

# **WEST VIRGINIA LEGISLATURE**

## **2024 REGULAR SESSION**

**Introduced**

### **Senate Bill 295**

By Senators Tarr and Stuart

[Introduced January 11, 2024; referred  
to the Committee on the Health and Human  
Resources]

1 A BILL to amend and reenact §16-5Y-2, §16-5Y-3, §16-5Y-5, §16-5Y-6, §16-5Y-7, and §16-5Y-13  
 2 of the Code of West Virginia, 1931, as amended; and to amend said code by adding  
 3 thereto a new article, designated §16-5EE-1, §16-5EE-2, §16-5EE-3, and §16-5EE-4, all  
 4 relating to opioid treatment programs; defining terms; making opioid treatment programs  
 5 unlawful; allowing for an administrative time frame for referral; requiring the imposition of  
 6 fees for noncompliance; and permitting injunctive relief.

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

**ARTICLE 5Y. MEDICATION ASSISTED TREATMENT PROGRAM LICENSING ACT.**

**§16-5Y-2. Definitions.**

1 "Addiction" means a primary, chronic disease of brain reward, motivation, memory, and  
 2 related circuitry. Dysfunction in these circuits leads to characteristic biological, psychological,  
 3 social, and spiritual manifestations which is reflected in an individual pathologically pursuing  
 4 reward or relief by substance use, or both, and other behaviors. Addiction is characterized by  
 5 inability to consistently abstain; impairment in behavioral control; craving; diminished recognition  
 6 of significant problems with one's behaviors; interpersonal problems with one's behaviors and  
 7 interpersonal relationships; a dysfunctional emotional response; and as addiction is currently  
 8 defined by the American Society of Addiction Medicine.

9 "Administrator" means an individual designated by the governing body to be responsible  
 10 for the day-to-day operation of the opioid medication-assisted treatment programs.

11 "Advanced alcohol and drug abuse counselor" means an alcohol and drug abuse  
 12 counselor who is certified by the West Virginia Certification Board for Addiction and Prevention  
 13 Professionals who demonstrates a high degree of competence in the addiction counseling field.

14 "Alcohol and drug abuse counselor" means a counselor certified by the West Virginia  
 15 Certification Board for Addiction and Prevention Professionals for specialized work with patients  
 16 who have substance use problems.

17 "Biopsychosocial" means of, relating to, or concerned with, biological, psychological, and

18 social aspects in contrast to the strictly biomedical aspects of disease.

19 "Center for Substance Abuse Treatment" means the center under the Substance Abuse  
20 and Mental Health Services Administration that promotes community-based substance abuse  
21 treatment and recovery services for individuals and families in the community and provides  
22 national leadership to improve access, reduce barriers, and promote high quality, effective  
23 treatment and recovery services.

24 "Controlled Substances Monitoring Program Database" means the database maintained  
25 by the West Virginia Board of Pharmacy pursuant to §60A-9-3 of this code that monitors and tracks  
26 certain prescriptions written or dispensed by dispensers and prescribers in West Virginia.

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

28 "Dispense" means the preparation and delivery of a medication-assisted treatment  
29 medication in an appropriately labeled and suitable container to a patient by a medication-assisted  
30 treatment program or pharmacist.

31 "Governing body" means the person or persons identified as being legally responsible for  
32 the operation of the ~~opioid~~ medication-assisted treatment program. A governing body may be a  
33 board, a single entity or owner, or a partnership. The governing body must comply with the  
34 requirements prescribed in rules promulgated pursuant to this article.

35 "Medical director" means a physician licensed within the State of West Virginia who  
36 assumes responsibility for administering all medical services performed by the medication-  
37 assisted treatment program, either by performing them directly or by delegating specific  
38 responsibility to authorized program physicians and health care professionals functioning under  
39 the medical director's direct supervision and functioning within their scope of practice.

40 "Medication-assisted treatment" means the use of medications and drug screens, in  
41 combination with counseling and behavioral therapies, to provide a holistic approach to the  
42 treatment of substance use disorders.

43 "Medication-assisted treatment program" means all publicly and privately owned ~~opioid~~

44 ~~treatment programs~~ and office-based, medication-assisted treatment programs, which prescribe  
45 medication-assisted treatment medications and treat substance use disorders, as those terms are  
46 defined in this article.

47 "Medication-assisted treatment medication" means any medication, excluding methadone,  
48 that is approved by the United States Food and Drug Administration under Section 505 of the  
49 Federal Food, Drug and Cosmetic Act, 21 U. S. C. § 355, for use in the treatment of substance use  
50 disorders that is an opioid agonist or partial opioid agonist and is listed on the Schedule of  
51 Controlled Substances in §60A-2-2201 et seq. of this code.

52 "Office-based, medication-assisted treatment" means all publicly or privately owned  
53 clinics, facilities, offices, or programs that provide medication-assisted treatment to individuals  
54 with substance use disorders through the prescription, administration, or dispensing of a  
55 medication-assisted treatment medication in the form of a partial opioid agonist.

56 "Opioid agonist" means substances that bind to and activate the opiate receptors resulting  
57 in analgesia and pain regulation, respiratory depression, and a wide variety of behavioral  
58 changes. As used in this article, the term "opioid agonist" does not include partial agonist  
59 medications used as an alternative to opioid agonists in the treatment of opioid addiction.

60 ~~"Opioid treatment program" means all publicly or privately owned medication-assisted~~  
61 ~~treatment programs in clinics, facilities, offices, or programs that provide medication-assisted~~  
62 ~~treatment to individuals with substance use disorders through on-site administration or dispensing~~  
63 ~~of a medication-assisted treatment medication in the form of an opioid agonist or partial opioid~~  
64 ~~agonist.~~

65 "Owner" means any person, partnership, association, or corporation listed as the owner of  
66 a medication-assisted treatment program on the licensing or registration forms required by this  
67 article.

68 "Partial opioid agonist" means a Federal Drug Administration approved medication that is  
69 used as an alternative to opioid agonists for the treatment of substance use disorders and that

70 binds to and activates opiate receptors, but not to the same degree as full agonists.

71 "Physician" means an individual licensed in this state to practice allopathic medicine or  
72 surgery by the West Virginia Board of Medicine or osteopathic medicine or surgery by the West  
73 Virginia Board of Osteopathic Medicine and that meets the requirements of this article.

74 "Prescriber" means a person authorized in this state, working within their scope of practice,  
75 to give direction, either orally or in writing, for the preparation and administration of a remedy to be  
76 used in the treatment of substance use disorders.

77 ~~"Program sponsor" means the person named in the application for the certification and~~  
78 ~~licensure of an opioid treatment program who is responsible for the administrative operation of the~~  
79 ~~opioid treatment program and who assumes responsibility for all of its employees, including any~~  
80 ~~practitioners, agents, or other persons providing medical, rehabilitative, or counseling services at~~  
81 ~~the program.~~

82 "Secretary" means the Secretary of the West Virginia Department of Health and Human  
83 Resources or his or her designee.

84 "State opioid treatment authority" means the agency or individual designated by the  
85 Governor to exercise the responsibility and authority of the state for governing the treatment of  
86 substance use disorders, including, but not limited to, the treatment of opiate addiction with opioid  
87 drugs.

88 "State oversight agency" means the agency or office of state government identified by the  
89 secretary to provide regulatory oversight of medication-assisted treatment programs on behalf of  
90 the State of West Virginia.

91 "Substance" means the following:

92 (1) Alcohol;

93 (2) Controlled substances defined by §60A-2-204, §60A-2-206, §60A-2-208, and §60A-2-  
94 210 of this code; or

95 (3) Any chemical, gas, drug, or medication consumed which causes clinically and

96 functionally significant impairment, such as health problems, disability, and failure to meet major  
97 responsibilities at work, school, or home.

98 "Substance Abuse and Mental Health Services Administration" means the agency under  
99 the United States Department of Health and Human Services responsible for the accreditation and  
100 certification of medication-assisted treatment programs and that provides leadership, resources,  
101 programs, policies, information, data, contracts, and grants for the purpose of reducing the impact  
102 of substance abuse and mental or behavioral illness.

103 "Substance use disorder" means patterns of symptoms resulting from use of a substance  
104 that the individual continues to take, despite experiencing problems as a result; or as defined in the  
105 most recent edition of the American Psychiatric Association's Diagnostic and Statistical Manual of  
106 Mental Disorders.

107 "Telehealth" means the mode of delivering health care services and public health via  
108 information and communication technologies to facilitate the diagnosis, consultation, treatment  
109 education, care management, and self-management of a patient's health care while the patient is  
110 at the originating site and the health care provider is at a distant site.

111 "Variance" means written permission granted by the secretary to a medication-assisted  
112 treatment program that a requirement of this article or rules promulgated pursuant to this article  
113 may be accomplished in a manner different from the manner set forth in this article or associated  
114 rules.

115 "Waiver" means a formal, time-limited agreement between the designated oversight  
116 agency and the medication-assisted treatment program that suspends a rule, policy, or standard  
117 for a specific situation so long as the health and safety of patients is better served in the situation  
118 by suspension of the rule, policy, or standard than by enforcement.

**§16-5Y-3. Opioid treatment programs to obtain license; application; fees and inspections.**

1 [Repealed.]

**§16-5Y-5. Operational requirements.**

1 (a) The medication-assisted treatment program shall be licensed and registered in this  
2 state with the secretary, the Secretary of State, the State Tax Department, and all other applicable  
3 business or licensing entities.

4 (b) The program sponsor need not be a licensed physician but shall employ a licensed  
5 physician for the position of medical director, when required by the rules promulgated pursuant to  
6 this article.

7 (c) Each medication-assisted treatment program shall designate a medical director. If the  
8 medication-assisted treatment program is accredited by a Substance Abuse and Mental Health  
9 Services Administration approved accrediting body that meets nationally accepted standards for  
10 providing medication-assisted treatment, including the Commission on Accreditation of  
11 Rehabilitation Facilities or the Joint Commission on Accreditation of Healthcare Organizations,  
12 then the program may designate a medical director to oversee all facilities associated with the  
13 accredited medication-assisted treatment program. The medical director shall be responsible for  
14 the operation of the medication-assisted treatment program, as further specified in the rules  
15 promulgated pursuant to this article. He or she may delegate the day-to-day operation of a  
16 medication-assisted treatment program as provided in rules promulgated pursuant to this article.  
17 Within 10 days after termination of a medical director, the medication-assisted treatment program  
18 shall notify the director of the identity of another medical director for that program. Failure to have  
19 a medical director practicing at the program may be the basis for a suspension or revocation of the  
20 program license. The medical director shall:

21 (1) Have a full, active, and unencumbered license to practice allopathic medicine or  
22 surgery from the West Virginia Board of Medicine or to practice osteopathic medicine or surgery  
23 from the West Virginia Board of Osteopathic Medicine in this state and be in good standing and not  
24 under any probationary restrictions;

25 (2) Meet both of the following training requirements:

26 (A) If the physician prescribes a partial opioid agonist, he or she shall complete the

27 requirements for the Drug Addiction Treatment Act of 2000; and

28 (B) Complete other programs and continuing education requirements as further described  
29 in the rules promulgated pursuant to this article;

30 (3) Practice at the licensed or registered medication-assisted treatment program a  
31 sufficient number of hours, based upon the type of medication-assisted treatment license or  
32 registration issued pursuant to this article, to ensure regulatory compliance, and carry out those  
33 duties specifically assigned to the medical director as further described in the rules promulgated  
34 pursuant to this article;

35 (4) Be responsible for monitoring and ensuring compliance with all requirements related to  
36 the licensing and operation of the medication-assisted treatment program;

37 (5) Supervise, control, and direct the activities of each individual working or operating at  
38 the medication-assisted treatment program, including any employee, volunteer, or individual  
39 under contract, who provides medication-assisted treatment at the program or is associated with  
40 the provision of that treatment. The supervision, control, and direction shall be provided in  
41 accordance with rules promulgated by the secretary; and

42 (6) Complete other requirements prescribed by the secretary by rule.

43 (d) Each medication-assisted treatment program shall designate counseling staff, either  
44 employees, or those used on a referral-basis by the program, which meet the requirements of this  
45 article and the rules promulgated pursuant to this article. The individual members of the  
46 counseling staff shall have one or more of the following qualifications:

47 (1) Be a licensed psychiatrist;

48 (2) Certification as an alcohol and drug counselor;

49 (3) Certification as an advanced alcohol and drug counselor;

50 (4) Be a counselor, psychologist, marriage and family therapist, or social worker with a  
51 master's level education with a specialty or specific training in treatment for substance use  
52 disorders, as further described in the rules promulgated pursuant to this article;



53           (5) Under the direct supervision of an advanced alcohol and drug counselor, be a  
54 counselor with a bachelor's degree in social work or another relevant human services field:  
55 *Provided*, That the individual practicing with a bachelor's degree under supervision applies for  
56 certification as an alcohol and drug counselor within three years of the date of employment as a  
57 counselor;

58           (6) Be a counselor with a graduate degree actively working toward licensure or certification  
59 in the individual's chosen field under supervision of a licensed or certified professional in that field  
60 and/or advanced alcohol and drug counselor;

61           (7) Be a psych-mental health nurse practitioner or a psych-mental health clinical nurse  
62 specialist; or

63           (8) Be a psychiatry CAQ-certified physician assistant.

64           (e) The medication-assisted treatment program shall be eligible for, and not prohibited  
65 from, enrollment with West Virginia Medicaid and other private insurance. Prior to directly billing a  
66 patient for any medication-assisted treatment, a medication-assisted treatment program must  
67 receive either a rejection of prior authorization, rejection of a submitted claim, or a written denial  
68 from a patient's insurer or West Virginia Medicaid denying coverage for such treatment: *Provided*,  
69 That the secretary may grant a variance from this requirement pursuant to §15-5Y-6 of this code.  
70 The program shall also document whether a patient has no insurance. At the option of the  
71 medication-assisted treatment program, treatment may commence prior to billing.

72           (f) The medication-assisted treatment program shall apply for and receive approval as  
73 required from the United States Drug Enforcement Administration, Center for Substance Abuse  
74 Treatment, or an organization designated by Substance Abuse and Mental Health and Mental  
75 Health Administration.

76           (g) All persons employed by the medication-assisted treatment program shall comply with  
77 the requirements for the operation of a medication-assisted treatment program established within  
78 this article or by any rule adopted pursuant to this article.

79 ~~(h) All employees of an opioid treatment program shall furnish fingerprints for a state and~~  
80 ~~federal criminal records check by the Criminal Identification Bureau of the West Virginia State~~  
81 ~~Police and the Federal Bureau of Investigation. The fingerprints shall be accompanied by a signed~~  
82 ~~authorization for the release of information and retention of the fingerprints by the Criminal~~  
83 ~~Identification Bureau and the Federal Bureau of Investigation. The opioid treatment program shall~~  
84 ~~be subject to the provisions of §16-49-1 et seq. of this code and subsequent rules promulgated~~  
85 ~~thereunder.~~

86 ~~(h)~~ (h) The medication-assisted treatment program shall not be owned by, nor shall it  
87 employ or associate with, any physician or prescriber:

88 (1) Whose Drug Enforcement Administration number is not currently full, active, and  
89 unencumbered;

90 (2) Whose application for a license to prescribe, dispense, or administer a controlled  
91 substance has been denied by and is not full, active, and unencumbered in any jurisdiction; or

92 (3) Whose license is anything other than a full, active, and unencumbered license to  
93 practice allopathic medicine or surgery by the West Virginia Board of Medicine or osteopathic  
94 medicine or surgery by the West Virginia Board of Osteopathic Medicine in this state, and who is in  
95 good standing and not under any probationary restrictions.

96 ~~(j)~~ (i) A person may not dispense any medication-assisted treatment medication, including  
97 a controlled substance as defined by §60A-1-101 of this code, on the premises of a licensed  
98 medication-assisted treatment program, unless he or she is a physician or pharmacist licensed in  
99 this state and employed by the medication-assisted treatment program unless the medication-  
100 assisted treatment program is a federally certified narcotic treatment program. Prior to dispensing  
101 or prescribing medication-assisted treatment medications, the treating physician must access the  
102 Controlled Substances Monitoring Program Database to ensure the patient is not seeking  
103 medication-assisted treatment medications that are controlled substances from multiple sources  
104 and to assess potential adverse drug interactions, or both. Prior to dispensing or prescribing

105 medication-assisted treatment medications, the treating physician shall also ensure that the  
106 medication-assisted treatment medication utilized is related to an appropriate diagnosis of a  
107 substance use disorder and approved for such usage. The physician shall also review the  
108 Controlled Substances Monitoring Program Database no less than quarterly and at each patient's  
109 physical examination. The results obtained from the Controlled Substances Monitoring Program  
110 Database shall be maintained with the patient's medical records.

111 ~~(k)~~ (j) A medication-assisted treatment program responsible for medication administration  
112 shall comply with:

- 113 (1) The West Virginia Board of Pharmacy regulations;
- 114 (2) The West Virginia Board of Examiners for Registered Professional Nurses regulations;
- 115 (3) All applicable federal laws and regulations relating to controlled substances; and
- 116 (4) Any requirements as specified in the rules promulgated pursuant to this article.

117 ~~(j)~~ (k) Each medication-assisted treatment program location shall be licensed separately,  
118 regardless of whether the program is operated under the same business name or management as  
119 another program.

120 ~~(m)~~ (l) The medication-assisted treatment program shall develop and implement patient  
121 protocols, treatment plans, or treatment strategies and profiles, which shall include, but not be  
122 limited by, the following guidelines:

123 (1) When a physician diagnoses an individual as having a substance use disorder, the  
124 physician may treat the substance use disorder by managing it with medication in doses not  
125 exceeding those approved by the United States Food and Drug Administration as indicated for the  
126 treatment of substance use disorders and not greater than those amounts described in the rules  
127 promulgated pursuant to this article. The treating physician and treating counselor's diagnoses  
128 and treatment decisions shall be made according to accepted and prevailing standards for  
129 medical care;

130 (2) The medication-assisted treatment program shall maintain a record of all of the

131 following:

132 (A) Medical history and physical examination of the individual;

133 (B) The diagnosis of substance use disorder of the individual;

134 (C) The plan of treatment proposed, the patient's response to the treatment, and any  
135 modification to the plan of treatment;

136 (D) The dates on which any medications were prescribed, dispensed, or administered, the  
137 name and address of the individual for whom the medications were prescribed, dispensed, or  
138 administered, and the amounts and dosage forms for any medications prescribed, dispensed, or  
139 administered;

140 (E) A copy of the report made by the physician or counselor to whom referral for evaluation  
141 was made, if applicable; and

142 (F) A copy of the coordination of care agreement, which is to be signed by the patient,  
143 treating physician, and treating counselor. If a change of treating physician or treating counselor  
144 takes place, a new agreement must be signed. The coordination of care agreement must be  
145 updated or reviewed at least annually. If the coordination of care agreement is reviewed, but not  
146 updated, this review must be documented in the patient's record. The coordination of care  
147 agreement will be provided in a form prescribed and made available by the secretary;

148 (3) Medication-assisted treatment programs shall report information, data, statistics, and  
149 other information as directed in this code, and the rules promulgated pursuant to this article to  
150 required agencies and other authorities;

151 (4) A prescriber authorized to prescribe a medication-assisted treatment medication who  
152 practices at a medication-assisted treatment program is responsible for maintaining the control  
153 and security of his or her prescription blanks and any other method used for prescribing a  
154 medication-assisted treatment medication. The prescriber shall comply with all state and federal  
155 requirements for tamper-resistant prescription paper. In addition to any other requirements  
156 imposed by statute or rule, the prescriber shall notify the secretary and appropriate law-

157 enforcement agencies in writing within 24 hours following any theft or loss of a prescription blank  
158 or breach of any other method of prescribing a medication-assisted treatment medication; and

159 (5) The medication-assisted treatment program shall have a drug testing program to  
160 ensure a patient is in compliance with the treatment strategy.

161 ~~(n) Medication-assisted treatment programs shall only prescribe, dispense, or administer~~  
162 ~~liquid methadone to patients pursuant to the restrictions and requirements of the rules~~  
163 ~~promulgated pursuant to this article.~~

164 ~~(o) (m)~~ The medication-assisted treatment program shall immediately notify the secretary,  
165 or his or her designee, in writing of any changes to its operations that affect the medication-  
166 assisted treatment program's continued compliance with the certification and licensure  
167 requirements.

168 ~~(p) (n)~~ If a physician treats a patient with more than 16 milligrams per day of buprenorphine  
169 then clear medical notes shall be placed in the patient's medical file indicating the clinical reason  
170 or reasons for the higher level of dosage.

171 ~~(q) (o)~~ If a physician is not the patient's obstetrical or gynecological provider, the physician  
172 shall consult with the patient's obstetrical or gynecological provider to the extent possible to  
173 determine whether the prescription is appropriate for the patient.

174 ~~(r) (p)~~ A practitioner providing medication-assisted treatment may perform certain aspects  
175 of telehealth if permitted under his or her scope of practice.

176 ~~(s) (q)~~ The physician shall follow the recommended manufacturer's tapering schedule for  
177 the medication-assisted treatment medication. If the schedule is not followed, the physician shall  
178 document in the patient's medical record and the clinical reason why the schedule was not  
179 followed. The secretary may investigate a medication-assisted treatment program if a high  
180 percentage of its patients are not following the recommended tapering schedule.

**§16-5Y-6. Restrictions; variances and waivers.**

1 (a) A medication-assisted treatment program shall not be located, operated, managed, or

2 owned at the same location where a chronic pain management clinic licensed and defined in  
3 article five-h, chapter sixteen of this code is located.

4 (b) Medication-assisted treatment programs shall not have procedures for offering a  
5 bounty, monetary, equipment, or merchandise reward, or free services for individuals in exchange  
6 for recruitment of new patients into the facility.

7 (c) Medication-assisted treatment programs shall not be located within one-half mile of a  
8 public or private licensed day care center or public or private K-12 school.

9 Existing medication-assisted treatment programs, including both opioid treatment  
10 programs and office based medication-assisted treatment programs that are located within one-  
11 half mile of a public or private licensed day care center or public or private K-12 school, shall be  
12 granted a variance, provided that the facility demonstrates adequate patient population controls  
13 and that it may otherwise meet the requirements of this article and the rules promulgated pursuant  
14 to this article.

15 (d) The secretary director may grant a waiver or a variance from any licensure or  
16 registration standard, or portion thereof, for the period during which the license or registration is in  
17 effect.

18 (1) Requests for waivers or variances of licensure or registration standards shall be in  
19 writing to the secretary and shall include:

20 (A) The specific section of this article or rules promulgated pursuant to this article for which  
21 a waiver or variance is sought;

22 (B) The rationale for requesting the waiver or variance;

23 (C) Documentation by the medication-assisted treatment program's medical director to the  
24 secretary that describes how the program will maintain the quality of services and patient safety if  
25 the wavier or variance is granted; and

26 (D) The consequences of not receiving approval of the requested wavier or variance.

27 (2) The secretary shall issue a written statement to the medication-assisted treatment

28 program granting or denying a request for a waiver or variance of program licensure or registration  
29 standards.

30 (3) The medication-assisted treatment program shall maintain a file copy of all requests for  
31 waivers or variances and the approval or denial of the requests for the period during which the  
32 license or registration is in effect.

33 (4) The Office of Health Facility Licensure and Certification shall inspect each medication-  
34 assisted treatment program prior to a waiver or variance being granted, including a review of  
35 patient records, to ensure and verify that any waiver or variance request meets the spirit and  
36 purpose of this article and the rules promulgated pursuant to this article. The Office of Health  
37 Facility Licensure and Certification may verify, by unannounced inspection, that the medication-  
38 assisted treatment program is in compliance with any waiver or variance granted by the secretary  
39 for the duration of such waiver or variance.

**§16-5Y-7. Inspection; inspection warrant.**

1 ~~(a) The Office of Health Facility Licensure and Certification shall inspect each opioid~~  
2 ~~treatment program annually, including a review of the patient records, to ensure that the program~~  
3 ~~complies with this article and the applicable rules. A pharmacist, employed or contracted by the~~  
4 ~~secretary, licensed in this state, and a law enforcement officer may be present at each inspection.~~

5 (b) (a) The Office of Health Facility Licensure and Certification shall perform unannounced  
6 complaint and verification inspections at office based medication-assisted treatment programs,  
7 including a review of the patient records, to ensure that the program complies with this article and  
8 the applicable rules. A pharmacist, employed or contracted by the secretary, licensed in this state  
9 and a law-enforcement officer may be present at each inspection.

10 ~~(e)~~ (b) During an onsite inspection, the inspectors shall make a reasonable attempt to  
11 discuss each violation with the medical director or other owners of the medication-assisted  
12 treatment program before issuing a formal written notification.

13 ~~(d)~~ (c) Any action taken to correct a violation shall be documented in writing by the medical

14 director or other owners of the medication-assisted treatment program and may be verified by  
15 follow-up visits by the Office of Health Facility Licensure and Certification.

16 ~~(e)~~ (d) Notwithstanding the existence or pursuit of any other remedy, the secretary general  
17 may, in the manner provided by law, maintain an action in the name of the state for an inspection  
18 warrant against any person, partnership, association or corporation to allow any inspection or  
19 seizure of records in order to complete any inspection allowed by this article or the rules  
20 promulgated pursuant to this article, or to meet any other purpose of this article or the rules  
21 promulgated pursuant to this article.

22 ~~(f)~~ (e) When possible, inspections for annual certification and licensure by the medication-  
23 assisted treatment programs will be done consecutively or concurrently. However, this provision  
24 does not limit the ability to conduct unannounced inspections pursuant to a complaint.

**§16-5Y-13. Rules; minimum standards for medication-assisted treatment programs.**

25 (a) The secretary shall promulgate rules in accordance with the provisions of chapter  
26 twenty-nine-a of this code for the licensure of medication-assisted treatment programs to ensure  
27 adequate care, treatment, health, safety, welfare, and comfort of patients at these facilities. These  
28 rules shall include, at a minimum:

29 (1) The process to be followed by applicants seeking a license;

30 (2) The qualifications and supervision of licensed and nonlicensed personnel at  
31 medication-assisted treatment programs and training requirements for all facility health care  
32 practitioners who are not regulated by another board;

33 (3) The provision and coordination of patient care, including the development of a written  
34 plan of care and patient contract;

35 (4) The management, operation, staffing and equipping of the medication-assisted  
36 treatment program;

37 (5) The clinical, medical, patient and business records kept by the medication-assisted  
38 treatment program;



39 (6) The procedures for inspections and for review of utilization and quality of patient care;

40 (7) The standards and procedures for the general operation of a medication-assisted  
41 treatment program, including facility operations, physical operations, infection control  
42 requirements, health and safety requirements and quality assurance;

43 (8) Identification of drugs, excluding methadone, that may be used to treat substance use  
44 disorders that identify a facility as a medication-assisted treatment program;

45 (9) Any other criteria that identify a facility as a medication-assisted treatment program;

46 (10) The standards and procedures to be followed by an owner in providing supervision,  
47 direction and control of individuals employed by or associated with a medication-assisted  
48 treatment program;

49 (11) Data collection and reporting requirements;

50 (12) Criteria and requirements related to specific medication-assisted treatment  
51 medications; and

52 (13) Such other standards or requirements as the secretary determines are appropriate.

53 (b) The Legislature finds that an emergency exists and, therefore, the secretary shall file an  
54 emergency rule to implement the provisions of this section pursuant to §29A-3-15 of this code.

**ARTICLE 5EE. OPIOID TREATMENT PROGRAMS ARE UNLAWFUL.**

**§16-5EE-1. Definitions.**

1 As used in this article:

2 "Director" means the director of the Office of Health Facility Licensure and Certification.

3 "Opioid treatment program" means a program or practitioner engaged in the treatment of  
4 individuals with substance use disorder through an on-site administration or dispensing of an  
5 opioid treatment medication in the form of an opioid agonist or partial agonist, typically methadone.  
6 This does not include programs or practitioners that issue prescriptions for partial opioid agonist  
7 medications.

**§16-5EE-2. Opioid Treatment Programs Unlawful.**

8 (a) Opioid treatment programs shall be considered unlawful in the State of West Virginia;

9 and

10 (b) An owner, operator, or other individual shall cease and desist operations of opioid  
11 treatment programs on the effective date of this article.

**§16-5EE-3. Care transition.**

12 (a) Notwithstanding the provisions of this article, an opioid treatment program may remain  
13 open for an administrative transition timeframe of 120 days after the effective date of this article, to  
14 assist patients in the transition of care. In no event may any patient be provided any opioid  
15 treatment program service during this administrative timeframe.

**§16-5EE-4. Civil penalties and injunctive relief.**

16 (a) If an owner, operator, or other individual operates an opioid treatment program after the  
17 effective date, the Director shall impose a civil money penalty upon the owner, operator, or  
18 individual not to exceed \$2,500 per day.

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

NOTE: Make opioid treatment programs unlawful and provide for penalties for violation of the article. The proposed bill permits an administrative timeframe for the transition of care. Requiring the Office for Health Facilities Licensure and Certification to seek penalties and the ability to seek injunctive relief for violations of the article.

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