

EXHIBIT A

WEST VIRGINIA LEGISLATURE

2021 REGULAR SESSION

Enrolled

Committee Substitute

for

Senate Bill 334

BY SENATORS TARR AND GRADY

[Passed April 10, 2021; in effect 90 days from passage (July 9, 2021)]

1 AN ACT 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, and §16-63-10, all relating to syringe services programs; defining terms;
4 providing license application requirements and process; establishing program
5 requirements; providing procedure for revocation or limitation of the syringe services
6 programs; setting forth administrative due process; providing for administrative and judicial
7 appeal; establishing reporting requirements and renewal provisions; providing for
8 rulemaking; providing criminal immunity in certain circumstances; providing civil immunity
9 in certain circumstances; providing for expungement; providing immunity from
10 professional sanction, detainment, arrest, or prosecution in certain circumstances;
11 providing for administrative penalties and allowing Office of Health Facilities Licensure
12 and Certification to seek injunctive relief; requiring a syringe services program to
13 coordinate with health care providers; requiring that a syringe services program that is
14 closing to post notice and provide transition care plan for individuals; requiring the Bureau
15 of Medical Services to amend the state plan; and providing for effective date.

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

ARTICLE 63. SYRINGE SERVICES 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 syringe services 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 article.

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

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

8 “Fixed site” means a building or single location where syringe exchange services are
9 provided.

10 “Harm reduction program” means a program that provides services intended to lessen the
11 adverse consequences of drug use and protect public health and safety, by providing direct
12 access to or a referral to: Syringe services program; substance use disorder treatment programs;
13 screenings; vaccinations; education about overdose prevention; wound care; opioid antagonist
14 distribution and education; and other medical services.

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

16 “License” means the document issued by the office authorizing the syringe services
17 program to operate.

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

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

22 “Mobile site” means a location accessible by foot or vehicle that is not at a fixed indoor
23 setting.

24 “Syringe services program” means a community-based program that provides access to
25 sterile syringes, facilitates safe disposal of used syringes, and is part of a harm reduction program.

26 “Syringe stick injury” means a penetrating wound from a syringe that may result in
27 exposure to blood.

28 “Syringe stick injury protocol” means policies and procedures to prevent syringe stick
29 injury to syringe exchange staff, including volunteers, community members, and to syringe
30 exchange participants.

31 “Service area” means the territorial jurisdiction of the syringe services program.

32 “Sharps waste” means used syringes and lancets.

“Staff” means a person who provides syringe services or harm reduction services on behalf of a program.

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

§16-63-2. Application for license to offer a syringe services program.

(a) All new and existing syringe services programs shall obtain a license from the Office for Health Facility Licensure and Certification.

(b) To be eligible for a license, a syringe services program shall:

(1) Submit an application on a form approved and provided by the office director;

(2) Provide the name of the program;

(3) Provide a description of the harm reduction program it is associated with and the harm reduction services provided in accordance with §16-2-3 of this code;

(4) Provide the contact information of the individual designated by the applicant as the administrator of the harm reduction program;

(5) Provide the hours of operation, location, and staffing. The description of hours of operation must include the specific days the syringe services program is open, opening and closing times, and frequency of syringe exchange services. The description of staffing must include number of staff, titles of positions, and descriptions of their functions;

(6) Provide a specific description of the applicant’s ability to refer to or facilitate entry into substance use treatment;

(7) Provide a 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;

(8) Pay an application fee in amount not to exceed \$500, to be determined by the director by legislative rule; and

(9) Provide a 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.

§16-63-3. Program requirements.

(a) To be approved for a license, a syringe services program shall be part of a harm reduction program which offers or refers an individual to the following services which shall be documented in the application:

- (1) HIV, hepatitis, and sexually transmitted diseases screening;
- (2) Vaccinations;
- (3) Birth control and long-term birth control;
- (4) Behavioral health services;
- (5) Overdose prevention supplies and education;
- (6) Syringe collection and sharps disposal;
- (7) Educational services related to disease transmission;
- (8) Assist or refer an individual to a substance use treatment program;
- (9) Refer to a health care practitioner or treat medical conditions; and
- (10) Programmatic guidelines including a sharps disposal plan, a staff training plan, a data collection and program evaluation plan, and a community relations plan.

(b) A syringe services program:

- (1) Shall offer services, at every visit, from a qualified licensed health care provider;
- (2) Shall exclude minors from participation in the syringe exchange, but may provide minors with harm reduction services;

- (3) Shall ensure a syringe is unique to the syringe services program;
- (4) Shall distribute syringes with a goal of a 1:1 model;
- (5) May substitute weighing the volume of syringes returned versus dispensed as specified. This substitution is only permissible if it can be done accurately and in the following manner:

- (A) The syringes shall be contained in a see-through container; and
- (B) A visual inspection of the container shall take place prior to the syringes being weighed;

- 48 (6) Shall distribute the syringe directly to the program recipient;
- 49 (7) Proof of West Virginia identification upon dispensing of the needles;
- 50 (8) Shall train staff on:
- 51 (A) The services and eligibility requirements of the program;
- 52 (B) The services provided by the program;
- 53 (C) The applicant's policies and procedures concerning syringe exchange transactions;
- 54 (D) Disposing of infectious waste;
- 55 (E) Sharps waste disposal education that ensures familiarity with the state law regulating
- 56 proper disposal of home-generated sharps waste;
- 57 (F) Procedures for obtaining or making referrals;
- 58 (G) Opioid antagonist administration;
- 59 (H) Cultural diversity and sensitivity to protected classes under state and federal law; and
- 60 (I) Completion of attendance logs for participation in mandatory training;
- 61 (9) Maintain a program for the public to report syringe litter and shall endeavor to collect
- 62 all syringe litter in the community.
- 63 (c) Each syringe services program shall have a syringe dispensing plan which includes,
- 64 but is not limited to the following:
- 65 (1) Maintaining records of returned syringes by participants for two years;
- 66 (2) Preventing syringe stick injuries;
- 67 (3) Tracking the number of syringes dispensed;
- 68 (4) Tracking the number of syringes collected;
- 69 (5) Tracking the number of syringes collected as a result of community reports of syringe
- 70 litter;
- 71 (6) Eliminating direct handling of sharps waste;
- 72 (7) Following a syringe stick protocol and plan;

(8) A budget for sharps waste disposal or an explanation if no cost is associated with sharps waste disposal; and

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

(d) If an applicant does not submit all of the documentation required in §16-63-2 of this code, the application shall be denied and returned to the applicant for completion.

(e) If an applicant fails to comply with the program requirements, the application shall be denied and returned to the applicant for completion.

(f) A license is effective for one year.

§16-63-4. Procedure for revocation or limitation of the syringe services programs.

(a) The director may revoke, suspend, or limit a syringe services program's ability to offer services for the following reasons:

(1) The syringe services program provides false or misleading information to the director;

(2) An inspection indicates the syringe services programs is in violation of the law or legislative rule;

(3) The syringe services program fails to cooperate with the director during a complaint investigation; or

(4) Recission of the letter of approval from a majority of the county commissioners or the governing body of a municipality.

(b) The director shall send written notice to the syringe services program of revocation, suspension, or limitation of its operations. The written notice shall include the following:

(1) Effective date of the revocation, suspension, or limitation;

(2) The basis for the revocation, suspension, or limitation;

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

(4) The remedial measures the syringe services programs shall take, if any, to consider reinstatement of the program or removal of the limitation; and

17 (5) Steps to appeal of the decision.

§16-63-5. Administrative due process.

1 (a) A syringe services program who disagrees with an administrative decision may, within
2 30 days after receiving notice of the decision, appeal the decision to the department's board of
3 review.

4 (b) All pertinent provisions of §29A-5-1 *et seq.* of this code apply to and govern any hearing
5 authorized by this statute.

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

§16-63-6. Administrative appeals and judicial review.

1 (a) A syringe services program who disagrees with the final administrative decision may,
2 within 30 days after the date the appellant received notice of the decision of the board of review,
3 appeal the decision to the Circuit Court of Kanawha County or in the county where the petitioner
4 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.

§16-63-7. Reporting requirements; renewal; rulemaking.

1 (a) A syringe services program shall renew its license annually on the anniversary date of
2 license approval.

3 (b) A syringe services program shall file an annual report with the director. The report shall
4 include:

5 (1) The total number of persons served;

(2) The total numbers and types of syringes, and syringes dispensed, collected, and disposed of;

(3) The total number of syringe stick injuries to non-participants;

(4) Statistics regarding the number of individuals entering substance use treatment; and

(5) The total and types of referrals made to substance use treatment and other services.

(c) The office shall promulgate and propose rules and regulations under §29A-1-1 *et seq.* of this code to carry out the intent and purposes of this article. Such rules and regulations shall be in accordance with evidence-based practices. The office shall promulgate an emergency rule by July 1, 2021. The emergency rule shall effectuate the provisions of this article in accordance with evidence-based practices.

§16-63-8. Immunity.

(a) Notwithstanding any provision of this code to the contrary, an employee, volunteer, or participant of a licensed syringe services program may not be arrested, charged with, or prosecuted for possession of any of the following:

(1) Sterile or used syringes, hypodermic syringes, injection supplies obtained from or returned to a program, or other safer drug use materials obtained from a program established pursuant to this article, including testing supplies for illicit substances.

(2) Residual amounts of a controlled substance contained in a used syringe, used injection supplies obtained from or returned to a program.

(b) A law-enforcement officer who, acting on good faith, arrests or charges a person who is thereafter determined to be entitled to immunity from prosecution under this section is not liable for the arrest or filing of charges.

(c) An individual who is wrongly detained, arrested or prosecuted under this section shall have the public record associated with the detainment, arrest or prosecution expunged.

14 (d) A health care professional, or an employee or volunteer of a licensed syringe services
15 program is not subject to professional sanction, detainment, arrest, or prosecution for carrying out
16 the provisions of this article.

17 (e) A business that has syringe litter on its property is immune from civil or criminal liability
18 in any action relating to the needle on its property unless the business owner acted in reckless
19 disregard for the safety of others.

§16-63-9. Civil penalties and injunctive relief.

1 (a) The Office of Health Facilities Licensure and Certification may assess an administrative
2 penalty of not less than \$500 nor more than \$10,000 per 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.

§16-63-10. Coordination of care.

5 (a) A syringe service program shall coordinate with other health care providers in its
6 services to render care to the individuals as set forth in the program requirements.

7 (b) In the event that the syringe services program is closed, the syringe services program
8 shall notify the participant of the closure of the service, prior to closure, in a conspicuous location,
9 and provide an individual with a transition care plan.

10 (c) The Bureau for Medical Services shall submit a state plan amendment to permit harm
11 reduction programs to be an eligible provider, except that the syringe exchange services shall not
12 be eligible for reimbursement under the state plan.

13 (d) Upon passage, any existing provider not offering the full array of harm reduction
14 services as set forth in this section shall cease and desist offering all needle exchange services.
15 Any provider offering the full array of harm reduction services shall have until January 1, 2022, to
16 come into compliance with this section. Any new provider shall have until January 1, 2022, to
17 come into compliance with the provisions of this section.

The Joint Committee on Enrolled Bills hereby certifies that the foregoing bill is correctly enrolled.

.....
Chairman, Senate Committee

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Chairman, House Committee

Originated in the Senate.

In effect 90 days from passage.

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Clerk of the Senate

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Clerk of the House of Delegates

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President of the Senate

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Speaker of the House of Delegates

The within this the.....
Day of, 2021.

.....
Governor

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

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

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

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

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

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

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

(A) Is not prohibited by local ordinance; and

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

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

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

§16-63-3. Program requirements.

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

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

(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.

WEST VIRGINIA LEGISLATURE

2021 REGULAR SESSION

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]

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

Be it enacted by the Legislature of West Virginia:

ARTICLE 63. NEEDLE EXCHANGE PROGRAMS.

§16-63-1. Definitions.

As used in this article, the term:

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

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

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

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

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

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

“Fixed site” means a building or single location where needle exchange services are 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

include number of staff, titles of positions, and descriptions of services;

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

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

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

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

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

(A) Is not prohibited by local ordinance; and

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

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

§16-63-3. Program requirements.

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

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

(A) Drug abuse treatment services;

(B) HIV and hepatitis screening and education;

(C) Hepatitis A, B, and C vaccination and testing;

(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

they should sign a contract of understanding; and

(H) The licensee, whether fixed or mobile, shall distribute the needle directly to the program recipient, and shall not distribute a needle to a program recipient for another person;

(3) A staff training protocol including, but not limited to, the following:

(A) Orientation to the applicant's services and eligibility requirements of the program;

(B) Overview of the needle exchange philosophy and the harm reduction model used by the program;

(C) The applicant's policies and procedures that explain syringe exchange transactions;

(D) Handling disposal of infectious waste and needlestick prevention management;

(E) Procedures for making referrals, including primary care, detoxification and drug treatment, HIV counseling and testing, prenatal care, tuberculosis, and Hepatitis A, B, and C screening and treatment, and screening and treatment for sexually transmitted diseases;

(F) Education that demonstrates Naloxone administration;

(G) Cultural diversity and sensitivity to protected classes under state and federal law; and

(H) Training logs for attendance at mandatory training;

(4) A syringe-dispensing plan including, but not limited to, the following that:

(A) An accounting for safe disposal of the syringes by participants for seven years;

(B) Prevents needlestick injuries;

(C) Tracks the "approximate" number of syringes dispensed;

(D) Tracks the number of syringes collected;

(E) Tracks the number of syringes collected as a result of community reports of needle litter;

(F) Eliminates direct handling of sharps waste;

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

(H) Includes sharps waste disposal education that ensures staff are familiar with state law

regulating proper disposal of home-generated sharps waste; and

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

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

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

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

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

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

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

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

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

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

(4) Recission of the letter of approval from majority of the county commissioners.

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

(1) Effective date of the revocation or limitation;

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

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

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

17 (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.

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.

WEST VIRGINIA LEGISLATURE

2021 REGULAR SESSION

Introduced

Senate Bill 334

**FISCAL
NOTE**

BY SENATORS TARR AND GRADY

[Introduced February 18, 2021; referred
to the Committee on Health and Human Resources]

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, and §16-63-10, all relating to harm reduction programs; creating
4 definitions; establishing licensure application process for harm reduction programs; setting
5 forth prohibition on the receipt of state funds; creating program requirements; establishing
6 revocation process; setting forth the reconsideration process; setting forth the
7 administrative due process provision; providing for administrative and judicial appeal;
8 establishing reporting requirements and renewal provisions; providing for immunity and
9 cost recoupment for businesses; and establishing civil penalties, criminal penalties, and
10 injunctive relief.

Be it enacted by the Legislature of West Virginia:

ARTICLE 63. HARM REDUCTION PROGRAMS.

§16-63-1. Definitions.

1 As used in this article, the term:
2 “Bloodborne pathogens” means pathogenic microorganisms that are present in human
3 blood and can cause disease in humans. These pathogens include, but are not limited to hepatitis
4 B virus, hepatitis C virus, and human immunodeficiency virus (HIV).
5 “Core services” means the primary services an entity undertakes in order to service its
6 clients.
7 “Director” means the Director of the Office of Health Facility Licensure and Certification
8 “Fixed site” means a building or single location, not a mobile site, where harm reduction
9 services are provided.
10 “Harm reduction program” means a program that provides services intended to lessen the
11 adverse consequences of drug use and protect public health and safety, this may include but not
12 be limited to a syringe exchange program but expressly excludes what is sometimes referred to
13 as a “safe injection site” or similar offering.

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

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

16 “License” means the document issued by the Bureau authorizing the Harm Reduction
17 Program (HRP) to operate.

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

20 “Local law enforcement officer” means the county sheriff or his or her designee where the
21 proposed or existing harm reduction program is or will be located.

22 “Location” means a site within the service area of a local health department. A location is
23 a fixed site.

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

26 “Needlestick injury protocol” means policies and procedures to prevent needlestick injury
27 to harm reduction staff, including volunteers, community members, and to harm reduction
28 participants.

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

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

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

34 “Staff” means anyone who provides harm reduction services on behalf of a program.

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

36 “Viral hepatitis” means any of the forms of hepatitis caused by the virus, including hepatitis
37 B (HBV) virus and hepatitis C virus (HCV).

§16-63-2. Application for license to offer Harm Reduction Programs, prohibition receipt of
state funds.

1 (a) All new and existing harm reduction programs shall require a license;

2 (b) To be eligible for a license, a harm reduction 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 harm reduction program;

10 (5) Provide the hours of operation in the location and staffing. The description of hours of
11 operation must include the specific days the harm reduction program is open, opening, and
12 closing times, and frequency of harm reduction services. The description of staffing must include
13 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 harm reduction 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) Provide a specific timeline for the program to achieve measurable health outcomes in
21 a specific population;

22 (10) Pay an applicable application fee to be determined by the Director;

23 (11) Provide a written statement from the entire county commission for the county in which
24 it is located or is proposing to locate that the harm reduction program:

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

26 (B) That the entire county commission supports the program.

27 (12) Provide letters of support from:

28 (A) The local health officer or Board of Health; and

29 (B) The local Sherriff from the county in which the applicant is located or is proposing to
30 locate the harm reduction program.

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

37 (c) No harm reduction program, offering a syringe exchange program, is eligible to receive
38 funds, from any source, within the State Treasury nor any grants administered by the use of public
39 resources whether the resources be monetary, personnel, real estate, or technology
40 infrastructure.

§16-63-3 Program requirements.

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

3 (1) A full array of harm reduction services including drug abuse treatment services, HIV
4 and hepatitis screening and education, Hepatitis A and Hepatitis B Vaccination, screening for
5 sexually transmitted diseases, the provision of long-term birth control, the provision of behavioral
6 health services, overdose prevention supplies and education, syringe collection and sharps
7 disposal plan, staff training plan, data collection and program evaluation plan, community relations
8 plan, and educational services related to disease transmission. Treatment shall be offered at
9 every visit by a qualified licensed health care provider. The applicant shall make services available
10 24/7 for participants to be able to enter rehabilitation or detoxification;

11 (2) A clean syringe exchange program, including a dedicated staff member assigned to

recover discarded syringes from the program in the service area, with the clear objective of
reducing the transmission of blood-borne diseases within a specific geographic area. This
program shall include: proof of identification upon dispensing of the needles, exclusion of minors
from participation in the program, and the ability to track each needle by unique serial number
that associates that needle directly to the harm reduction program and the individual issued the
needle. Needles are to be distributed with the 1:1 model only with an exchange required. A
program or facility may not substitute weighing the volume of needles returned versus dispensed
to measure if a 1:1 protocol has been met. Rather, accounting for every needle is required.
Participants shall be advised of this requirement when enrolled in the program and they should
sign a contract of understanding. Needles cannot be distributed by a secondary exchange or
proxy:

(3) A staff training protocol that includes at a minimum: orientation to the applicant's
services and eligibility requirements of the program, overview of the harm reduction philosophy
and the harm reduction model used by the program; the applicant's policies and procedures that
explain syringe exchange transactions, handling disposal of infectious waste, and needlestick
prevention management; procedures for making referrals, including primary care, detoxification
and drug treatment, HIV counseling and testing, prenatal care, tuberculosis, and Hepatitis A, B,
and C screening and treatment, screening and treatment for sexually transmitted diseases;
education that demonstrates Naloxone administration; cultural diversity and sensitivity to
protected classes under state and federal law; and training logs for attendance at mandatory
training;

(4) A syringe dispensing plan that includes at a minimum: an accounting for safe disposal
of the syringes by participants for seven years, that prevents needlestick injuries, that tracks the
exact number of syringes dispensed, that tracks the exact number of syringes collected on a 1:1
basis to each program participant, that tracks the exact number of syringes returned, that tracks
the number of syringes collected as a result of community reports of needle litter, that eliminates

direct handling of sharps waste, that includes a needlestick protocol and plan for ensuring staff and participant familiarity with the protocol, that includes sharps waste disposal education that ensures staff are familiar with state law regulating proper disposal of home-generated sharps waste, and that includes a plan and budget for sharps waste disposal or an explanation if no cost is associated with sharps waste disposal:

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

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

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

§16-63-4. Procedure for Revocation or limitation of the harm reduction program.

(a) The Director may revoke or limit a harm reduction's ability to offer services for the following reasons:

(1) The harm reduction program provides false or misleading information to the Director at any time;

(2) Monitoring or inspection indicates the harm reduction program is in violation of the law;

(3) The harm reduction program fails to cooperate with the Director, during the investigation of any complaint;

(4) Community complaints indicate safety concerns, abuse, or other practices detrimental to the well-being of individuals being treated by the harm reduction program or the community at large;

(5) Recission of the letter of approval from any one county commissioner; or

(6) Recission of the letter of approval from the County Sherriff.

(b) The Director shall send written notice to the harm reduction program of revocation or

14 limitation of its operations. The written notice shall include the following:

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

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

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

18 (4) The remedial measures the harm reduction program shall take, if any, to take to
19 consider reinstatement of the program or removal of the limitation; and

20 (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 causes,
3 then the Director shall grant the request. Upon request, the Director may grant a public hearing
4 to consider the request for reconsideration.

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

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

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

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

14 (d) The Director shall receive a request for reconsideration within 30 days after the date
15 of 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 harm reduction 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 harm reduction program shall be required, at their cost, to be represented by legal
5 counsel at the hearing.

6 (c) All pertinent provisions of §29A-5-1 et seq. and §69-1-1 et seq. apply to and govern
7 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.

10 (e) If the Director does not rule in favor of the owner or operator of the harm reduction
11 program, the owner or operator of the harm reduction program will be required to reimburse the
12 Department for any expenses incurred by the Department that are directly related to the final
13 appeal.

§16-63-7. Administrative Appeals and Judicial Review.

1 (a) An owner or operator of a harm reduction 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
4 in 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 timeframe set forth in this

10 article.

§16-63-8. Reporting Requirements; Renewal Requests.

1 (a) A harm reduction 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; and

8 (3) The total numbers and types of referrals made to drug treatment and other services.

9 (b) A harm reduction program licensed pursuant to this statute shall within 45 days prior
10 to the expiration of the license, or at any other time directed by the Director, submit a report
11 verified, in writing, by the chief executive officer containing the following information:

12 (1) The current status of the project;

13 (2) The cause of causes of any delays encountered;

14 (3) Changes in the project; and

15 (4) The projected total cost.

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

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

1 Any business, excluding the operator of a harm reduction 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. Any business may seek to recover the costs of cleaning up their
5 property at three times the amount of the cost incurred from the operator of the harm reduction
6 program that is identified as the source of the needle constituting the litter.

§16-63-10. Civil Penalties Criminal Penalties and Injunctive Relief.

1 The Office of Health Facilities Licensure and Certification shall assess a civil penalty of
2 not less than \$5000 per day nor more than \$25,000 per year for a violation of this article. Any
3 person or entity offering harm reduction services or syringe exchange services without a license
4 is guilty of a misdemeanor and may be punishable by no more than one year in jail. The Office of
5 Health Facilities Licensure and Certification may seek injunctive relief to enforce the provisions of
6 this article.

NOTE: The purpose of this bill is to establish a license application process for harm reduction programs. The bill sets forth the requirements for the application and program criteria for approval. The bill states that harm reduction programs, operating syringe exchange programs, are not eligible for funding from the state treasury. The bill includes an appeal process, reporting requirements, immunity for businesses that have needle litter, and provides for civil penalties, criminal penalties, and injunctive relief.

Strike-throughs indicate language that would be stricken from a heading or the present law and underscoring indicates new language that would be added.

West Virginia House of Delegates

85th Legislature - Regular Session 2021

SB 334

**Establishing license application process for needle
exchange program**

RCS# 638

4/10/2021 10:05 PM

Passage

Yeas: 67 Nays: 32 Absent: 1 Passed

Yea: 67

| | | | |
|------------|--------------|------------|-------------|
| Barnhart | Graves | Kessinger | Riley |
| Booth | Hamrick | Kimble | Rohrbach |
| Bridges | Hanna | Linville | Rowan |
| Bruce | Hardy | Longanacre | Smith |
| Burkhammer | Haynes | Mallow | Steele |
| Capito | Higginbotham | Mandt | Storch |
| Clark | Holstein | Martin | Summers |
| Conley | Horst | Maynard | Sypolt |
| Criss | Hott | Mazzocchi | Toney |
| Dean | Householder | Nestor | Tully |
| Ellington | Howell | Pack, J. | Wamsley |
| Espinosa | Jeffries, D. | Pack, L. | Ward, B. |
| Fast | Jeffries, J. | Paynter | Ward, G. |
| Ferrell | Jennings | Phillips | Westfall |
| Forsht | Keaton | Pinson | Zatezalo |
| Foster | Kelly, D. | Queen | Mr. Speaker |
| Gearheart | Kelly, J. | Reynolds | |

Nay: 32

| | | | |
|----------|-------------|----------|----------|
| Anderson | Evans | Lovejoy | Skaff |
| Barach | Fleischauer | McGeehan | Statler |
| Barrett | Fluharty | Miller | Thompson |
| Bates | Garcia | Pethtel | Walker |
| Boggs | Griffith | Pritt | Williams |
| Brown | Hansen | Pushkin | Worrell |
| Diserio | Hornbuckle | Reed | Young |
| Doyle | Kimes | Rowe | Zukoff |

Not Voting: 1

Cooper

West Virginia House of Delegates

85th Legislature - Regular Session 2021

SB 334

**Establishing license application process for needle
exchange program**

RCS# 637

4/10/2021 09:44 PM

ADOPTION

Yeas: 31 Nays: 69 Absent: 0 Rejected

Yea: 31

Barach
Bates
Boggs
Brown
Bruce
Capito
Dean
Diserio

Doyle
Fleischauer
Fluharty
Forsht
Garcia
Griffith
Hansen
Hornbuckle

Kimes
Lovejoy
Pack, L.
Paynter
Pethtel
Pritt
Pushkin
Queen

Rowe
Skaff
Thompson
Walker
Williams
Young
Zukoff

Nay: 69

Anderson
Barnhart
Barrett
Booth
Bridges
Burkhammer
Clark
Conley
Cooper
Criss
Ellington
Espinosa
Evans
Fast
Ferrell
Foster
Gearheart
Graves

Hamrick
Hanna
Hardy
Haynes
Higginbotham
Holstein
Horst
Hott
Householder
Howell
Jeffries, D.
Jeffries, J.
Jennings
Keaton
Kelly, D.
Kelly, J.
Kessinger
Kimble

Linville
Longanacre
Mallow
Mandt
Martin
Maynard
Mazzocchi
McGeehan
Miller
Nestor
Pack, J.
Phillips
Pinson
Reed
Reynolds
Riley
Rohrbach
Rowan

Smith
Statler
Steele
Storch
Summers
Sypolt
Toney
Tully
Wamsley
Ward, B.
Ward, G.
Westfall
Worrell
Zatezalo
Mr. Speaker

West Virginia Senate

Roll Call

SB 334

Establishing license application process for needle exchange programs

Yea: 27

Nay: 7

Absent: 0

Excused: 0

| | | |
|-------------|-------------|----------------|
| Y AZINGER | Y MARONEY | N STOVER |
| Y BALDWIN | Y MARTIN | Y SWOPE |
| N BEACH | Y MAYNARD | Y SYPOLT |
| Y BOLEY | Y NELSON | Y TAKUBO |
| N CAPUTO | Y PHILLIPS | Y TARR |
| Y CLEMENTS | Y PLYMALE | Y TRUMP |
| Y GRADY | Y ROBERTS | N UNGER |
| Y HAMILTON | N ROMANO | Y WELD |
| N IHLENFELD | Y RUCKER | Y WOELFEL |
| Y JEFFRIES | Y SMITH | Y WOODRUM |
| Y KARNES | N STOLLINGS | Y MR PRESIDENT |
| Y LINDSAY | | |

Effective From Passage

West Virginia Senate

Roll Call

SB 334

Establishing license application process for needle exchange programs

Yea: 27

Nay: 7

Absent: 0

Excused: 0

| | | |
|-------------|-------------|----------------|
| Y AZINGER | Y MARONEY | N STOVER |
| Y BALDWIN | Y MARTIN | Y SWOPE |
| N BEACH | Y MAYNARD | Y SYPOLT |
| Y BOLEY | Y NELSON | Y TAKUBO |
| N CAPUTO | Y PHILLIPS | Y TARR |
| Y CLEMENTS | Y PLYMALE | Y TRUMP |
| Y GRADY | Y ROBERTS | N UNGER |
| Y HAMILTON | N ROMANO | Y WELD |
| N IHLENFELD | Y RUCKER | Y WOELFEL |
| Y JEFFRIES | Y SMITH | Y WOODRUM |
| Y KARNES | N STOLLINGS | Y MR PRESIDENT |
| Y LINDSAY | | |

Concur as Amended & Pass

West Virginia House of Delegates

85th Legislature - Regular Session 2021

SB 334

**Establishing license application process for needle
exchange programs**

RCS# 546

4/9/2021 12:32 PM

Passage

Yeas: 85 Nays: 13 Absent: 2 Passed

Yea: 85

| | | | |
|------------|--------------|------------|-------------|
| Anderson | Ferrell | Kelly, D. | Riley |
| Barach | Fluharty | Kelly, J. | Rohrbach |
| Barnhart | Forsht | Kessinger | Rowan |
| Barrett | Garcia | Kimble | Rowe |
| Bates | Gearheart | Linville | Skaff |
| Boggs | Graves | Longanacre | Smith |
| Booth | Griffith | Lovejoy | Storch |
| Bridges | Hamrick | Mallow | Summers |
| Brown | Hanna | Mandt | Sypolt |
| Bruce | Hardy | Martin | Toney |
| Burkhammer | Haynes | Maynard | Tully |
| Capito | Higginbotham | Mazzocchi | Wamsley |
| Clark | Holstein | Nestor | Ward, B. |
| Conley | Hornbuckle | Pack, J. | Ward, G. |
| Cooper | Horst | Pack, L. | Westfall |
| Criss | Hott | Paynter | Worrell |
| Dean | Householder | Pethel | Zatezalo |
| Diserio | Howell | Phillips | Zukoff |
| Ellington | Jeffries, D. | Pinson | Mr. Speaker |
| Espinosa | Jeffries, J. | Pushkin | |
| Evans | Jennings | Queen | |
| Fast | Keaton | Reynolds | |

Nay: 13

| | | | |
|-------------|--------|----------|-------|
| Doyle | Kimes | Statler | Young |
| Fleischauer | Miller | Steele | |
| Foster | Pritt | Walker | |
| Hansen | Reed | Williams | |

Not Voting: 2

| | |
|----------|----------|
| McGeehan | Thompson |
|----------|----------|

West Virginia House of Delegates

85th Legislature - Regular Session 2021

SB 334

**Establishing license application process for needle
exchange programs**

RCS# 545

4/9/2021 12:12 PM

HFA CAPITO 4-9 #1

Yeas: 36 Nays: 62 Absent: 2 Rejected

Yea: 36

| | | | |
|---------|--------------|-----------|-------------|
| Barach | Evans | Kelly, D. | Rowe |
| Barrett | Fleischauer | Lovejoy | Skaff |
| Bates | Fluharty | Mallow | Storch |
| Boggs | Garcia | Nestor | Walker |
| Brown | Griffith | Pack, L. | Westfall |
| Capito | Hanna | Pethtel | Williams |
| Cooper | Hansen | Pushkin | Young |
| Diserio | Higginbotham | Queen | Zukoff |
| Doyle | Hornbuckle | Reed | Mr. Speaker |

Nay: 62

| | | | |
|------------|--------------|------------|----------|
| Anderson | Gearheart | Kimes | Rohrbach |
| Barnhart | Graves | Linville | Rowan |
| Booth | Hamrick | Longanacre | Smith |
| Bridges | Hardy | Mandt | Statler |
| Bruce | Haynes | Martin | Steele |
| Burkhammer | Holstein | Maynard | Summers |
| Clark | Horst | Mazzocchi | Sypolt |
| Conley | Hott | McGeehan | Toney |
| Criss | Householder | Miller | Tully |
| Dean | Howell | Pack, J. | Wamsley |
| Ellington | Jeffries, D. | Paynter | Ward, B. |
| Espinosa | Jeffries, J. | Phillips | Ward, G. |
| Fast | Jennings | Pinson | Worrell |
| Ferrell | Keaton | Pritt | Zatezalo |
| Forsht | Kessinger | Reynolds | |
| Foster | Kimble | Riley | |

Not Voting: 2

| | |
|-----------|----------|
| Kelly, J. | Thompson |
|-----------|----------|

West Virginia Senate

Roll Call

SB 334

Establishing license application process for needle exchange programs

Yea: 22

Nay: 11

Absent: 1

Excused: 0

| | | |
|-------------|-------------|----------------|
| Y AZINGER | Y MARONEY | N STOVER |
| N BALDWIN | Y MARTIN | Y SWOPE |
| N BEACH | Y MAYNARD | Y SYPOLT |
| Y BOLEY | Y NELSON | Y TAKUBO |
| N CAPUTO | Y PHILLIPS | Y TARR |
| Y CLEMENTS | N PLYMALE | Y TRUMP |
| Y GRADY | Y ROBERTS | N UNGER |
| N HAMILTON | N ROMANO | Y WELD |
| N IHLENFELD | Y RUCKER | Y WOELFEL |
| Y JEFFRIES | Y SMITH | Y WOODRUM |
| A KARNES | N STOLLINGS | Y MR PRESIDENT |
| N LINDSAY | | |

3rd Reading

Delegate Zukoff moves to amend the House of Delegates amendment, as amended by the Senate, on page one, section two, subsection (a), after the word Certification by inserting the following:

"*Provided*, That faith-based programs shall be given priority in the license application review process."

Adopted

Rejected

Senator Maroney moved to amend the bill by striking out the title and substituting therefor a new title, to read as follows:

Eng. Com. Sub. for Senate Bill 334A BILL to amend the Code of West Virginia, 1931, as amended, by adding thereto a new article, designated §16-63-1, §16-63-2, §16-63-3, §16-63-4, §16-63-5, §16-63-6, §16-63-7, §16-63-8, §16-63-9, and §16-63-10, all relating to syringe services programs; defining terms; providing license application requirements and process; establishing program requirements; providing procedure for revocation or limitation of the syringe services programs; setting forth administrative due process; providing for administrative and judicial appeal; establishing reporting requirements and renewal provisions; providing for rulemaking; providing criminal immunity in certain circumstances; providing civil immunity in certain circumstances; providing for expungement; providing immunity from professional sanction, detainment, arrest, or prosecution in certain circumstances; providing for administrative penalties and allowing Office of Health Facilities Licensure and Certification to seek injunctive relief; requiring a syringe services program to coordinate with health care providers; requiring that a syringe services program that is closing to post notice and provide transition care plan for individuals; requiring the Bureau of Medical Services to amend the state plan; and providing for effective date.

Adopted

Rejected

Senator Maroney moved to amend the House of Delegates amendment on page two, section two, subsection (a), subdivision (9), after the word statement by inserting the words of support;

On page three, section three, subsection (b), after subdivision (6) by inserting a new subdivision, designated subdivision (7), to read as follows:

(7) Proof of West Virginia identification upon dispensing of the needles;;

And by renumbering the remaining subdivisions;

On page six, section seven, subsection (c), after 2021 by striking out the comma and remainder of the sentence;

And,

On page seven, section ten, after subsection (c) by inserting a new subsection, designated subsection (d), to read as follows:

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

Adopted

Rejected

Senator Maroney moved to amend the House of Delegates amendment on page two, section two, subsection (a), subdivision (9), after the word statement by inserting the words of support;

On page three, section three, subsection (b), after subdivision (6) by inserting a new subdivision, designated subdivision (7), to read as follows:

(7) Proof of West Virginia identification upon dispensing of the needles;;

And by renumbering the remaining subdivisions;

On page six, section seven, subsection (c), after 2021 by striking out the comma and remainder of the sentence;

And,

On page seven, section ten, after subsection (c) by inserting a new subsection, designated subsection (d), to read as follows:

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

Adopted

Rejected

Delegate Capito moves to amend the title as follows:

S.B. 334 - A BILL to amend the Code of West Virginia, 1931, as amended, by adding thereto a new article, designated §16-63-1, §16-63-2, §16-63-3, §16-63-4, §16-63-5, §16-63-6, §16-63-7, §16-63-8, §16-63-9, and §16-63-10, all relating to syringe services programs; defining terms; providing license application requirements and process; establishing program requirements; providing procedure for revocation or limitation of the syringe services programs; setting forth administrative due process; providing for administrative and judicial appeal; establishing reporting requirements and renewal provisions; providing for rulemaking; providing criminal immunity in certain circumstances; providing civil immunity in certain circumstances; providing for expungement; providing immunity from professional sanction, detainment, arrest, or prosecution in certain circumstances; providing for administrative penalties and allowing Office of Health Facilities Licensure and Certification to seek injunctive relief; requiring a syringe services program to coordinate with health care providers; requiring that a syringe services program that is closing to post notice and provide transition care plan for individuals; and requiring the Bureau of Medical Services to amend the state plan.

The Committee on the Judiciary moved to amend the bill on page 1, by striking everything after the enacting clause and inserting in lieu thereof the following:

" Article 63. Syringe services programs.

§16-63-1. Definitions.

As used in this article, the term:

Administrator means a person having the authority and responsibility for operation of the syringe services program and serves as the contact for communication with the director of the Harm Reduction Program.

Applicant means the entity applying for a license under this article.

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

Director means the Director of the Office of Health Facility Licensure and Certification.

Fixed site means a building or single location where syringe exchange services are provided.

Harm reduction program means a program that provides services intended to lessen the adverse consequences of drug use and protect public health and safety, by providing direct access to or a referral to: syringe services program; substance use disorder treatment programs; screenings; vaccinations; education about overdose prevention; wound care; opioid antagonist distribution and education; and other medical services.

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

License means the document issued by the office authorizing the syringe services program to operate.

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

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

Mobile site means a location accessible by foot or vehicle that is not at a fixed indoor setting.

Syringe services program means a community based program that provides access to sterile syringes, facilitates safe disposal of used syringes, and is part of a harm reduction program.

Syringe stick injury means a penetrating wound from a syringe that may result in exposure to blood.

Syringe stick injury protocol means policies and procedures to prevent syringe stick injury to

syringe exchange staff, including volunteers, community members, and to syringe exchange participants.

Service area means the territorial jurisdiction of the syringe services program.

Sharps waste means used syringes and lancets.

Staff means a person who provides syringe services or harm reduction services on behalf of a program.

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

§16-63-2. Application for license to offer a syringe services program.

(a) All new and existing syringe services programs shall obtain a license from the Office for Health Facility Licensure and Certification.

(b) To be eligible for a license, a syringe services program shall:

(1) Submit an application on a form approved and provided by the office director;

(2) Provide the name of the program;

(3) Provide a description of the harm reduction program it is associated with and the harm reduction services provided in accordance with §16-2-3;

(4) Provide the contact information of the individual designated by the applicant as the administrator of the harm reduction program;

(5) Provide the hours of operation, location, and staffing. The description of hours of operation must include the specific days the syringe services program is open, opening and closing times, and frequency of syringe exchange services. The description of staffing must include number of staff, titles of positions, and descriptions of their functions;

(6) Provide a specific description of the applicants ability to refer to or facilitate entry into substance use treatment;

(7) Provide a specific description of the applicants ability to encourage usage of medical care and mental health services as well as social welfare and health promotion; and

(8) Pay an application fee in amount not to exceed \$500, to be determined by the director by legislative rule.

§16-63-3. Program requirements.

(a) To be approved for a license, a syringe services program shall be part of a harm reduction program which offers or refers an individual to the following services which shall be documented in the application:

(1) HIV, hepatitis and sexually transmitted diseases screening;

(2) Vaccinations;

(3) Birth control and long-term birth control;
(4) Behavioral health services;
(5) Overdose prevention supplies and education;
(6) Syringe collection and sharps disposal;
(7) Educational services related to disease transmission;
(8) Assist or refer an individual to a substance use treatment program;
(9) Refer to a health care practitioner or treat medical conditions; and
(10) Programmatic guidelines including a sharps disposal plan, a staff training plan, a data collection and program evaluation plan, and a community relations plan.

(b) A syringe services program:

(1) Shall offer services, at every visit, from a qualified licensed health care provider;
(2) Shall exclude minors from participation in the syringe exchange, but may provide minors with harm reduction services;

(3) Shall ensure a syringe is unique to the syringe services program;
(4) Shall distribute syringes with a goal of a 1:1 model;
(5) May substitute weighing the volume of syringes returned versus dispensed as specified. This substitution is only permissible if it can be done accurately and in the following manner:-

(A) The syringes shall be contained in a see-through container; and

(B) A visual inspection of the container shall take place prior to the syringes being weighed;

(6) Shall distribute the syringe directly to the program recipient;

(7) Shall train staff on:

(A) The services and eligibility requirements of the program;

(B) The services provided by the program;

(C) The applicants policies and procedures concerning syringe exchange transactions;

(D) Disposing of infectious waste;

(E) Sharps waste disposal education that ensures familiarity with the state law regulating proper disposal of home-generated sharps waste;

(F) Procedures for obtaining or making referrals;

(G) Opioid antagonist administration;

(H) Cultural diversity and sensitivity to protected classes under state and federal law; and

(I) Completion of attendance logs for participation in mandatory training.

(8) Maintain a program for the public to report syringe litter and shall endeavor to collect all syringe

litter in the community.

(c) Each syringe services program shall have a syringe dispensing plan which includes, but is not limited to the following:

(1) Maintaining records of returned syringes by participants for two years;

(2) Preventing syringe stick injuries;

(3) Tracking the number of syringes dispensed;

(4) Tracking the number of syringes collected;

(5) Tracking the number of syringes collected as a result of community reports of syringe litter;

(6) Eliminating direct handling of sharps waste;

(7) Following a syringe stick protocol and plan;

(8) A budget for sharps waste disposal or an explanation if no cost is associated with sharps waste disposal; and

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

(d) If an applicant does not submit all of the documentation required in §16-63-2 of this code, the application shall be denied and returned to the applicant for completion.

(e) If an applicant fails to comply with the program requirements, the application shall be denied and returned to the applicant for completion.

(f) A license is effective for one year.

§16-63-4. Procedure for revocation or limitation of the syringe services programs.

(a) The director may revoke, suspend or limit a syringe services programs ability to offer services for the following reasons:

(1) The syringe services program provides false or misleading information to the director;

(2) An inspection indicates the syringe services programs is in violation of the law or legislative rule;

or

(3) The syringe services program fails to cooperate with the director during a complaint investigation.

(b) The director shall send written notice to the syringe services program of revocation, suspension, or limitation of its operations. The written notice shall include the following:

(1) Effective date of the revocation, suspension, or limitation;

(2) The basis for the revocation, suspension or limitation;

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

(4) The remedial measures the syringe services programs shall take, if any, to consider

reinstatement of the program or removal of the limitation; and

(5) Steps to appeal of the decision.

§16-63-5. Administrative due process.

(a) A syringe services program who disagrees with an administrative decision may, within 30 days after receiving notice of the decision, appeal the decision to the departments board of review.

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

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

§16-63-6. Administrative appeals and judicial review.

(a) A syringe services program who disagrees with the final administrative decision may, within 30 days after the date the appellant received notice of the decision of the board of review, appeal the decision to the Circuit Court of Kanawha County or in the county where the petitioner resides or does business.

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

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

§16-63-7. Reporting requirements; renewal; rulemaking.

(a) A syringe services program shall renew its license annually on the anniversary date of license approval.

(b) A syringe services program shall file an annual report with the director. The report shall include:

(1) The total number of persons served;

(2) The total numbers and types of syringes and syringe s dispensed, collected, and disposed of;

(3) The total number of syringe stick injuries to non-participants;

(4) Statistics regarding the number of individuals entering substance use treatment; and

(5) The total and types of referrals made to substance use treatment and other services.

(c) The office shall promulgate and propose rules and regulations under §29A-1-1 et seq. of this code to carry out the intent and purposes of this article. Such rules and regulations shall be in accordance with evidence-based practices. The office shall promulgate an emergency rule by July 1, 2021, which shall require compliance of the provisions of this article by December 1, 2021. The emergency rule shall effectuate the provisions of this article in accordance with evidence-based practices.

§16-63-8. Immunity.

(a) Notwithstanding any provision of this code to the contrary, an employee, volunteer, or participant of a licensed syringe services program may not be arrested, charged with or prosecuted for possession of any of the following:

(1) Sterile or used syringes, hypodermic syringes, injection supplies obtained from or returned to a program, or other safer drug use materials obtained from a program established pursuant to this article, including testing supplies for illicit substances.

(2) Residual amounts of a controlled substance contained in a used syringe, used injection supplies obtained from or returned to a program.

(b) A law enforcement officer who, acting on good faith, arrests or charges a person who is thereafter determined to be entitled to immunity from prosecution under this section is not liable for the arrest or filing of charges.

(c) An individual who is wrongly detained, arrested or prosecuted under this section shall have the public record associated with the detainment, arrest or prosecution expunged.

(d) A health care professional, or an employee or volunteer of a licensed syringe services program is not subject to professional sanction, detainment, arrest, or prosecution for carrying out the provisions of this article.

§16-63-9. Civil penalties and injunctive relief.

(a) The Office of Health Facilities Licensure and Certification may assess an administrative penalty of not less than \$500 nor more than \$10,000 per violation of this article.

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

§16-63-10. Coordination of care.

(a) A syringe service program shall coordinate with other health care providers in its services to render care to the individuals as set forth in the program requirements.

(b) In the event that the syringe services program is closed, the syringe services program shall notify the participant of the closure of the service, prior to closure, in a conspicuous location, and provide an individual with a transition care plan.

(c) The Bureau for Medical Services shall submit a state plan amendment to permit harm programs to be an eligible provider.

SB334 HFA HJUD 4-7 #2

Becker 3258

The Committee on the Judiciary moved to amend its strike and insert amendment on page 7, section 10, subsection (c), lines 10 and 11, by striking everything after the word amendment and inserting in lieu thereof the following:

to permit harm reduction programs to be an eligible provider, except that the syringe exchange services shall not be eligible for reimbursement under the state plan.

Adopted

Rejected

Delegate Capito moves to amend the title as follows:

S.B. 334 - A BILL to amend the Code of West Virginia, 1931, as amended, by adding thereto a new article, designated §16-63-1, §16-63-2, §16-63-3, §16-63-4, §16-63-5, §16-63-6, §16-63-7, §16-63-8, §16-63-9, and §16-63-10, all relating to syringe services programs; defining terms; providing license application requirements and process; establishing program requirements; providing procedure for revocation or limitation of the syringe services programs; setting forth administrative due process; providing for administrative and judicial appeal; establishing reporting requirements and renewal provisions; providing for rulemaking; providing criminal immunity in certain circumstances; providing civil immunity in certain circumstances; providing for expungement; providing immunity from professional sanction, detainment, arrest, or prosecution in certain circumstances; providing for administrative penalties and allowing Office of Health Facilities Licensure and Certification to seek injunctive relief; requiring a syringe services program to coordinate with health care providers; requiring that a syringe services program that is closing to post notice and provide transition care plan for individuals; and requiring the Bureau of Medical Services to amend the state plan.

Delegate Capito moves to amend the amendment on page 1, section 2, line 2 after the word

Certification., by inserting the following language:

Upon receipt of an application for a syringe services program, the Office for Health Facility Licensure and Certification shall provide notice to the municipality or county commission, as applicable. A municipality or county commission may adopt an ordinance prohibiting syringe services programs in its jurisdiction. The municipality shall submit such ordinance to the Office for Health Facility Licensure and Certification. Upon receipt of such ordinance from a municipality or county commission, the Office for Health Facility Licensure and Certification shall not consider applications for a syringe services program in such jurisdiction until such jurisdiction repeals the ordinance."

And,

On page 7, section 9, line 16, by inserting a new subsection (e) to read as follows:

"(e) A business that has syringe litter on its property is immune from civil or criminal liability in any action relating to the needle on its property unless the business owner acted in reckless disregard for the safety of others."

Adopted

Rejected

Delegate Kessinger moved to amend the amendment on page 2, section 2, line 17, by striking the word, "and";

And,

On page 2, section 2, line 19, by striking the period inserting a semicolon and the following: "and, (9) Provide a written statement 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."

And,

On page 4, section 4, line 5, by striking the word, "or";

And,

On page 4, section 4, line 7 by striking the period and inserting and a semicolon and the following: "or,

(4) Recission of the letter of approval from majority of the county commissioners or the governing body of a municipality."

And,

On page 7, section 9, line 16, by inserting a new subsection (e) to read as follows:

"(e) A business that has syringe litter on its property is immune from civil or criminal liability in any action relating to the needle on its property unless the business owner acted in reckless disregard for the safety of others."

Adopted

Rejected

SB334 HFA HJUD 4-7 #2

Becker 3258

The Committee on the Judiciary moved to amend its strike and insert amendment on page 7, section 10, subsection (c), lines 10 and 11, by striking everything after the word amendment and inserting in lieu thereof the following:

to permit harm reduction programs to be an eligible provider, except that the syringe exchange services shall not be eligible for reimbursement under the state plan.

Adopted

Rejected

The Committee on the Judiciary moved to amend the bill on page 1, by striking everything after the enacting clause and inserting in lieu thereof the following:

" Article 63. Syringe services programs.

§16-63-1. Definitions.

As used in this article, the term:

Administrator means a person having the authority and responsibility for operation of the syringe services program and serves as the contact for communication with the director of the Harm Reduction Program.

Applicant means the entity applying for a license under this article.

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

Director means the Director of the Office of Health Facility Licensure and Certification.

Fixed site means a building or single location where syringe exchange services are provided.

Harm reduction program means a program that provides services intended to lessen the adverse consequences of drug use and protect public health and safety, by providing direct access to or a referral to: syringe services program; substance use disorder treatment programs; screenings; vaccinations; education about overdose prevention; wound care; opioid antagonist distribution and education; and other medical services.

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

License means the document issued by the office authorizing the syringe services program to operate.

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

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

Mobile site means a location accessible by foot or vehicle that is not at a fixed indoor setting.

Syringe services program means a community based program that provides access to sterile syringes, facilitates safe disposal of used syringes, and is part of a harm reduction program.

Syringe stick injury means a penetrating wound from a syringe that may result in exposure to blood.

Syringe stick injury protocol means policies and procedures to prevent syringe stick injury to

syringe exchange staff, including volunteers, community members, and to syringe exchange participants.

Service area means the territorial jurisdiction of the syringe services program.

Sharps waste means used syringes and lancets.

Staff means a person who provides syringe services or harm reduction services on behalf of a program.

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

§16-63-2. Application for license to offer a syringe services program.

(a) All new and existing syringe services programs shall obtain a license from the Office for Health Facility Licensure and Certification.

(b) To be eligible for a license, a syringe services program shall:

(1) Submit an application on a form approved and provided by the office director;

(2) Provide the name of the program;

(3) Provide a description of the harm reduction program it is associated with and the harm reduction services provided in accordance with §16-2-3;

(4) Provide the contact information of the individual designated by the applicant as the administrator of the harm reduction program;

(5) Provide the hours of operation, location, and staffing. The description of hours of operation must include the specific days the syringe services program is open, opening and closing times, and frequency of syringe exchange services. The description of staffing must include number of staff, titles of positions, and descriptions of their functions;

(6) Provide a specific description of the applicants ability to refer to or facilitate entry into substance use treatment;

(7) Provide a specific description of the applicants ability to encourage usage of medical care and mental health services as well as social welfare and health promotion; and

(8) Pay an application fee in amount not to exceed \$500, to be determined by the director by legislative rule.

§16-63-3. Program requirements.

(a) To be approved for a license, a syringe services program shall be part of a harm reduction program which offers or refers an individual to the following services which shall be documented in the application:

(1) HIV, hepatitis and sexually transmitted diseases screening;

(2) Vaccinations;

(3) Birth control and long-term birth control;
(4) Behavioral health services;
(5) Overdose prevention supplies and education;
(6) Syringe collection and sharps disposal;
(7) Educational services related to disease transmission;
(8) Assist or refer an individual to a substance use treatment program;
(9) Refer to a health care practitioner or treat medical conditions; and
(10) Programmatic guidelines including a sharps disposal plan, a staff training plan, a data collection and program evaluation plan, and a community relations plan.

(b) A syringe services program:

(1) Shall offer services, at every visit, from a qualified licensed health care provider;
(2) Shall exclude minors from participation in the syringe exchange, but may provide minors with harm reduction services;

(3) Shall ensure a syringe is unique to the syringe services program;
(4) Shall distribute syringes with a goal of a 1:1 model;
(5) May substitute weighing the volume of syringes returned versus dispensed as specified. This substitution is only permissible if it can be done accurately and in the following manner:-

(A) The syringes shall be contained in a see-through container; and

(B) A visual inspection of the container shall take place prior to the syringes being weighed;

(6) Shall distribute the syringe directly to the program recipient;

(7) Shall train staff on:

(A) The services and eligibility requirements of the program;

(B) The services provided by the program;

(C) The applicants policies and procedures concerning syringe exchange transactions;

(D) Disposing of infectious waste;

(E) Sharps waste disposal education that ensures familiarity with the state law regulating proper disposal of home-generated sharps waste;

(F) Procedures for obtaining or making referrals;

(G) Opioid antagonist administration;

(H) Cultural diversity and sensitivity to protected classes under state and federal law; and

(I) Completion of attendance logs for participation in mandatory training.

(8) Maintain a program for the public to report syringe litter and shall endeavor to collect all syringe

litter in the community.

(c) Each syringe services program shall have a syringe dispensing plan which includes, but is not limited to the following:

(1) Maintaining records of returned syringes by participants for two years;

(2) Preventing syringe stick injuries;

(3) Tracking the number of syringes dispensed;

(4) Tracking the number of syringes collected;

(5) Tracking the number of syringes collected as a result of community reports of syringe litter;

(6) Eliminating direct handling of sharps waste;

(7) Following a syringe stick protocol and plan;

(8) A budget for sharps waste disposal or an explanation if no cost is associated with sharps waste disposal; and

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

(d) If an applicant does not submit all of the documentation required in §16-63-2 of this code, the application shall be denied and returned to the applicant for completion.

(e) If an applicant fails to comply with the program requirements, the application shall be denied and returned to the applicant for completion.

(f) A license is effective for one year.

§16-63-4. Procedure for revocation or limitation of the syringe services programs.

(a) The director may revoke, suspend or limit a syringe services programs ability to offer services for the following reasons:

(1) The syringe services program provides false or misleading information to the director;

(2) An inspection indicates the syringe services programs is in violation of the law or legislative rule;

or

(3) The syringe services program fails to cooperate with the director during a complaint investigation.

(b) The director shall send written notice to the syringe services program of revocation, suspension, or limitation of its operations. The written notice shall include the following:

(1) Effective date of the revocation, suspension, or limitation;

(2) The basis for the revocation, suspension or limitation;

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

(4) The remedial measures the syringe services programs shall take, if any, to consider

reinstatement of the program or removal of the limitation; and

(5) Steps to appeal of the decision.

§16-63-5. Administrative due process.

(a) A syringe services program who disagrees with an administrative decision may, within 30 days after receiving notice of the decision, appeal the decision to the departments board of review.

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

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

§16-63-6. Administrative appeals and judicial review.

(a) A syringe services program who disagrees with the final administrative decision may, within 30 days after the date the appellant received notice of the decision of the board of review, appeal the decision to the Circuit Court of Kanawha County or in the county where the petitioner resides or does business.

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

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

§16-63-7. Reporting requirements; renewal; rulemaking.

(a) A syringe services program shall renew its license annually on the anniversary date of license approval.

(b) A syringe services program shall file an annual report with the director. The report shall include:

(1) The total number of persons served;

(2) The total numbers and types of syringes and syringe s dispensed, collected, and disposed of;

(3) The total number of syringe stick injuries to non-participants;

(4) Statistics regarding the number of individuals entering substance use treatment; and

(5) The total and types of referrals made to substance use treatment and other services.

(c) The office shall promulgate and propose rules and regulations under §29A-1-1 et seq. of this code to carry out the intent and purposes of this article. Such rules and regulations shall be in accordance with evidence-based practices. The office shall promulgate an emergency rule by July 1, 2021, which shall require compliance of the provisions of this article by December 1, 2021. The emergency rule shall effectuate the provisions of this article in accordance with evidence-based practices.

§16-63-8. Immunity.

(a) Notwithstanding any provision of this code to the contrary, an employee, volunteer, or participant of a licensed syringe services program may not be arrested, charged with or prosecuted for possession of any of the following:

(1) Sterile or used syringes, hypodermic syringes, injection supplies obtained from or returned to a program, or other safer drug use materials obtained from a program established pursuant to this article, including testing supplies for illicit substances.

(2) Residual amounts of a controlled substance contained in a used syringe, used injection supplies obtained from or returned to a program.

(b) A law enforcement officer who, acting on good faith, arrests or charges a person who is thereafter determined to be entitled to immunity from prosecution under this section is not liable for the arrest or filing of charges.

(c) An individual who is wrongly detained, arrested or prosecuted under this section shall have the public record associated with the detainment, arrest or prosecution expunged.

(d) A health care professional, or an employee or volunteer of a licensed syringe services program is not subject to professional sanction, detainment, arrest, or prosecution for carrying out the provisions of this article.

§16-63-9. Civil penalties and injunctive relief.

(a) The Office of Health Facilities Licensure and Certification may assess an administrative penalty of not less than \$500 nor more than \$10,000 per violation of this article.

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

§16-63-10. Coordination of care.

(a) A syringe service program shall coordinate with other health care providers in its services to render care to the individuals as set forth in the program requirements.

(b) In the event that the syringe services program is closed, the syringe services program shall notify the participant of the closure of the service, prior to closure, in a conspicuous location, and provide an individual with a transition care plan.

(c) The Bureau for Medical Services shall submit a state plan amendment to permit harm programs to be an eligible provider.

Senator Lindsay moved to amend the bill on page seven, section three, line seventy-one, after the word licensee by changing the period to a colon and inserting the following proviso: *Provided*, That a needle exchange program which operates for at least three consecutive years without being suspended or limited pursuant to section four of this article shall have their granted license or renewal be effective for three years: *Provided, however*, That the needle exchange program is still subject to random inspections by the Office of Health Facility Licensure and Certification.;

On page eleven, section ten, lines one and two, by striking out all of subsection (a);

And,

On page eleven, section ten, line three, by striking out (b).

Adopted

Rejected

Senator Stollings moved to amend the bill by striking out everything after the enacting clause and inserting in lieu thereof the following:

Article 54. Opioid reduction act.

§16-54-10. Surcharge on Schedule II Opioid Drugs.

(a) For the purpose of providing additional revenue for local health departments and other state agencies on the front lines of the opioid epidemic including, but not limited to, responsible needle exchange programs, effective counseling and rehabilitation, and necessary medical treatment, there is hereby authorized and imposed on and after the first day of July, two thousand and twenty-one, on the first sale of every opioid drug in this State a surcharge equal to one cent per pill, patch, or five cubic centimeters in liquid form of every opioid drug unit. The surcharge imposed by this section shall be charged against and paid by the manufacturer or distributor making such first sale and shall accrue at the time of such sale.

(b) There shall be a rebuttal presumption that any sale of an opioid drug unit in this State is the first sale.

(c) This opioid surcharge shall be collected and remitted to the secretary on a quarterly basis on or before the twenty-fifth day of the month succeeding the end of the quarter in which it is collected, except for the fourth quarter for which the surcharge shall be remitted on or before the first day of March of the succeeding year.

(d) Any person failing or refusing to collect and remit to the secretary any opioid surcharge and whose surcharge payments are not postmarked by the due dates for quarterly filing is liable for a civil penalty of up to one hundred dollars for each day of delinquency, to be assessed by the secretary.

(e) All money from the opioid surcharge and civil penalties shall be collected by the secretary who shall disburse the money received from the surcharge into a special account in the State Treasury, designated the Opioid Recovery Fund.

(f) The secretary shall promulgate emergency rules and propose legislative rules for legislative approval in accordance with the provision of article three, chapter twenty-nine-a of this code to effectuate the requirements of this section.

(g) There is hereby created in the State Treasury a special revenue account, which shall be an interest bearing account, to be known as the Opioid Recovery Fund. The special revenue account shall consist of the opioid surcharge, any appropriations that may be made by the Legislature, income from the

investment of moneys held in the special revenue account and all other sums available for deposit to the special revenue account from any source, public or private. No expenditures, for purposes of this section, are authorized from collections except in accordance with the provisions of article three [§§ 12-3-1 et seq.], chapter twelve of this code and upon fulfillment of the provisions set forth in article two [§§ 11B-2-1 et seq.], chapter eleven-b of this code. Any balance remaining in the special revenue account at the end of any state fiscal year does not revert to the General Revenue Fund but remains in the special revenue account and shall be used solely in a manner consistent with this article. The secretary is authorized to expend funds from the account to develop and implement effective opioid counseling, rehabilitation, and recovery programs; assist and support needle exchange programs including, but not limited to, ensuring safe and responsible needle litter disposal; assist and support local health departments in their general mission of public health and addressing the opioid epidemic; and to defray necessary expenses incidental to those and other activities associated with opioid addiction and recovery.

Article 63. Needle Exchange Programs.

§16-63-1. Definitions.

As used in this article, the term:

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

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

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

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

Core services means the primary services an entity undertakes in order to service its clients.

Director means the Director of the Office of Health Facility Licensure and Certification.

Fixed site means a building or single location where needle exchange services are provided.

Good faith means compliance with the best practices of the Centers for Disease and Control or the American Medical Association relating to syringe services programs.

Harm reduction services means services intended to lessen the adverse consequences of drug use and protect public health and safety, and includes, but is not limited to, a referral to substance disorder treatment programs, screening, care and treatment for hepatitis and HIV, education about overdose prevention, vaccinations, screening for sexually transmitted diseases, abscess wound care, Naloxone

distribution and education, and referral to social, mental, and other medical services.

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

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

License means the document issued by the Bureau authorizing the Harm Reduction Program to operate.

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

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

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

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

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

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

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

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

Service area means the territorial jurisdiction of the local board of health.

Sharps waste means used needles, syringes, and lancets.

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

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

Viral hepatitis means any of the forms of hepatitis caused by the virus, including HBV HCV.

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

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

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

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

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

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

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

(5) Provide the hours of operation of the location, and staffing;

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

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

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

(9) Pay an application fee of not more than one hundred dollars;

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

(A) Is not prohibited by local ordinance; and

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

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

§16-63-3. Program requirements.

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

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

(A) Drug abuse treatment services;

(B) HIV and hepatitis screening and education;

(C) Hepatitis A, B, and C vaccination and testing;

(D) Screening for sexually transmitted diseases;

(E) The provision of long-term birth control;

(F) The provision of behavioral health services;

(G) Overdose prevention supplies and education;

(H) Syringe collection and sharps disposal;

(I) Educational services related to disease transmission;

(J) Treatment shall be offered at every visit by a qualified licensed health care provider; (K) The applicant shall make services available for participants to facilitate the individual entering rehabilitation or detoxification;

(L) The applicant shall make the appropriate referral to existing providers for treatment of medical conditions; and

(M) Programmatic guidelines including a sharps disposal plan, a staff training plan, a data collection and program evaluation plan, and a community relations plan; and

(2) A clean syringe exchange program, including, but not limited to, the following:

(A) A dedicated staff member assigned to recover discarded syringes from the program in the service area, with the clear objective of reducing the transmission of blood-borne diseases within a specific geographic area;

(B) Exclusion of minors from participation in the program;

(C) A good faith effort to uniquely identify each needle provided by the needle exchange program with a goal to track each needle;

(D) A good faith effort to recover or otherwise assure proper and safe disposal of each needle distributed by the needle exchange program;

(E) A program or facility may substitute weighing the volume of needles returned versus dispensed as specified;

(F) This substitution is only permissible if it can be done accurately and in the following circumstances;

(i) The needles shall be contained in a clear container; and

(ii) A visual inspection of the container shall take place prior to the needles being weighed; and

(G) The licensee, whether fixed or mobile, shall distribute the needle directly to the program recipient, and shall not distribute a needle to a program recipient for another person;

(3) A staff training protocol including, but not limited to, the following:

(A) Orientation to the applicants services and eligibility requirements of the program;

(B) Overview of the needle exchange philosophy and the harm reduction model used by the program;

(C) The applicants policies and procedures that explain syringe exchange transactions; (D) Handling disposal of infectious waste and needlestick prevention management;

(E) Procedures for making referrals, including primary care, detoxification and drug treatment, HIV counseling and testing, prenatal care, tuberculosis, and Hepatitis A, B, and C screening and treatment, and screening and treatment for sexually transmitted diseases;

(F) Education that demonstrates Naloxone administration;

(G) Cultural diversity and sensitivity to protected classes under state and federal law; and (H)

Training logs for attendance at mandatory training;

(4) A syringe-dispensing plan including, but not limited to, the following that:

(A) An accounting for safe disposal of the syringes by participants for seven years;

(B) Prevents needlestick injuries;

(C) Tracks the approximate number of syringes dispensed;

(D) Tracks the number of syringes collected;

(E) Tracks the number of syringes collected as a result of community reports of needle litter;

(F) Eliminates direct handling of sharps waste;

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

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

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

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

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

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

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

That a needle exchange program which operates for at least three consecutive years without being suspended or limited pursuant to section four of this article shall have their granted license or renewal be effective for three years. Provided, however, That the needle exchange program is still subject to random inspections by the Office of Health Facility Licensure and Certification.

§16-63-4. Department of Health and Human Resources Needle Exchange Pilot Program

(a) Any licensed needle exchange program pursuant to this article may apply to the Department of Health and Human Resources to be a participant in a pilot program administered by the Department.

(b) The Department of Health and Human Resources may exempt an approved, participating needle exchange program from any requirements of this article. Provided, Any approved, participating needle exchange program shall adhere to the best practices of the Centers for Disease and Control and the American Medical Association. Provided further, That the Department shall ensure detailed monitoring and data collection of this approved, participating needle exchange program.

(c) The secretary shall promulgate emergency rules and propose legislative rules for legislative approval in accordance with the provision of article three, chapter twenty-nine-a of this code to effectuate the requirements of this section.

(d) The secretary shall submit an annual report to the Joint Committee on Health related to all approved, participating needle exchange programs.

§16-63-5. Procedure for revocation or limitation of the needle exchange program.

(a) The director may revoke or limit a needle exchange programs ability to offer services for the following reasons:

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

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

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

(4) Recission of the letter of approval from majority of the county commissioners.

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

(1) Effective date of the revocation or limitation;

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

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

(4) The remedial measures the needle exchange program shall take, if any, to consider

reinstatement of the program or removal of the limitation; and

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

§16-63-6. Reconsideration procedure.

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

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

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

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

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

(c) The director shall receive a request for reconsideration within 30 days after the date of the bureaus decision.

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

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

§16-63-7. Administrative due process.

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

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

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

(d) The filing of a request for a hearing does not stay or supersede enforcement of the final decision

of the director. The director may, upon good cause shown, stay such enforcement.

§16-63-8. Administrative appeals and judicial review.

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

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

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

§16-63-9. Reporting requirements; renewal requests.

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

(1) The total number of persons served;

(2) The total numbers and types of syringes and needles dispensed, collected, and disposed of;

(3) The total number of needlestick injuries to non-participants;

(4) Statistics regarding the number of individuals entering rehabilitation; and

(5) The total numbers and types of referrals made to drug treatment and other services.

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

(1) The current status of the project;

(2) The cause or causes of any delays encountered;

(3) Changes in the project; and

(4) The projected total cost.

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

requirements of this section. Any subsequent renewal may be granted for up to 12 months.

§16-63-10. Immunity and cost recoupment.

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

§16-63-11. Civil injunctive relief.

The Office of Health Facilities Licensure and Certification may seek injunctive relief to enforce the provisions of this article.

§16-63-12. Coordination with continuum of care.

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

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

Adopted

Rejected

Senator Tarr moved to amend the bill on page four, section two, line twenty-four, by striking out the word and;

On page four, section two, after line twenty-four, by inserting the following:

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

And by renumbering the remaining subdivision;

On page six, section three, line thirty-four, by striking out the word and;

On page six, section three, line thirty-six, after the word person; by inserting the word and;

On page six, section three, after line thirty-six, by inserting the following:

(l) Proof of West Virginia identification upon dispensing of the needles.;

On page seven, section four, line nine, after the word commissioners by inserting the words or the county sheriff;

On page eleven, section eleven, by striking out the section caption and inserting in lieu thereof the following:

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

And,

On page eleven, section eleven, after line five, by adding the following:

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

Adopted

Rejected

Senator Stollings moved to amend the bill by striking out everything after the enacting clause and inserting in lieu thereof the following:

Article 54. Opioid reduction act.

§16-54-10. Surcharge on Schedule II Opioid Drugs.

(a) For the purpose of providing additional revenue for local health departments and other state agencies on the front lines of the opioid epidemic including, but not limited to, responsible needle exchange programs, effective counseling and rehabilitation, and necessary medical treatment, there is hereby authorized and imposed on and after the first day of July, two thousand and twenty-one, on the first sale of every opioid drug in this State a surcharge equal to one cent per pill, patch, or five cubic centimeters in liquid form of every opioid drug unit. The surcharge imposed by this section shall be charged against and paid by the manufacturer or distributor making such first sale and shall accrue at the time of such sale.

(b) There shall be a rebuttal presumption that any sale of an opioid drug unit in this State is the first sale.

(c) This opioid surcharge shall be collected and remitted to the secretary on a quarterly basis on or before the twenty-fifth day of the month succeeding the end of the quarter in which it is collected, except for the fourth quarter for which the surcharge shall be remitted on or before the first day of March of the succeeding year.

(d) Any person failing or refusing to collect and remit to the secretary any opioid surcharge and whose surcharge payments are not postmarked by the due dates for quarterly filing is liable for a civil penalty of up to one hundred dollars for each day of delinquency, to be assessed by the secretary.

(e) All money from the opioid surcharge and civil penalties shall be collected by the secretary who shall disburse the money received from the surcharge into a special account in the State Treasury, designated the Opioid Recovery Fund.

(f) The secretary shall promulgate emergency rules and propose legislative rules for legislative approval in accordance with the provision of article three, chapter twenty-nine-a of this code to effectuate the requirements of this section.

(g) There is hereby created in the State Treasury a special revenue account, which shall be an interest bearing account, to be known as the Opioid Recovery Fund. The special revenue account shall consist of the opioid surcharge, any appropriations that may be made by the Legislature, income from the

investment of moneys held in the special revenue account and all other sums available for deposit to the special revenue account from any source, public or private. No expenditures, for purposes of this section, are authorized from collections except in accordance with the provisions of article three [§§ 12-3-1 et seq.], chapter twelve of this code and upon fulfillment of the provisions set forth in article two [§§ 11B-2-1 et seq.], chapter eleven-b of this code. Any balance remaining in the special revenue account at the end of any state fiscal year does not revert to the General Revenue Fund but remains in the special revenue account and shall be used solely in a manner consistent with this article. The secretary is authorized to expend funds from the account to develop and implement effective opioid counseling, rehabilitation, and recovery programs; assist and support needle exchange programs including, but not limited to, ensuring safe and responsible needle litter disposal; assist and support local health departments in their general mission of public health and addressing the opioid epidemic; and to defray necessary expenses incidental to those and other activities associated with opioid addiction and recovery.

Article 63. Needle Exchange Programs.

§16-63-1. Definitions.

As used in this article, the term:

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

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

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

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

Core services means the primary services an entity undertakes in order to service its clients.

Director means the Director of the Office of Health Facility Licensure and Certification.

Fixed site means a building or single location where needle exchange services are provided.

Good faith means compliance with the best practices of the Centers for Disease and Control or the American Medical Association relating to syringe services programs.

Harm reduction services means services intended to lessen the adverse consequences of drug use and protect public health and safety, and includes, but is not limited to, a referral to substance disorder treatment programs, screening, care and treatment for hepatitis and HIV, education about overdose prevention, vaccinations, screening for sexually transmitted diseases, abscess wound care, Naloxone

distribution and education, and referral to social, mental, and other medical services.

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

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

License means the document issued by the Bureau authorizing the Harm Reduction Program to operate.

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

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

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

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

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

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

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

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

Service area means the territorial jurisdiction of the local board of health.

Sharps waste means used needles, syringes, and lancets.

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

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

Viral hepatitis means any of the forms of hepatitis caused by the virus, including HBV HCV.

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

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

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

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

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

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

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

(5) Provide the hours of operation of the location, and staffing;

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

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

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

(9) Pay an application fee of not more than one hundred dollars;

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

(A) Is not prohibited by local ordinance; and

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

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

§16-63-3. Program requirements.

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

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

(A) Drug abuse treatment services;

(B) HIV and hepatitis screening and education;

(C) Hepatitis A, B, and C vaccination and testing;

(D) Screening for sexually transmitted diseases;

(E) The provision of long-term birth control;

(F) The provision of behavioral health services;

(G) Overdose prevention supplies and education;

(H) Syringe collection and sharps disposal;

(I) Educational services related to disease transmission;

(J) Treatment shall be offered at every visit by a qualified licensed health care provider; (K) The applicant shall make services available for participants to facilitate the individual entering rehabilitation or detoxification;

(L) The applicant shall make the appropriate referral to existing providers for treatment of medical conditions; and

(M) Programmatic guidelines including a sharps disposal plan, a staff training plan, a data collection and program evaluation plan, and a community relations plan; and

(2) A clean syringe exchange program, including, but not limited to, the following:

(A) A dedicated staff member assigned to recover discarded syringes from the program in the service area, with the clear objective of reducing the transmission of blood-borne diseases within a specific geographic area;

(B) Exclusion of minors from participation in the program;

(C) A good faith effort to uniquely identify each needle provided by the needle exchange program with a goal to track each needle;

(D) A good faith effort to recover or otherwise assure proper and safe disposal of each needle distributed by the needle exchange program;

(E) A program or facility may substitute weighing the volume of needles returned versus dispensed as specified;

(F) This substitution is only permissible if it can be done accurately and in the following circumstances;

(i) The needles shall be contained in a clear container; and

(ii) A visual inspection of the container shall take place prior to the needles being weighed; and

(G) The licensee, whether fixed or mobile, shall distribute the needle directly to the program recipient, and shall not distribute a needle to a program recipient for another person;

(3) A staff training protocol including, but not limited to, the following:

(A) Orientation to the applicants services and eligibility requirements of the program;

(B) Overview of the needle exchange philosophy and the harm reduction model used by the program;

(C) The applicants policies and procedures that explain syringe exchange transactions; (D) Handling disposal of infectious waste and needlestick prevention management;

(E) Procedures for making referrals, including primary care, detoxification and drug treatment, HIV counseling and testing, prenatal care, tuberculosis, and Hepatitis A, B, and C screening and treatment, and screening and treatment for sexually transmitted diseases;

(F) Education that demonstrates Naloxone administration;

(G) Cultural diversity and sensitivity to protected classes under state and federal law; and (H)

Training logs for attendance at mandatory training;

(4) A syringe-dispensing plan including, but not limited to, the following that:

(A) An accounting for safe disposal of the syringes by participants for seven years;

(B) Prevents needlestick injuries;

(C) Tracks the approximate number of syringes dispensed;

(D) Tracks the number of syringes collected;

(E) Tracks the number of syringes collected as a result of community reports of needle litter;

(F) Eliminates direct handling of sharps waste;

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

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

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

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

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

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

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

That a needle exchange program which operates for at least three consecutive years without being suspended or limited pursuant to section four of this article shall have their granted license or renewal be effective for three years. Provided, however, That the needle exchange program is still subject to random inspections by the Office of Health Facility Licensure and Certification.

§16-63-4. Department of Health and Human Resources Needle Exchange Pilot Program

(a) Any licensed needle exchange program pursuant to this article may apply to the Department of Health and Human Resources to be a participant in a pilot program administered by the Department.

(b) The Department of Health and Human Resources may exempt an approved, participating needle exchange program from any requirements of this article. Provided, Any approved, participating needle exchange program shall adhere to the best practices of the Centers for Disease and Control and the American Medical Association. Provided further, That the Department shall ensure detailed monitoring and data collection of this approved, participating needle exchange program.

(c) The secretary shall promulgate emergency rules and propose legislative rules for legislative approval in accordance with the provision of article three, chapter twenty-nine-a of this code to effectuate the requirements of this section.

(d) The secretary shall submit an annual report to the Joint Committee on Health related to all approved, participating needle exchange programs.

§16-63-5. Procedure for revocation or limitation of the needle exchange program.

(a) The director may revoke or limit a needle exchange programs ability to offer services for the following reasons:

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

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

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

(4) Recission of the letter of approval from majority of the county commissioners.

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

(1) Effective date of the revocation or limitation;

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

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

(4) The remedial measures the needle exchange program shall take, if any, to consider

reinstatement of the program or removal of the limitation; and

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

§16-63-6. Reconsideration procedure.

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

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

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

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

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

(c) The director shall receive a request for reconsideration within 30 days after the date of the bureaus decision.

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

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

§16-63-7. Administrative due process.

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

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

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

(d) The filing of a request for a hearing does not stay or supersede enforcement of the final decision

of the director. The director may, upon good cause shown, stay such enforcement.

§16-63-8. Administrative appeals and judicial review.

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

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

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

§16-63-9. Reporting requirements; renewal requests.

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

(1) The total number of persons served;

(2) The total numbers and types of syringes and needles dispensed, collected, and disposed of;

(3) The total number of needlestick injuries to non-participants;

(4) Statistics regarding the number of individuals entering rehabilitation; and

(5) The total numbers and types of referrals made to drug treatment and other services.

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

(1) The current status of the project;

(2) The cause or causes of any delays encountered;

(3) Changes in the project; and

(4) The projected total cost.

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

requirements of this section. Any subsequent renewal may be granted for up to 12 months.

§16-63-10. Immunity and cost recoupment.

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

§16-63-11. Civil injunctive relief.

The Office of Health Facilities Licensure and Certification may seek injunctive relief to enforce the provisions of this article.

§16-63-12. Coordination with continuum of care.

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

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

Adopted

Rejected

Senator Lindsay moved to amend the bill on page seven, section three, line seventy-one, after the word licensee by changing the period to a colon and inserting the following proviso: *Provided*, That a needle exchange program which operates for at least three consecutive years without being suspended or limited pursuant to section four of this article shall have their granted license or renewal be effective for three years: *Provided, however*, That the needle exchange program is still subject to random inspections by the Office of Health Facility Licensure and Certification.;

On page eleven, section ten, lines one and two, by striking out all of subsection (a);

And,

On page eleven, section ten, line three, by striking out (b).

Adopted

Rejected

Senator Lindsay moved to amend the bill on page seven, section three, line seventy-one, after the word licensee by changing the period to a colon and inserting the following proviso: *Provided*, That a needle exchange program which operates for at least three consecutive years without being suspended or limited pursuant to section four of this article shall have their granted license or renewal be effective for three years. *Provided however*, That the needle exchange program is still subject to random inspections by the Office of Health Facility Licensure and Certification.;

On page eleven, section ten, lines one and two, by striking out all of subsection (a);

And, on page eleven, section ten, line three, by striking out (b).

Adopted

Rejected

Senator Tarr moved to amend the bill on page four, section two, line twenty-four, by striking out the word and;

On page four, section two, after line twenty-four, by inserting the following:

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

And by renumbering the remaining subdivision;

On page six, section three, line thirty-four, by striking out the word and;

On page six, section three, line thirty-six, after the word person; by inserting the word and;

On page six, section three, after line thirty-six, by inserting the following:

(l) Proof of West Virginia identification upon dispensing of the needles.;

On page seven, section four, line nine, after the word commissioners by inserting the words or the county sheriff;

On page eleven, section eleven, by striking out the section caption and inserting in lieu thereof the following:

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

And,

On page eleven, section eleven, after line five, by adding the following:

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

Adopted

Rejected

The Committee on Health and Human Resources moved to amend the bill on page 1, by striking everything after the enacting clause and inserting in lieu thereof the following:

" Article 63. Syringe services programs.

§16-63-1. Definitions.

As used in this article, the term:

Administrator means a person having the authority and responsibility for operation of the syringe services program and serves as the contact for communication with the director of the Harm Reduction Program.

Applicant means the entity applying for a license under this article.

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

Director means the Director of the Office of Health Facility Licensure and Certification.

Fixed site means a building or single location where syringe exchange services are provided.

Harm reduction program means a program that provides services intended to lessen the adverse consequences of drug use and protect public health and safety, by providing direct access to or a referral to: syringe services program; substance use disorder treatment programs; screenings; vaccinations; education about overdose prevention; wound care; opioid antagonist distribution and education; and other medical services.

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

License means the document issued by the office authorizing the syringe services program to operate.

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

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

Mobile site means a location accessible by foot or vehicle that is not at a fixed indoor setting.

Syringe services program means a community based program that provides access to sterile syringes, facilitates safe disposal of used syringes, and is part of a harm reduction program.

Syringe stick injury means a penetrating wound from a syringe that may result in exposure to blood.

Syringe stick injury protocol means policies and procedures to prevent syringe stick injury to

syringe exchange staff, including volunteers, community members, and to syringe exchange participants.

Service area means the territorial jurisdiction of the syringe services program.

Sharps waste means used syringes and lancets.

Staff means a person who provides syringe services or harm reduction services on behalf of a program.

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

§16-63-2. Application for license to offer a syringe services program.

(a) All new and existing syringe services programs shall obtain a license from the Office for Health Facility Licensure and Certification.

(b) To be eligible for a license, a syringe services program shall:

(1) Submit an application on a form approved and provided by the office director;

(2) Provide the name of the program;

(3) Provide a description of the harm reduction program it is associated with and the harm reduction services provided in accordance with §16-2-3;

(4) Provide the contact information of the individual designated by the applicant as the administrator of the harm reduction program;

(5) Provide the hours of operation, location, and staffing. The description of hours of operation must include the specific days the syringe services program is open, opening and closing times, and frequency of syringe exchange services. The description of staffing must include number of staff, titles of positions, and descriptions of their functions;

(6) Provide a specific description of the applicants ability to refer to or facilitate entry into substance use treatment;

(7) Provide a specific description of the applicants ability to encourage usage of medical care and mental health services as well as social welfare and health promotion;

(8) Pay an application fee in amount not to exceed \$500, to be determined by the director by legislative rule; and

(9) Provide a written statement from a majority of the county commission or a majority of governing body of a municipality in which it is located or is proposing to locate, that the needle exchange program.

§16-63-3. Program requirements.

(a) To be approved for a license, a syringe services program shall be part of a harm reduction program which offers or refers an individual to the following services which shall be documented in the application:

(1) HIV, hepatitis and sexually transmitted diseases screening;
(2) Vaccinations;
(3) Birth control and long-term birth control;
(4) Behavioral health services;
(E) Overdose prevention supplies and education;
(F) Syringe collection and sharps disposal;
(G) Educational services related to disease transmission;
(H) Assist or refer an individual to a substance use treatment program;
(I) Refer to a health care practitioner or treat medical conditions; and
(J) Programmatic guidelines including a sharps disposal plan, a staff training plan, a data collection and program evaluation plan, and a community relations plan.

(b) A syringe services program:

(1) Shall offer services, at every visit, by a qualified licensed health care provider;
(2) Shall exclude minors from participation in the syringe exchange, but may provide minors with harm reduction services;

(3) Shall ensure a syringe is unique to the syringe services programs;
(4) Shall distribute syringes with a goal of a 1:1 model;
(5) May substitute weighing the volume of syringes returned versus dispensed as specified. This substitution is only permissible if it can be done accurately and in the following manner:

(A) The syringes shall be contained in a see-through container; and
(B) A visual inspection of the container shall take place prior to the syringes being weighed;

(6) Shall distribute the syringe directly to the program recipient;
(7) Shall require proof of West Virginia identification upon providing the syringe;

(8) Shall train staff on:

(A) The services and eligibility requirements of the program;
(B) The services provided by the program;
(C) The applicants policies and procedures concerning syringe exchange transactions;

(D) Disposing of infectious waste;

(E) Sharps waste disposal education that ensures familiarity with the state law regulating proper disposal of home-generated sharps waste;

(F) Procedures for obtaining or making referrals;

(G) Opioid antagonist administration;

(H) Cultural diversity and sensitivity to protected classes under state and federal law; and

(I) Completion of attendance logs for participation in mandatory training.

(9) Maintain a program for the public to report syringe litter and shall endeavor to collect all syringe litter in the community.

(c) A syringe dispensing plan including, but not limited to:

(1) Maintain records of returned syringes by participants for two years;

(2) Prevention of syringe stick injuries;

(3) Tracking the number of syringes dispensed;

(4) Tracking the number of syringes collected;

(5) Tracking the number of syringes collected as a result of community reports of syringe litter;

(6) Eliminating direct handling of sharps waste;

(7) Following a syringe stick protocol and plan;

(8) A budget for sharps waste disposal or an explanation if no cost is associated with sharps waste disposal; and

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

(d) If an applicant does not submit all of the documentation required in §16-63-2 of this code, the application shall be denied and returned to the applicant for completion.

(e) If an applicant fails to comply with the program requirements, the application shall be denied and returned to the applicant for completion.

(f) A license is effective for one year.

§16-63-4. Procedure for revocation or limitation of the syringe services programs.

(a) The director may revoke, suspend or limit a syringe services program's ability to offer services for the following reasons:

(1) The syringe services program provides false or misleading information to the director;

(2) An inspection indicates the syringe services program is in violation of the law or legislative rule;

or

(3) The syringe services program fails to cooperate with the director during a complaint investigation.

(b) The director shall send written notice to the syringe services program of revocation, suspension, or limitation of its operations. The written notice shall include the following:

(1) Effective date of the revocation, suspension, or limitation;

(2) The basis for the revocation, suspension or limitation;

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

(4) The remedial measures the syringe services programs shall take, if any, to consider reinstatement of the program or removal of the limitation; and

(5) Steps to appeal of the decision.

§16-63-5. Administrative due process.

(a) A syringe services program who disagrees with an administrative decision may, within 30 days after receiving notice of the decision, appeal the decision to the departments board of review.

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

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

§16-63-6. Administrative appeals and judicial review.

(a) A syringe services program who disagrees with the final administrative decision may, within 30 days after the date the appellant received notice of the decision of the board of review, appeal the decision to the Circuit Court of Kanawha County or in the county where the petitioner resides or does business.

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

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

§16-63-7. Reporting requirements; renewal; rulemaking.

(a) A syringe services program shall renew its license annually on the anniversary date of license approval.

(b) A syringe services program shall file an annual report with the director. The report shall include:

(1) The total number of persons served;

(2) The total numbers and types of syringes and syringe s dispensed, collected, and disposed of;

(3) The total number of syringe stick injuries to non-participants;

(4) Statistics regarding the number of individuals entering substance use treatment; and

(5) The total and types of referrals made to substance use treatment and other services.

(c) The office shall promulgate an emergency rule by July 1, 2021, which shall require compliance of the provisions of this article by December 1, 2021. The emergency rule shall effectuate the provisions of this article in accordance with evidence-based practices.

§16-63-8. Immunity.

(a) Notwithstanding any provision of this code to the contrary, an employee, volunteer, or participant of a licensed syringe services program may not be arrested, charged with or prosecuted for possession of any of the following:

(1) Sterile or used syringes, hypodermic syringes, injection supplies obtained from or returned to a program, or other safer drug use materials obtained from a program established pursuant to this article, including testing supplies for illicit substances.

(2) Residual amounts of a controlled substance contained in a used syringe, used injection supplies obtained from or returned to a program.

(b) A law enforcement officer who, acting on good faith, arrests or charges a person who is thereafter determined to be entitled to immunity from prosecution under this section is not liable for the arrest or filing of charges.

(c) An individual who is wrongly detained, arrested or prosecuted under this section shall have the public record associated with the detainment, arrest or prosecution expunged.

(d) A health care professional, or an employee or volunteer of a licensed syringe services program is not subject to professional sanction, detainment, arrest or prosecution for carrying out the provisions of this article.

§16-63-9. Civil penalties and injunctive relief.

(a) The Office of Health Facilities Licensure and Certification may assess an administrative penalty of not less than \$10 nor more than \$500 per a violation of this article.

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

(c) Any person who operates in this state without a license or operates under a license that has been inactive, revoked, or suspended as a result of disciplinary action, or surrendered to the office, is guilty of a misdemeanor and, upon conviction, shall be fined not more than \$10,000 or imprisoned in a correctional facility for not more than one year, or both fined and imprisoned.

§16-63-10. Coordination of care.

(a) A syringe service program shall coordinate with other health care providers in its services to render care to the individuals as set forth in the program requirements.

(b) In the event that the syringe services program is closed, the syringe services program shall notify the participant of the closure of the service, prior to closure, in a conspicuous location, and provide an individual with a transition care plan.

(c) The Bureau for Medical Service shall submit a state plan amendment to permit harm programs to be an eligible provider.