

# **WEST VIRGINIA LEGISLATURE**

**2021 REGULAR SESSION**

**Engrossed**

**Committee Substitute**

**for**

**Senate Bill 334**

BY SENATORS TARR AND GRADY

[Originating in the Committee on Health and Human

Resources; reported on March 4, 2021]



1 A BILL to amend the Code of West Virginia, 1931, as amended, by adding thereto a new article,  
2 designated §16-63-1, §16-63-2, §16-63-3, §16-63-4, §16-63-5, §16-63-6, §16-63-7, §16-  
3 63-8, §16-63-9, §16-63-10, and §16-63-11, all relating to needle exchange programs;  
4 defining terms; establishing licensure application process for needle exchange programs;  
5 creating program requirements; establishing revocation process; setting forth the  
6 reconsideration process; setting forth the administrative due process provision; providing  
7 for administrative and judicial appeal; establishing reporting requirements and renewal  
8 provisions; providing for immunity; setting requirements for continuum of care; and  
9 establishing civil penalties and injunctive relief.

*Be it enacted by the Legislature of West Virginia:*

**ARTICLE 63. NEEDLE EXCHANGE PROGRAMS.**

**§16-63-1. Definitions.**

1 As used in this article, the term:

2 “Administrator” means a person having the authority and responsibility for operation of the  
3 needle exchange program and serves as the contact for communication with the Director of the  
4 Harm Reduction Program.

5 “Applicant” means the entity applying for a license under this section.

6 “Bloodborne pathogens” means pathogenic microorganisms that are present in human  
7 blood and can cause disease in humans. These pathogens include, but are not limited to, hepatitis  
8 B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus (HIV).

9 “Board of Review” means the board established in §9-2-6(13) of this code.

10 “Core services” means the primary services an entity undertakes in order to service its  
11 clients.

12 “Director” means the Director of the Office of Health Facility Licensure and Certification.

13 “Fixed site” means a building or single location where needle exchange services are  
14 provided.

15 “Harm reduction services” means services intended to lessen the adverse consequences  
16 of drug use and protect public health and safety, and includes, but is not limited to, a referral to  
17 substance disorder treatment programs, screening, care and treatment for hepatitis and HIV,  
18 education about overdose prevention, vaccinations, screening for sexually transmitted diseases,  
19 abscess wound care, Naloxone distribution and education, and referral to social, mental, and  
20 other medical services.

21 “HIV” means the etiologic virus of AIDS or Human Immunodeficiency Virus.

22 “Injection drug user” means a person who uses a syringe to self-administer drugs.

23 “License” means the document issued by the Bureau authorizing the Harm Reduction  
24 Program to operate.

25 “Local health department” means a health department operated by local boards of health,  
26 created, established, and maintained pursuant to §16-2-1 et seq. of this code.

27 “Location” means a site within the service area of a local health department. A location  
28 can be a fixed site or a mobile site.

29 “Mobile site” means a location accessible by foot or vehicle that is not at a fixed indoor  
30 setting. A provider shall have a fixed site located in West Virginia in order to operate a mobile site  
31 in the state or have received an independent license to operate the mobile location.

32 “Needle” means both the needle and syringe used to inject fluids into the body.

33 “Needle exchange program” means a community based program that provides access to  
34 sterile needles and syringes, facilitates safe disposal of used needles, and provides a link to other  
35 important services and programs including, but not limited to, a referral to substance use disorder  
36 treatment programs, screening, care and treatment for hepatitis and HIV, education about  
37 overdose prevention, vaccinations, screening for sexually transmitted diseases, abscess wound  
38 care, Naloxone distribution and education, and referral to social, mental, and other medical  
39 services.

40 “Needlestick injury” means a penetrating wound from a needle that may result in exposure  
41 to blood.

42 “Needlestick injury protocol” means policies and procedures to prevent needlestick injury  
43 to needle exchange staff, including volunteers, community members, and to needle exchange  
44 participants.

45 “Public comment period” means a 30-day public comment period commencing from the  
46 date the applicant posts information about an application in a newspaper of general circulation in  
47 the service area of the local health department.

48 “Service area” means the territorial jurisdiction of the local board of health.

49 “Sharps waste” means used needles, syringes, and lancets.

50 “Staff” means anyone who provides needle exchange services on behalf of a program.

51 “Syringe” means both the needle and syringe used to inject fluids into the body.

52 “Viral hepatitis” means any of the forms of hepatitis caused by the virus, including HBV  
53 HCV.

**§16-63-2. Application for license to offer needle exchange programs.**

1 (a) All new and existing needle exchange programs shall require a license.

2 (b) To be eligible for a license, a needle exchange program shall:

3 (1) Submit an application to the Office for Health Facility Licensure and Certification on a  
4 form approved by the director;

5 (2) Provide the name under which it will be operating;

6 (3) Provide a brief description of the services, including how each requirement for  
7 licensure will be met (i.e. behavioral health, birth control, etc.);

8 (4) Provide the full name, title, email address, and telephone number of the individual  
9 designated by the applicant as the administrator of the needle exchange program;

10 (5) Provide the hours of operation of the location, and staffing. The description of hours of  
11 operation must include the specific days the needle exchange program is open, opening and

12 closing times, and frequency of needle exchange services. The description of staffing must  
13 include number of staff, titles of positions, and descriptions of services;

14 (6) Provide a specific description of services related to the provision of education and  
15 materials for the reduction or absence of other needle exchange services in the proposed location;

16 (7) Provide a specific description of the proposed applicant's ability to provide referrals to  
17 facilitate entry into drug abuse treatment, including opioid substitution therapy;

18 (8) Provide a specific description of the proposed applicant's ability to encourage usage  
19 of medical care and mental health services as well as social welfare and health promotion;

20 (9) Pay an application fee to be determined by the director;

21 (10) Provide a written statement from a majority of the county commission for the county  
22 in which it is located or is proposing to locate, that the needle exchange program:

23 (A) Is not prohibited by local ordinance; and

24 (B) That a majority of the county commission supports the program;

25 (11) The sheriff from the county in which the applicant is located or proposing to locate  
26 the needle exchange program shall provide a letter of support; and

27 (12) Publish a notice beginning the 30-day public comment period, not to exceed 150  
28 words, in a newspaper of general circulation in the proposed service area and posted on the  
29 applicant's website that provides a summary of the proposed application and includes the name  
30 of the applicant's organization. The notice must state in all caps "PROPOSED NEEDLE  
31 EXCHANGE PROGRAM IN" the proposed county. The public may submit comments about an  
32 application during the 30-day public comment period.

**§16-63-3. Program requirements.**

1 (a) In order to be approved for a license, a needle exchange program shall offer the  
2 following, which shall be documented in the application:

3 (1) A full array of harm reduction services including, but not limited to, the following:

4 (A) Drug abuse treatment services;

- 5           (B) HIV and hepatitis screening and education;
- 6           (C) Hepatitis A, B, and C vaccination and testing;
- 7           (D) Screening for sexually transmitted diseases;
- 8           (E) The provision of long-term birth control;
- 9           (F) The provision of behavioral health services;
- 10          (G) Overdose prevention supplies and education;
- 11          (H) Syringe collection and sharps disposal;
- 12          (I) Educational services related to disease transmission;
- 13          (J) Treatment shall be offered at every visit by a qualified licensed health care provider;
- 14          (K) The applicant shall make services available for participants to facilitate the individual
- 15          entering rehabilitation or detoxification;
- 16          (L) The applicant shall make the appropriate referral to existing providers for treatment of
- 17          medical conditions; and
- 18          (M) Programmatic guidelines including a sharps disposal plan, a staff training plan, a data
- 19          collection and program evaluation plan, and a community relations plan; and
- 20          (2) A clean syringe exchange program, including, but not limited to, the following:
- 21           (A) A dedicated staff member assigned to recover discarded syringes from the program in
- 22          the service area, with the clear objective of reducing the transmission of blood-borne diseases
- 23          within a specific geographic area;
- 24           (B) Exclusion of minors from participation in the program;
- 25           (C) The ability to track each needle uniquely by the needle exchange program;
- 26           (D) Needles are to be distributed with a goal of a 1:1 model;
- 27           (E) A program or facility may substitute weighing the volume of needles returned versus
- 28          dispensed as specified;
- 29           (F) This substitution is only permissible if it can be done accurately and in the following
- 30          circumstances:

- 31 (i) The needles shall be contained in a clear container; and
- 32 (ii) A visual inspection of the container shall take place prior to the needles being weighed;
- 33 (G) Participants shall be advised of this requirement when enrolled in the program and  
34 they should sign a contract of understanding;
- 35 (H) The licensee, whether fixed or mobile, shall distribute the needle directly to the  
36 program recipient, and shall not distribute a needle to a program recipient for another person; and
- 37 (I) Proof of West Virginia identification upon dispensing of the needles:
- 38 (3) A staff training protocol including, but not limited to, the following:
- 39 (A) Orientation to the applicant's services and eligibility requirements of the program;
- 40 (B) Overview of the needle exchange philosophy and the harm reduction model used by  
41 the program;
- 42 (C) The applicant's policies and procedures that explain syringe exchange transactions;
- 43 (D) Handling disposal of infectious waste and needlestick prevention management;
- 44 (E) Procedures for making referrals, including primary care, detoxification and drug  
45 treatment, HIV counseling and testing, prenatal care, tuberculosis, and Hepatitis A, B, and C  
46 screening and treatment, and screening and treatment for sexually transmitted diseases;
- 47 (F) Education that demonstrates Naloxone administration;
- 48 (G) Cultural diversity and sensitivity to protected classes under state and federal law; and
- 49 (H) Training logs for attendance at mandatory training;
- 50 (4) A syringe-dispensing plan including, but not limited to, the following that:
- 51 (A) An accounting for safe disposal of the syringes by participants for seven years;
- 52 (B) Prevents needlestick injuries;
- 53 (C) Tracks the "approximate" number of syringes dispensed;
- 54 (D) Tracks the number of syringes collected;
- 55 (E) Tracks the number of syringes collected as a result of community reports of needle  
56 litter;



57 (F) Eliminates direct handling of sharps waste;

58 (G) Includes a needlestick protocol and plan for ensuring staff and participant familiarity  
59 with the protocol;

60 (H) Includes sharps waste disposal education that ensures staff are familiar with state law  
61 regulating proper disposal of home-generated sharps waste; and

62 (I) Includes a plan and budget for sharps waste disposal or an explanation if no cost is  
63 associated with sharps waste disposal;

64 (5) A plan to coordinate with the continuum of care, including the requirements set forth in  
65 this section.

66 (b) If an applicant for a license does not submit all of the documentation required in §16-  
67 63-2 of this code, the application for a license shall be denied.

68 (c) If an applicant for a license fails to comply with the program requirements, then the  
69 application shall be denied.

70 (d) If the license is granted it shall be effective for one year, subject to random inspection  
71 by the Office of Health Facility Licensure and Certification and a request for renewal by the  
72 licensee.

**§16-63-4. Procedure for revocation or limitation of the needle exchange program.**

1 (a) The director may revoke or limit a needle exchange program's ability to offer services  
2 for the following reasons:

3 (1) The needle exchange program provides willful or intentional false or misleading  
4 information to the director at any time;

5 (2) Monitoring or inspection indicates the needle exchange program is in violation of the  
6 law;

7 (3) The needle exchange program fails to cooperate with the director during the  
8 investigation of any complaint; and

9           (4) Recission of the letter of approval from majority of the county commissioners or the  
10 county sheriff.

11           (b) The director shall send written notice to the needle exchange program of revocation or  
12 limitation of its operations. The written notice shall include the following:

13           (1) Effective date of the revocation or limitation;

14           (2) The basis for the revocation or limitation on the certificate;

15           (3) The location to which the revocation or limitation applies;

16           (4) The remedial measures the needle exchange program shall take, if any, to consider  
17 reinstatement of the program or removal of the limitation; and

18           (5) Steps to request reconsideration or appeal of the decision.

**§16-63-5. Reconsideration procedure.**

1           (a) An owner or operator may request, in writing, reconsideration of a decision rendered  
2 by the director on an action taken. If the request for reconsideration establishes good cause, then  
3 the director shall grant the request. Upon request, the director may grant a public hearing to  
4 consider the request for reconsideration.

5           (b) A request for reconsideration is considered to have shown good cause if, in a detailed  
6 statement, it:

7           (1) Presents significant, relevant information not previously considered by the director,  
8 and demonstrates that with reasonable diligence that information could not have been presented  
9 before the board made its decision;

10           (2) Demonstrates that there have been significant changes in factors or circumstances  
11 relied upon by the director in reaching its decision;

12           (3) Demonstrates that the board has materially failed to follow its adopted procedures in  
13 reaching its decision; or

14           (c) The director shall receive a request for reconsideration within 30 days after the date of  
15 the bureau's decision.

16 (d) The director or his or her designee shall hold a hearing, if any, upon a request for  
17 reconsideration within 30 days of the bureau's receipt of the request. The director may extend  
18 this time for good cause.

19 (e) The director shall issue its written decision which states the basis of its decision upon  
20 request for reconsideration within 45 days after the conclusion of the hearing.

**§16-63-6. Administrative due process.**

1 (a) An owner or operator of a needle exchange program who disagrees with the final  
2 administrative decision may, within 30 days after receiving notice of the decision, appeal the  
3 decision to the department's board of review.

4 (b) The needle exchange program shall be required to be represented by legal counsel at  
5 the hearing.

6 (c) All pertinent provisions of §29A-5-1 et seq. of this code and §69-1-1 et seq. of this code  
7 apply to and govern any hearing authorized by this statute.

8 (d) The filing of a request for a hearing does not stay or supersede enforcement of the  
9 final decision of the director. The director may, upon good cause shown, stay such enforcement.

**§16-63-7. Administrative appeals and judicial review.**

1 (a) An owner or operator of a needle exchange program who disagrees with the final  
2 administrative decision may, within 30 days after the date the appellant received notice of the  
3 decision of the board of review, appeal the decision to the Circuit Court of Kanawha County or in  
4 the county where the petitioner resides or does business.

5 (b) The filing of the petition for appeal does not stay or supersede enforcement of the final  
6 decision or order of the director. An appellant may apply to the circuit court for a stay of or to  
7 supersede the final decision or order for good cause shown.

8 (c) No circuit court has jurisdiction to consider a decision of the board if the petitioner has  
9 failed to file a request for review with the board of review within the time frame set forth in this  
10 article.

**§16-63-8. Reporting requirements; renewal requests.**

1           (a) A needle exchange program licensed pursuant to this statute shall file a quarterly report  
2 with the director, by email, and file an annual request for renewal on the anniversary date of  
3 license approval each and every year of the program's operation under the director's review. The  
4 report shall include:

- 5           (1) The total number of persons served;  
6           (2) The total numbers and types of syringes and needles dispensed, collected, and  
7 disposed of;  
8           (3) The total number of needlestick injuries to non-participants;  
9           (4) Statistics regarding the number of individuals entering rehabilitation; and  
10           (5) The total numbers and types of referrals made to drug treatment and other services.

11           (b) A syringe exchange program licensed pursuant to this statute shall within 45 days prior  
12 to the expiration of the license, or at any other time directed by the director, submit a report  
13 verified, in writing, by the administrator, containing the following information:

- 14           (1) The current status of the project;  
15           (2) The cause or causes of any delays encountered;  
16           (3) Changes in the project; and  
17           (4) The projected total cost.

18           (c) Upon good cause shown, and if the needle exchange program is in substantial  
19 compliance with the reporting requirements set forth in this section, the director may grant a  
20 renewal for up to six months for the initial renewal period. Forty-five days prior to the expiration of  
21 the license, the needle exchange program shall submit a request for renewal addressing the  
22 criteria in subsection (b) of this section. In order to be considered for renewal, the needle  
23 exchange program must be in substantial compliance with the reporting requirements of this  
24 section. Any subsequent renewal may be granted for up to 12 months.

**§16-63-9. Immunity and cost recoupment.**

1        Any business, excluding the operator of a needle exchange program, that has needle litter  
2 on their property and subsequently incurs a loss, is immune from civil or criminal liability in any  
3 action relating to the needle on their property unless the business owner acted in reckless  
4 disregard for the safety of others.

**§16-63-10. Civil penalties and injunctive relief.**

1        (a) The Office of Health Facilities Licensure and Certification shall assess a civil penalty  
2 of not less than \$5,000 per day nor more than \$25,000 per year for a violation of this article.

3        (b) The Office of Health Facilities Licensure and Certification may seek injunctive relief to  
4 enforce the provisions of this article.

**§16-63-11. Coordination with continuum of care and effective date.**

1        (a) A provider shall coordinate with other existing providers in its services to render care  
2 to the individuals in the needle exchange program as set forth in the program requirements.

3        (b) In the event that the needle exchange program is closed, the needle exchange  
4 program shall notify the patient of the closure of the service, prior to closure, in a conspicuous  
5 location and provide an individual notice to enable the person to transition their care.

6        (c) Upon passage, any existing provider not offering the full array of harm reduction  
7 services, six months prior to passage, as set forth in this section shall cease and desist offering  
8 all needle exchange services. Any provider offering the full array of harm reduction services shall  
9 have until January 1, 2022, to come into compliance with this section. Any new provider shall  
10 have until January 1, 2022, to come into compliance with the provisions of this section.