# **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]

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 harm reduction programs; creating definitions; establishing licensure application process for harm reduction programs; setting forth prohibition on the receipt of state funds; 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 and cost recoupment for businesses; and establishing civil penalties, criminal penalties, and injunctive relief.

Be it enacted by the Legislature of West Virginia:

## **ARTICLE 63. HARM REDUCTION PROGRAMS.**

### §16-63-1. Definitions.

1 <u>As used in this article, the term:</u>

"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, hepatitis C virus, and human immunodeficiency virus (HIV).

"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, not a mobile site, where harm reduction
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, this may include but not be limited to a syringe exchange program but expressly excludes what is sometimes referred to 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 me (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.

(12) Provide letters of support from:

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

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

(13) 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;

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

## §16-63-3 Program requirements.

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

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

(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 littler, that eliminates

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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 <u>following reasons:</u> (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 <u>large;</u> (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.

(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.

#### §16-63-6. Administrative Due Process.

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- (a) An owner or operator of a harm reduction program who disagrees with the final
   administrative decision may, within 30 days after receiving notice of the decision, appeal the
   decision to the Department's Board of Review.
  - (b) The harm reduction program shall be required, at their cost, to be represented by legal counsel at the hearing.
  - (c) All pertinent provisions of §29A-5-1 et seq. and §69-1-1 et seq. 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.
- (e) If the Director does not rule in favor of the owner or operator of the harm reduction

  program, the owner or operator of the harm reduction program will be required to reimburse the

  Department for any expenses incurred by the Department that are directly related to the final appeal.

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

- (a) An owner or operator of a harm reduction 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 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

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

may be granted for up to 12 months.

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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.