

WEST VIRGINIA LEGISLATURE

2025 REGULAR SESSION

Introduced

House Bill 3158

By Delegate Flanigan

[Introduced March 05, 2025; referred to the
Committee on Health and Human Resources]

1 A BILL to amend and reenact §16B-13-2, §16B-13-3, §16B-13-4, §16B-13-5, and §16B-13-9 of
2 the Code of West Virginia, 1931, as amended, relating to abolishing methadone clinics.

Be it enacted by the Legislature of West Virginia:

ARTICLE 13. MEDICATION-ASSISTED TREATMENT PROGRAM LICENSING ACT.

§16B-13-2.

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 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 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

national leadership to improve access, reduce barriers, and promote high quality, effective treatment and recovery services.

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

"Director" means the Director of the Office of Health Facility Licensure and Certification, or his or her designee.

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

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

"Inspector General" means the Inspector General of the Office of Inspector General as described in §16B-2-1 of this code, or his or her designee.

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

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

"Medication-assisted treatment program" means all publicly and privately owned opioid treatment programs and office-based, medication-assisted treatment programs, which prescribe

medication-assisted treatment medications, excluding opioid agonists, and treat substance use disorders, as those terms are defined in this article.

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

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

"Office of Health Facility Licensure and Certification" means the West Virginia Office of Health Facility Licensure and Certification within the Office of Inspector General.

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

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

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

"Partial opioid agonist" means a Federal Drug Administration approved medication that is

used as an alternative to opioid agonists for the treatment of substance use disorders and that binds to and activates opiate receptors, but not to the same degree as full agonists.

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

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

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

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

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

"Substance" means the following:

(1) Alcohol;

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

(3) Any chemical, gas, drug, or medication consumed which causes clinically and functionally significant impairment, such as health problems, disability, and failure to meet major

100 responsibilities at work, school, or home.

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

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

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

114 "Variance" means written permission granted by the Inspector General, or designee, to a
115 medication-assisted treatment program that a requirement of this article or rules promulgated
116 pursuant to this article may be accomplished in a manner different from the manner set forth in this
117 article or associated rules.

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

§16B-13-3. Opioid treatment programs to obtain license; application; fees and inspections.

1 (a) No person, partnership, association, or corporation may operate an opioid treatment
2 program without first obtaining a license from the director in accordance with the provisions of this
3 article and the rules lawfully promulgated pursuant to this article.

4 (b) Any person, partnership, association, or corporation desiring a license to operate an
5 opioid treatment program in this state shall file with the Office of Health Facility Licensure and
6 Certification an application in such form and with such information as the director shall prescribe
7 and furnish accompanied by an application fee.

8 (c) The Director of the Office of Health Facility Licensure and Certification or his or her
9 designee shall inspect each facility and review all documentation submitted with the application.
10 The director shall then approve or deny the application for a license. The director shall issue a
11 license if the facility is in compliance with the provisions of this article and with the rules lawfully
12 promulgated pursuant to this article.

13 (d) A license shall be issued in one of three categories:

14 (1) An initial 12 month license shall be issued to an opioid treatment program establishing a
15 new program or service for which there is insufficient consumer participation to demonstrate
16 substantial compliance with this article and with all rules promulgated pursuant to this article;

17 (2) A provisional license shall be issued when an opioid treatment program seeks a
18 renewal license, or is an existing program as of the effective date of this article and is seeking an
19 initial license, and the opioid treatment program is not in substantial compliance with this article
20 and with all rules promulgated pursuant to this article, but does not pose a significant risk to the
21 rights, health and safety of a consumer. It shall expire not more than six months from the date of
22 issuance, and may not be consecutively reissued; or

23 (3) A renewal license shall be issued when an opioid treatment program is in substantial
24 compliance with this article and with all rules promulgated pursuant to this article. A renewal
25 license shall expire not more than one year from the date of issuance.

26 (e) At least 60 days prior to the license expiration date, an application for renewal shall be
27 submitted by the opioid treatment program to the director on forms furnished by the director. A
28 license shall be renewed if the director determines that the applicant is in compliance with this
29 article and with all rules promulgated pursuant to this article. A license issued to one program

location pursuant to this article is not transferrable or assignable. Any change of ownership of a licensed medication-assisted treatment program requires submission of a new application. The medication-assisted treatment program shall notify the director of any change in ownership within 10 days of the change and must submit a new application within the time frame prescribed by the director.

(f) Any person, partnership, association, or corporation that seeks to obtain or renew a license for an opioid treatment program in this state must submit to the director the following documentation:

- (1) Full operating name of the program as advertised;
- (2) Legal name of the program as registered with the West Virginia Secretary of State;
- (3) Physical address of the program;
- (4) Preferred mailing address for the program;
- (5) Email address to be used as the primary contact for the program;
- (6) Federal Employer Identification Number assigned to the program;
- (7) All business licenses issued to the program by this state, the State Tax Department, the Secretary of State and all other applicable business entities;
- (8) Brief description of all services provided by the program;
- (9) Hours of operation;
- (10) Legal Registered Owner Name – name of the person registered as the legal owner of the program. If more than one legal owner (i.e., partnership, corporation, etc.) list each legal owner separately, indicating the percentage of ownership;
- (11) Medical director's full name, medical license number, Drug Enforcement Administration registration number, and a list of all current certifications;
- (12) For each employee of the program, provide the following:
 - (A) Employee's role and occupation within the program;
 - (B) Full legal name;

- (C) Medical license, if applicable;
- (D) Drug Enforcement Administration registration number, if applicable;
- (E) Drug Enforcement Administration identification number to prescribe buprenorphine for addiction, if applicable; and
- (F) Number of hours per week worked at program;
- (13) Name and location address of all programs owned or operated by the applicant;
- (14) Notarized signature of applicant;
- (15) Check or money order for licensing fee and inspection fee;
- (16) Verification of education and training for all physicians, counselors and social workers practicing at or used by referral by the program such as fellowships, additional education, accreditations, board certifications and other certifications;
- (17) Board of Pharmacy Controlled Substance Prescriber Report for each prescriber practicing at the program for the three months preceding the date of application; and
- (18) If applicable, a copy of a valid Certificate of Need or a letter of exemption from the West Virginia Health Care Authority.
- (g) Upon satisfaction that an applicant has met all of the requirements of this article, the director shall issue a license to operate an opioid treatment program. An entity that obtains this license may possess, have custody, or control of, and dispense drugs indicated and approved by the United States Food and Drug Administration for the treatment of substance use disorders.
- (h) The opioid treatment program shall display the current license in a prominent location where services are provided and in clear view of all patients.
- (i) The director or his or her designee shall inspect on a periodic basis all opioid treatment programs that are subject to this article and all rules adopted pursuant to this article to ensure continued compliance.
- (j) No license shall be granted for any medication-assisted program that uses opioid agonists as a form of treatment, and no medication-assisted program may use or prescribe opioid

82 agonists.

**§16B-13-4. Office-based, medication-assisted treatment programs to obtain registration;
application; fees and inspections.**

1 (a) No person, partnership, association, or corporation may operate an office-based,
2 medication-assisted treatment program without first obtaining a registration from the director in
3 accordance with the provisions of this article and the rules lawfully promulgated pursuant to this
4 article.

5 (b) Any person, partnership, association, or corporation desiring a registration to operate
6 an office-based, medication-assisted treatment program in this state shall file with the Office of
7 Health Facility Licensure and Certification an application in such form and with such information as
8 the director shall prescribe and furnish accompanied by an application fee.

9 (c) The Director of the Office of Health Facility Licensure and Certification or his or her
10 designee shall inspect and review all documentation submitted with the application. The director
11 shall approve or deny the application for registration. The director shall issue a registration if the
12 facility is in compliance with the provisions of this article and with the rules lawfully promulgated
13 pursuant to this article.

14 (d) A registration shall be issued in one of three categories:

15 (1) An initial 12-month registration shall be issued to an office-based, medication-assisted
16 treatment program establishing a new program or service for which there is insufficient consumer
17 participation to demonstrate substantial compliance with this article and with all rules promulgated
18 pursuant to this article;

19 (2) A provisional registration shall be issued when an office-based, medication-assisted
20 treatment program seeks a renewal registration, or is an existing program as of the effective date
21 of this article and is seeking an initial registration, and the office-based, medication-assisted
22 treatment program is not in substantial compliance with this article and with all rules promulgated
23 pursuant to this article, but does not pose a significant risk to the rights, health, and safety of a

consumer. It shall expire not more than six months from the date of issuance, and may not be consecutively reissued; or

(3) A renewal registration shall be issued when an office-based, medication-assisted treatment program is in substantial compliance with this article and with all rules promulgated pursuant to this article. A renewal registration shall expire not more than one year from the date of issuance.

(e) At least 60 days prior to the registration expiration date, an application for renewal shall be submitted by the office-based, medication-assisted treatment program to the director on forms furnished by the director. A registration shall be renewed if the director determines that the applicant is in compliance with this article and with all rules promulgated pursuant to this article. A registration issued to one program location pursuant to this article is not transferrable or assignable. Any change of ownership of a registered office-based, medication-assisted treatment program requires submission of a new application. The office-based, medication-assisted treatment program shall notify the director of any change in ownership within 10 days of the change and must submit a new application within the time frame prescribed by the director.

(f) Any person, partnership, association, or corporation seeking to obtain or renew a registration for an office-based, medication-assisted treatment program in this state must submit to the director the following documentation:

- (1) Full operating name of the program as advertised;
- (2) Legal name of the program as registered with the West Virginia Secretary of State;
- (3) Physical address of the program;
- (4) Preferred mailing address for the program;
- (5) Email address to be used as the primary contact for the program;
- (6) Federal Employer Identification Number assigned to the program;
- (7) All business licenses issued to the program by this state, the state Tax Department, the Secretary of State, and all other applicable business entities;

- (8) Brief description of all services provided by the program;
- (9) Hours of operation;
- (10) Legal Registered Owner Name – name of the person registered as the legal owner of the program. If more than one legal owner (i.e., partnership, corporation, etc.) list each legal owner separately, indicating the percentage of ownership;
- (11) Medical director's full name, medical license number, Drug Enforcement Administration registration number, and a listing of all current certifications;
- (12) For each physician, counselor, or social worker of the program, provide the following:
- (A) Employee's role and occupation within the program;
 - (B) Full legal name;
 - (C) Medical license, if applicable;
 - (D) Drug Enforcement Administration registration number, if applicable;
 - (E) Drug Enforcement Administration identification number to prescribe buprenorphine for addiction, if applicable; and
 - (F) Number of hours worked at program per week;
- (13) Name and location address of all programs owned or operated by the applicant;
- (14) Notarized signature of applicant;
- (15) Check or money order for registration fee;
- (16) Verification of education and training for all physicians, counselors, and social workers practicing at or used by referral by the program such as fellowships, additional education, accreditations, board certifications, and other certifications; and
- (17) Board of Pharmacy Controlled Substance Prescriber Report for each prescriber practicing at the program for the three months preceding the date of application.
- (g) Upon satisfaction that an applicant has met all of the requirements of this article, the director shall issue a registration to operate an office-based, medication-assisted treatment program. An entity that obtains this registration may possess, have custody or control of, and

76 dispense drugs indicated and approved by the United States Food and Drug Administration for the
77 treatment of substance use disorders, ~~with the exception of opioid agonists.~~

78 (h) The office-based, medication-assisted treatment program shall display the current
79 registration in a prominent location where services are provided and in clear view of all patients.

80 (i) The director or his or her designee shall perform complaint and verification inspections
81 on all office-based, medication-assisted treatment programs that are subject to this article and all
82 rules adopted pursuant to this article to ensure continued compliance.

83 (j) Any person, partnership, association, or corporation operating an office-based,
84 medication-assisted treatment program shall be permitted to continue operation until the effective
85 date of the new rules promulgated pursuant to this article. At that time a person, partnership,
86 association, or corporation shall file for registration within six months pursuant to the licensing
87 procedures and requirements of this section and the new rules promulgated hereunder. The
88 existing procedures of the person, partnership, association, or corporation shall remain effective
89 until receipt of the registration.

90 (k) A person, partnership, association, or corporation providing office-based, medication-
91 assisted treatment to no more than 30 patients of their practice or program is exempt from the
92 registration requirement contained in §16-5Y-4(a) of this code: *Provided*, That it:

93 (1) Attests to the Office of Health Facility Licensure and Certification on a form prescribed
94 by the director that the person, partnership, association, or corporation requires counselling and
95 drug screens, has implemented diversion control measures, has completed medical education
96 training on addiction treatment encompassing all forms of medication-assisted treatment, will
97 provide patient numbers upon request, and will provide any other information required by the
98 director related to patient health and safety; and

99 (2) Is prohibited from establishing an office-based, medication-assisted treatment at any
100 other location or facility after the submission of an attestation submitted pursuant to §16-5Y-4(k)(2)
101 of this code. This subdivision includes any person, partnership, association, or corporation that

has an ownership interest in a partnership, association, or corporation or other corporate entity providing office-based, medication-assisted treatment.

(l) A licensed behavioral health center, pursuant to Behavioral Health Center Licensure, 64 CSR 11, providing office-based medication-assisted treatment is exempt from the registration requirement contained in §16-5Y-4(a) of this code: *Provided*, That it:

(1) Attests to the Office of Health Facility Licensure and Certification on a form prescribed by the director that the person, partnership, association, or corporation requires counseling and drugs screens, has implemented diversion control measures, will provide patient numbers upon request, and will provide any other information required by the director related to patient health and safety; and

(2) Must notify the Office of Health Facility Licensure and Certification prior to establishing or terminating an office-based medication-assisted treatment program at any other licensed behavioral health center location after the submission of an attestation submitted pursuant to §16-5Y-4(l)(1) of this code.

(m) No person, partnership, association, or corporation may operate an office-based, medication-assisted treatment program that utilizes or prescribes opioid agonists as a form of treatment.

§16B-13-5. Operational requirements.

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

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

(c) Each medication-assisted treatment program shall designate a medical director. If the 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;

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

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

(6) Complete other requirements prescribed by the Inspector General by rule.

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

(1) Be a licensed psychiatrist;

(2) Certification as an alcohol and drug counselor;

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

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

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

(6) Be a counselor with a graduate degree actively working toward licensure or certification in the individual's chosen field under supervision of a licensed or certified professional in that field 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 director, in consultation with the Inspector General, may grant a variance from this
70 requirement pursuant to §16B-13-6 of this code. The program shall also document whether a
71 patient has no insurance. At the option of the medication-assisted treatment program, treatment
72 may commence prior to billing.

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

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

80 (h) All employees of an opioid treatment program shall furnish fingerprints for a state and
81 federal criminal records check by the Criminal Identification Bureau of the West Virginia State
82 Police and the Federal Bureau of Investigation. The fingerprints shall be accompanied by a signed
83 authorization for the release of information and retention of the fingerprints by the Criminal
84 Identification Bureau and the Federal Bureau of Investigation. The opioid treatment program shall
85 be subject to the provisions of §16B-15-1 *et seq.* of this code and subsequent rules promulgated
86 thereunder.

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

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

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

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

(j) A person may not dispense any medication-assisted treatment medication, including a controlled substance as defined by §60A-1-101 of this code, on the premises of a licensed medication-assisted treatment program, unless he or she is a physician or pharmacist licensed in this state and employed by the medication-assisted treatment program unless the medication-assisted treatment program is a federally certified narcotic treatment program. Prior to dispensing or prescribing medication-assisted treatment medications, the treating physician must access the Controlled Substances Monitoring Program Database to ensure the patient is not seeking medication-assisted treatment medications that are controlled substances from multiple sources and to assess potential adverse drug interactions, or both. Prior to dispensing or prescribing medication-assisted treatment medications, the treating physician shall also ensure that the medication-assisted treatment medication utilized is related to an appropriate diagnosis of a substance use disorder and approved for such usage. The physician shall also review the Controlled Substances Monitoring Program Database no less than quarterly and at each patient's physical examination. The results obtained from the Controlled Substances Monitoring Program Database shall be maintained with the patient's medical records.

(k) A medication-assisted treatment program responsible for medication administration

shall comply with:

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

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

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

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

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

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

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

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

(D) The dates on which any medications were prescribed, dispensed, or administered, the name and address of the individual for whom the medications were prescribed, dispensed, or

administered, and the amounts and dosage forms for any medications prescribed, dispensed, or administered;

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

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

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

(4) A prescriber authorized to prescribe a medication-assisted treatment medication who practices at a medication-assisted treatment program is responsible for maintaining the control and security of his or her prescription blanks and any other method used for prescribing a medication-assisted treatment medication. The prescriber shall comply with all state and federal requirements for tamper-resistant prescription paper. In addition to any other requirements imposed by statute or rule, the prescriber shall notify the director and appropriate law-enforcement agencies in writing within 24 hours following any theft or loss of a prescription blank or breach of any other method of prescribing a medication-assisted treatment medication; and

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

(n) Medication-assisted treatment programs shall ~~only~~ never prescribe, dispense, or administer liquid methadone to patients ~~pursuant to the restrictions and requirements of the rules promulgated pursuant to this article.~~

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

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

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

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

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

§16B-13-9. Violations; penalties; injunction.

(a) Any person, partnership, association, or corporation which establishes, conducts, manages, or operates a medication-assisted treatment program without first obtaining a license or registration as herein provided, or who violates any provisions of this article or any rule lawfully promulgated pursuant to this article, shall be assessed a civil penalty by the director, in consultation with the Inspector General, in accordance with this subsection. Each day of continuing violation after conviction shall be considered a separate violation:

(1) If a medication-assisted treatment program or any owner or medical director is found to be in violation of any provision of this article, unless otherwise noted herein, the director, in consultation with the Inspector General, may limit, suspend or revoke the program's license or

10 registration;

11 (2) If the program's medical director knowingly and intentionally misrepresents actions
12 taken to correct a violation, the director, in consultation with the Inspector General, may impose a
13 civil money penalty not to exceed \$10,000 and, in the case of any owner-operator medication-
14 assisted treatment program, limit or revoke a medication-assisted treatment program's license or
15 registration;

16 (3) If any owner or medical director of a medication-assisted treatment program
17 concurrently operates an unlicensed or unregistered medication-assisted treatment program, the
18 director, in consultation with the Inspector General, may impose a civil money penalty upon the
19 owner or medical director, or both, not to exceed \$5,000 per day;

20 (4) If the owner of a medication-assisted treatment program that requires a license or
21 registration under this article fails to apply for a new license or registration for the program upon a
22 change of ownership and operates the program under new ownership, the director, in consultation
23 with the Inspector General, may impose a civil money penalty upon the owner, not to exceed
24 \$5,000; or

25 (5) If a physician operates, owns or manages an unlicensed or unregistered medication-
26 assisted treatment program that is required to be licensed or registered pursuant to this article;
27 knowingly prescribes or dispenses or causes to be prescribed or dispensed, a medication-
28 assisted treatment medication through misrepresentation or fraud; prescribes or dispenses an
29 opioid agonist; procures, or attempts to procure, a license or registration for a medication-assisted
30 treatment program for any other person by making or causing to be made any false
31 representation, the director, in consultation with the Inspector General, may assess a civil money
32 penalty of not more than \$20,000. The penalty may be in addition to or in lieu of any other action
33 that may be taken by the director, in consultation with the Inspector General, or any other board,
34 court or entity.

35 (b) Notwithstanding the existence or pursuit of any other remedy, the Inspector General

may, in the manner provided by law, maintain an action in the name of the state for an injunction against any person, partnership, association or corporation to restrain or prevent the establishment, conduct, management or operation of any medication-assisted treatment program or violation of any provision of this article or any rule lawfully promulgated thereunder without first obtaining a license or registration in the manner herein provided.

(c) In determining whether a penalty is to be imposed and in fixing the amount of the penalty, the director, in consultation with the Inspector General, shall consider the following factors:

(1) The gravity of the violation, including the probability that death or serious physical or emotional harm to a patient has resulted, or could have resulted, from the medication-assisted treatment program's actions or the actions of the medical director or any practicing physician, the severity of the action or potential harm, and the extent to which the provisions of the applicable laws or rules were violated;

(2) What actions, if any, the owner or medical director took to correct the violations;

(3) Whether there were any previous violations at the medication-assisted treatment program; and

(4) The financial benefits that the medication-assisted treatment program derived from committing or continuing to commit the violation.

(d) Upon finding that a physician has violated the provisions of this article or rules adopted pursuant to this article, the director shall provide notice of the violation to the applicable licensing board.

NOTE: The purpose of this bill is to make methadone clinics illegal.

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