate education and training, as infection control officers to develop and implement policies and governing control of infections and communicable diseases for participants and personnel.

12.5. Employees, contracted individuals, and volunteers should assume that blood and other bodily fluids from participants are potentially infectious and require infection control precautions at all times, including, but not limited to:

12.5.1. Routine use of barriers such as gloves, goggles, closed-toe and closed-heel shoes;

12.5.2. Immediate washing of hands and other skin surfaces after contact with blood or bodily fluids; and

12.5.3. Careful handling and disposal of sharp instruments during and after use.

12.6. Each syringe services program shall have a plan and policies for post-exposure management of employees, contracted individuals, and volunteers.

§71-24-13. License Denial, Suspension, or Revocation; Closure.

13.1. Grounds for Suspension or Revocation.

13.1.1. The Director, in consultation with the Inspector General, may suspend or revoke a syringe services program license issue pursuant to this rule if any provisions of federal or state law or this rule are violated based upon the findings and results of any periodic, complaint, or other inspection and evaluation. Any period of suspension for the license of a syringe services program shall be prescribed by the Director but may not exceed one year.

13.1.2. The Director, in consultation with the Inspector General, may suspend or revoke a syringe services program license for one or more of the following reasons:

13.1.2.a. The Director makes a determination that fraud or other illegal action has been committed by any owner or administrator of the syringe services program;

13.1.2.b. The syringe services program has violated federal, state, or local law relating to licensure, building, health, fire protection, safety, sanitation, or zoning;

13.1.2.c. The written statement of support from a majority of the members of the county commission or a majority of the members of a governing body of a municipality in which a syringe services program is located has been rescinded;

13.1.2.d. The syringe services program has failed or refused to submit reports or make records available as requested by the Director;

13.1.2.e. A syringe services program has refused to provide access to its location or records as requested by the Director;

13.1.2.f. A syringe services program's administrator has knowingly and intentionally misrepresented actions taken to correct a violation;

13.1.2.g. An owner or program administrator of a syringe services program concurrently operates an unlicensed syringe services program;

13.1.2.h. An owner of a syringe services program knowingly operates, owns, or manages an unlicensed syringe services program that is required to be licensed;

13.1.2.i. The owners of a syringe services program fail to apply for a new license for the program upon a change of ownership and operate the program under the new ownership; or

13.1.2.j. An owner or administrator acquires or attempts to acquire a license for a syringe services program through misrepresentation or fraud or procures or attempts to procure a license for a syringe services program for any other person by making or causing to be made any false representation.

13.2. Effect of Denial, Suspension, or Revocation.

13.2.1. If a license for a syringe services program has been denied, suspended, or revoked, the Director, in consultation with the Inspector General, may stay the effective date of the denial, revocation, or suspension if the program administrator or owner of the syringe services program can show that the stay is necessary to ensure appropriate referral of participants.

13.2.2. If the license of a syringe services program is denied, suspended, or revoked, no person, firm, association, or corporation may operate the program as a syringe services program as of the effective date of the denial, suspension, or revocation. The owner of the syringe services program is responsible for removing all signs and symbols identifying the premises as a syringe services program within 30 days of the date of the denial, suspension, or revocation.

13.2.3. If a license for a syringe services program has been denied, suspended, or revoked the syringe services program must supply, at a minimum, a copy of the following information to the Director;

13.2.3.a. A closure notice to be posted and given to all participants prior to closure;

13.2.3.b. The date the closure notice will be posted;

13.2.3.c. The number of active participants; and

13.2.3.d. Contact information the syringe services program has supplied to participants who may need help locating new services.

13.2.4. Upon the effective date of the denial, suspension, or revocation, the program administrator of the syringe services program shall advise the Director of the disposition of any sterile and non-sterile syringes and injection equipment located on the premises.

13.2.5. If a syringe services program license is denied or revoked, a new application for licensure shall be considered by the Director, if, when, and after the conditions upon which denial or revocation was based have been corrected and evidence of this fact has been furnished. A new license may then be granted after proper inspection has been made and the Director makes a written finding that all provisions of W. Va. Code §§16-64-1, *et seq.*, and this rule have been satisfied.

13.3. Voluntary and Involuntary Closure.

13.3.1. If a syringe services program chooses to voluntarily close, the syringe services program shall provide written notice to the Director no less than 60 days before the anticipated closure date and end of operations. This notice shall include the information required in subsection 13.3.2. of this rule.

13.3.2. In the event of a voluntary or involuntary closure, the syringe services program shall provide to the Director written notice to include the following:

13.3.2.a. A closure notice to be posted and given to all participants prior to closure;

13.3.2.b. The date the closure notice will be posted;

13.3.2.c. The number of active participants; and

13.3.2.d. Contact information the syringe services program has supplied to participants who may need help locating new services.

13.3.3. Upon the closure and end of operations of the syringe services program, the program administrator of the syringe services program shall advise the Director of the disposition of any sterile and non-sterile syringes and injection equipment located on the premises.

13.3.4. The syringe services program shall surrender the physical registration for the syringe services program to the Director within seven days of the last day of operations.

13.3.5. The syringe services program shall provide other information as required by the Director during the closing and ending of operations by the syringe services program. Additional information required by the Director shall be provided to the syringe services program in writing.

13.3.6. The owner of the syringe services program is responsible for removing all signs and symbols identifying the premises as a syringe services program within 30 days of the closure date and end of operations as a syringe services program.

§71-24-14. Penalties and Equitable Relief.

14.1. Grounds for Penalties and Injunctions.

14.1.1. Any person, partnership, association, or corporation that establishes, conducts, manages, or operates a syringe services program without first obtaining a license therefore or which violates any provisions of W. Va. Code §§16-64-1, *et seq.*, or this rule shall be assessed a civil money penalty by the Director, in consultation with the Inspector General, in accordance with this rule.

14.1.2. Each day of continuing violation after notification of the infraction shall be considered a separate violation.

14.1.3. If the syringe services program fails to timely file reports required by section 10 of this rule and W. Va. Code §16-64-7, the Director, in consultation with the Inspector General, may impose a civil money penalty not to exceed $500 per day.

14.1.4. If the syringe services program's owner or program administrator, or both, knowingly and intentionally misrepresents actions taken to correct a violation, the Director, in consultation with the Inspector General, may impose a civil money penalty not to exceed $5,000, and deny or revoke the syringe services program's license.

14.1.5. If an owner of a syringe services program concurrently operates an unlicensed syringe services program, the Director, in consultation with the Inspector General, may impose a civil money penalty upon the owner or program administrator, or both, not to exceed $2,500 per day.

14.1.6. If the owner of a syringe services program that requires a license under W. Va. Code §§16-64-1, *et seq.*, fails to apply for a new license for the syringe services program upon a change of ownership and operates the syringe services program under the new ownership, the Director, in consultation with the Inspector General, may impose a civil money penalty not to exceed $2,500.

14.1.7. If a syringe services program knowingly operates, owns, or manages an unlicensed syringe services program that is required to be registered pursuant to W. Va. Code §§16-64-1, *et seq.*, obtains a license to operate a syringe services program through misrepresentation or fraud; procures or attempts to procure a license for a syringe services program for any other person by making or causing to be made any false representation, the Director, in consultation with the Inspector General, may assess a civil money penalty of not more than $10,000. The penalty may be in addition to or in lieu of any other action that may be taken by the Director, in consultation with the Inspector General, or any other board, court, or entity.

14.2. In determining whether a penalty is to be imposed and in fixing the amount of the penalty, the Director, in consultation with the Inspector General, shall consider the following factors:

14.2.1. The gravity of the violation, including the probability that death or serious physical or emotional harm to a participant has resulted, or could have resulted, from the syringe services program's actions or the actions of the program administrator or any employee, contracted individual, or volunteer associated with the syringe services program, the severity of the action or potential harm, and the extent to which the provisions of the applicable laws or rules were violated;

14.2.2. What actions, if any, the program administrator, took to correct the violations;

14.2.3. Whether there were any previous violations at the syringe services program; and

14.2.4. The financial benefits that the syringe services program derived from committing or continuing to commit the violation.

14.3. Notwithstanding the existence or pursuit of any other remedy, the Inspector General, or his or her designee, may, in the manner provided by law, maintain an action in the name of the State for an injunction against any person, partnership, association, or corporation to restrain or prevent the establishment, conduct, management, or operation of any syringe services program or violation of any provisions of this rule without first obtaining a license therefore in the manner hereinbefore provided.

14.3.1. The Inspector General, or his or her designee, may also seek injunctive relief if the establishment, conduct, management, or operation of any syringe services program, whether licensed or not, jeopardizes the health, safety, or welfare of any or all of its participants.

14.4. Upon finding that a licensed professional has violated the provisions of this rule, the Director shall provide notice of the violation to the applicable professional licensing board.

§71-24-15. Administrative Due Process.

15.1. Before any syringe services program license is denied, suspended, penalized, or revoked, written notice shall be given to the program administrator of the syringe services program, stating the grounds of the denial, suspension, penalty, or revocation and the date set for any enforcement action and the location to which it applies. The notice shall also include the remedial measures the syringe services program shall take, if any, to consider reinstatement or removal of suspension of the license and the due process rights of the syringe services program.

15.1.1. The notice shall be sent by electronic mail to the program administrator at the email address provided to the Office of Health Facility Licensure and Certification or as updated by the syringe services program with the Office of Health Facility Licensure and Certification.

15.1.2. Within 30 days of receipt of the notice, the owner or program administrator may submit a request for an administrative hearing to address and resolve the findings.

15.1.3. The syringe services program and its owner shall be entitled to be represented by legal counsel at the administrative hearing at their own expense.

15.1.4. All of the pertinent provisions of W. Va. Code §§29A-5-1, *et seq.*, and W. Va. Code R. §§69-1-1, *et seq*., shall apply to and govern any hearing authorized by this rule.

15.1.5. If an owner fails to request an administrative hearing within the time frame specified, he or she shall be subject to the full penalty imposed.

15.1.6. The filing of a request for an administrative hearing does not stay or supersede enforcement of the final decision or order of the Director. The Director, in consultation with the Inspector General, may, upon good cause shown, stay such enforcement.

§71-24-16. Administrative Appeals and Judicial Review.

16.1. Any owner of a syringe services program who disagrees with the final administrative decision as a result of the administrative hearing may, within 30 days after receiving notice of the decision, appeal the decision to the West Virginia Intermediate Court of Appeals.

16.2. The filing of a petition for appeal does not stay or supersede enforcement of the final decision or order of the Board of Review. An appellant may apply to the court for a stay of or to supersede the final decision or order.

16.3. West Virginia Intermediate Court of Appeals may affirm, modify, or reverse the final administrative decision. No court has jurisdiction to affirm, modify, or reverse a decision of the Board of Review if the syringe services program failed to request an administrative hearing with the Board of Review in the time frame allowed. The owner or owners, or the Inspector General, may appeal the court's decision to the West Virginia Supreme Court of Appeals.