

WEST VIRGINIA LEGISLATURE

2023 REGULAR SESSION

Introduced

House Bill 2541

By Delegates Criss, Heckert, Fehrenbacher, W. Hall

and Rohrbach

[Introduced January 13, 2023; Referred to the
Committee on Prevention and Treatment of
Substance Abuse then 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, §16-5Y-8, and
 2 §16-5Y-10 of the Code of West Virginia, 1931, as amended, all relating to creating a
 3 licensing requirement for the operation of inpatient provider facilities treating substance
 4 use disorder.

Be it enacted by the Legislature of West Virginia:

**ARTICLE 5Y. MEDICATION-ASSISTED TREATMENT PROGRAM AND INPATIENT
SUBSTANCE USE DISORDER FACILITY 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 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 treatment program. A governing body may be a board, a single entity or
33 owner, or a partnership. The governing body must comply with the requirements prescribed in
34 rules promulgated pursuant to this article.

35 "Inpatient substance use disorder treatment facility" means a facility in which any patient
36 resides in the facility during the course of the treatment for substance use disorder and addiction;

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

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

44 treatment of substance use disorders.

45 "Medication-assisted treatment program" means all publicly and privately owned opioid
46 treatment programs and office-based, medication-assisted treatment programs, which prescribe
47 medication-assisted treatment medications and treat substance use disorders, as those terms are
48 defined in this article.

49 "Medication-assisted treatment medication" means any medication that is approved by the
50 United States Food and Drug Administration under Section 505 of the Federal Food, Drug and
51 Cosmetic Act, 21 U. S. C. § 355, for use in the treatment of substance use disorders that is an
52 opioid agonist or partial opioid agonist and is listed on the Schedule of Controlled Substances in
53 §60A-2-2201 *et seq.* of this code.

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

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

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

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

70 "Partial opioid agonist" means a Federal Drug Administration approved medication that is
71 used as an alternative to opioid agonists for the treatment of substance use disorders and that
72 binds to and activates opiate receptors, but not to the same degree as full agonists.

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

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

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

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

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

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

93 "Substance" means the following:

94 (1) Alcohol;

95 (2) Controlled substances defined by §60A-2-204, §60A-2-206, §60A-2-208, and §60A-2-

96 210 of this code; or

97 (3) Any chemical, gas, drug, or medication consumed which causes clinically and
98 functionally significant impairment, such as health problems, disability, and failure to meet major
99 responsibilities at work, school, or home.

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

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

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

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

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

§16-5Y-3. Opioid and all inpatient substance use disorder treatment programs to obtain

license; application; fees and inspections.

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

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

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

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

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

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

26 reissued; or

27 (3) A renewal license shall be issued when an opioid treatment program or inpatient
28 substance use disorder treatment facility is in substantial compliance with this article and with all
29 rules promulgated pursuant to this article. A renewal license shall expire not more than one year
30 from the date of issuance.

31 (e) At least sixty days prior to the license expiration date, an application for renewal shall
32 be submitted by the opioid treatment program or inpatient substance use disorder treatment
33 facility to the secretary on forms furnished by the secretary. A license shall be renewed if the
34 secretary determines that the applicant is in compliance with this article and with all rules
35 promulgated pursuant to this article. A license issued to one program location pursuant to this
36 article is not transferrable or assignable. Any change of ownership of a licensed medication-
37 assisted treatment program requires submission of a new application. The medication-assisted
38 treatment program shall notify the secretary of any change in ownership within ten days of the
39 change and must submit a new application within the time frame prescribed by the secretary.

40 (f) Any person, partnership, association or corporation that seeks to obtain or renew a
41 license for an opioid treatment program or an inpatient substance use disorder treatment program
42 in this state must submit to the secretary the following documentation:

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

- 52 (9) Hours of operation;
- 53 (10) Legal Registered Owner Name – name of the person registered as the legal owner of
- 54 the program. If more than one legal owner (i.e., partnership, corporation, etc.) list each legal
- 55 owner separately, indicating the percentage of ownership;
- 56 (11) Medical director’s full name, medical license number, Drug Enforcement
- 57 Administration registration number, and a list of all current certifications;
- 58 (12) For each employee of the program, provide the following:
- 59 (A) Employee’s role and occupation within the program;
- 60 (B) Full legal name;
- 61 (C) Medical license, if applicable;
- 62 (D) Drug Enforcement Administration registration number, if applicable;
- 63 (E) Drug Enforcement Administration identification number to prescribe buprenorphine for
- 64 addiction, if applicable; and
- 65 (F) Number of hours per week worked at program;
- 66 (13) Name and location address of all programs owned or operated by the applicant;
- 67 (14) Notarized signature of applicant;
- 68 (15) Check or money order for licensing fee and inspection fee;
- 69 (16) Verification of education and training for all physicians, counselors and social workers
- 70 practicing at or used by referral by the program such as fellowships, additional education,
- 71 accreditations, board certifications and other certifications;
- 72 (17) Board of Pharmacy Controlled Substance Prescriber Report for each prescriber
- 73 practicing at the program for the three months preceding the date of application; and
- 74 (18) If applicable, a copy of a valid Certificate of Need or a letter of exemption from the
- 75 West Virginia Health Care Authority.
- 76 (19) In order to obtain a license, inpatient substance use disorder treatment facilities must
- 77 provide a letter of support that it received from the municipality where it is or will be located, in

78 addition to a letter of support from the county commission in the county wherein the provider
79 intends to operate.

80 (g) Upon satisfaction that an applicant has met all of the requirements of this article, the
81 secretary shall issue a license to operate an opioid treatment program or an inpatient substance
82 use disorder treatment program. An entity that obtains this license may possess, have custody or
83 control of, and dispense drugs indicated and approved by the United States Food and Drug
84 Administration for the treatment of substance use disorders.

85 (h) The opioid treatment program or an inpatient substance use disorder treatment facility
86 shall display the current license in a prominent location where services are provided and in clear
87 view of all patients.

88 (i) The secretary or his or her designee shall inspect on a periodic basis all opioid treatment
89 programs that are subject to this article and all rules adopted pursuant to this article to ensure
90 continued compliance.

91 (j) Any license in effect at the time of the passage of this section in the 2016 regular session
92 of the Legislature shall remain in effect until such time as new legislative rules promulgated
93 pursuant to this article become effective. Upon the effective date of the new rules any licensee
94 shall file for a new license within six months pursuant to the licensing procedures and
95 requirements of this section and the new rules promulgated hereunder. The existing license shall
96 remain effective until receipt of the new license.

§16-5Y-5. Operational requirements.

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

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

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

27 (A) If the physician prescribes a partial opioid agonist, he or she shall complete the
28 requirements for the Drug Addiction Treatment Act of 2000; and

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

31 (3) Practice at the licensed or registered medication-assisted treatment program a
32 sufficient number of hours, based upon the type of medication-assisted treatment license or

33 registration issued pursuant to this article, to ensure regulatory compliance, and carry out those
34 duties specifically assigned to the medical director as further described in the rules promulgated
35 pursuant to this article;

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

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

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

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

48 (1) Be a licensed psychiatrist;

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

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

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

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

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

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

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

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

76 (f) The medication-assisted treatment program or inpatient substance use disorder
77 treatment facility shall apply for and receive approval as required from the United States Drug
78 Enforcement Administration, Center for Substance Abuse Treatment, or an organization
79 designated by Substance Abuse and Mental Health and Mental Health Administration.

80 (g) All persons employed by the medication-assisted treatment program or inpatient
81 substance use disorder treatment facility shall comply with the requirements for the operation of a
82 medication-assisted treatment program or inpatient substance use disorder treatment facility
83 established within this article or by any rule adopted pursuant to this article.

84 (h) All employees of an opioid treatment program or inpatient substance use disorder

85 treatment facility shall furnish fingerprints for a state and federal criminal records check by the
86 Criminal Identification Bureau of the West Virginia State Police and the Federal Bureau of
87 Investigation. The fingerprints shall be accompanied by a signed authorization for the release of
88 information and retention of the fingerprints by the Criminal Identification Bureau and the Federal
89 Bureau of Investigation. The opioid treatment program shall be subject to the provisions of §16-49-
90 1 *et seq.* of this code and subsequent rules promulgated thereunder.

91 (i) The medication-assisted treatment program or inpatient substance use disorder
92 treatment facility shall not be owned by, nor shall it employ or associate with, any physician or
93 prescriber:

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

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

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

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

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

117 (k) A medication-assisted treatment program or inpatient substance use disorder
118 treatment facility responsible for medication administration shall comply with:

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

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

126 (m) The medication-assisted treatment program or inpatient substance use disorder
127 treatment facility shall develop and implement patient protocols, treatment plans, or treatment
128 strategies and profiles, which shall include, but not be limited by, the following guidelines:

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

136 (2) The medication-assisted treatment program or inpatient substance use disorder

137 treatment facility shall maintain a record of all of the following:

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

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

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

142 (D) The dates on which any medications were prescribed, dispensed, or administered, the
143 name and address of the individual for whom the medications were prescribed, dispensed, or
144 administered, and the amounts and dosage forms for any medications prescribed, dispensed, or
145 administered;

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

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

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

157 (4) A prescriber authorized to prescribe a medication-assisted treatment medication who
158 practices at a medication-assisted treatment program or inpatient substance use disorder
159 treatment facility is responsible for maintaining the control and security of his or her prescription
160 blanks and any other method used for prescribing a medication-assisted treatment medication.
161 The prescriber shall comply with all state and federal requirements for tamper-resistant
162 prescription paper. In addition to any other requirements imposed by statute or rule, the prescriber

163 shall notify the secretary and appropriate law-enforcement agencies in writing within 24 hours
164 following any theft or loss of a prescription blank or breach of any other method of prescribing a
165 medication-assisted treatment medication; and

166 (5) The medication-assisted treatment program or inpatient substance use disorder
167 treatment facility shall have a drug testing program to ensure a patient is in compliance with the
168 treatment strategy.

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

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

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

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

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

183 (s) The physician shall follow the recommended manufacturer's tapering schedule for the
184 medication-assisted treatment medication. If the schedule is not followed, the physician shall
185 document in the patient's medical record and the clinical reason why the schedule was not
186 followed. The secretary may investigate a medication-assisted treatment program if a high
187 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 or inpatient substance use disorder
2 treatment facility shall not be located, operated, managed or owned at the same location where a
3 chronic pain management clinic licensed and defined in article five-h, chapter sixteen of this code
4 is located.

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

8 (c) Medication-assisted treatment programs or inpatient substance use disorder treatment
9 facility shall not be located within one-half mile of a public or private licensed day care center or
10 public or private K-12 school.

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

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

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

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

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

24 (C) Documentation by the medication-assisted treatment program's medical director or
25 inpatient substance use disorder treatment facility's medical director to the secretary that
26 describes how the program will maintain the quality of services and patient safety if the wavier or

27 variance is granted; and

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

29 (2) The secretary shall issue a written statement to the medication-assisted treatment
30 program or inpatient substance use disorder treatment facility granting or denying a request for a
31 waiver or variance of program licensure or registration standards.

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

35 (4) The Office of Health Facility Licensure and Certification shall inspect each medication-
36 assisted treatment program prior to a waiver or variance being granted, including a review of
37 patient records, to ensure and verify that any waiver or variance request meets the spirit and
38 purpose of this article and the rules promulgated pursuant to this article. The Office of Health
39 Facility Licensure and Certification may verify, by unannounced inspection, that the medication-
40 assisted treatment program is in compliance with any waiver or variance granted by the secretary
41 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 and inpatient substance use disorder treatment program annually, including a
3 review of the patient records, to ensure that the program complies with this article and the
4 applicable rules. A pharmacist, employed or contracted by the secretary, licensed in this state,
5 and a law-enforcement officer may be present at each inspection.

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

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

14 (d) Any action taken to correct a violation shall be documented in writing by the medical
15 director or other owners of the medication-assisted treatment program and may be verified by
16 follow-up visits by the Office of Health Facility Licensure and Certification.

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

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

§16-5Y-8. License and registration limitation; denial; suspension; revocation.

1 (a) The secretary may, by order, impose a ban on the admission of patients or reduce the
2 patient capacity of the medication-assisted treatment program or inpatient substance use disorder
3 treatment facility, or any combination thereof, when he or she finds upon inspection of the
4 medication-assisted treatment program that the licensee or registrant is not providing adequate
5 care under the medication-assisted treatment program's or inpatient substance use disorder
6 treatment facility's existing patient quota, and that a reduction in quota or imposition of a ban on
7 admissions, or any combination thereof, would place the licensee or registrant in a position to
8 render adequate care. Any notice to a licensee or registrant of reduction in quota or ban on new
9 admissions shall include the terms of the order, the reasons therefor and the date set for
10 compliance.

11 (b) The secretary shall deny, suspend or revoke a license or registration issued pursuant to
12 this article if the provisions of this article or of the rules promulgated pursuant to this article are
13 violated. The secretary may revoke a program's or facility's license or registration and prohibit all
14 physicians and licensed disciplines associated with that medication-assisted treatment program
15 from practicing at the program location based upon an annual, periodic, complaint, verification or
16 other inspection and evaluation.

17 (c) Before any such license or registration is denied, suspended or revoked, however,
18 written notice shall be given to the licensee or registrant, stating the grounds for such denial,
19 suspension or revocation.

20 (d) An applicant, licensee or registrant has ten working days after receipt of the secretary's
21 order denying, suspending or revoking a license or registration to request a formal hearing
22 contesting such denial, suspension or revocation of a license or registration under this article. If a
23 formal hearing is requested, the applicant, licensee or registrant and the secretary shall proceed in
24 accordance with the provisions of article five, chapter twenty-nine-a of this code.

25 (e) If a license or registration is denied or revoked as herein provided, a new application for
26 license or registration shall be considered by the secretary if, when and after the conditions upon
27 which the denial or revocation was based have been corrected and evidence of this fact has been
28 furnished. A new license or registration shall then be granted after proper inspection, if applicable,
29 has been made and all provisions of this article and rules promulgated pursuant to this article have
30 been satisfied.

31 (f) Any applicant, licensee or registrant who is dissatisfied with the decision of the secretary
32 as a result of the hearing provided in this section may, within thirty days after receiving notice of the
33 decision, petition the circuit court of Kanawha County, in term or in vacation, for judicial review of
34 the decision.

35 (g) The court may affirm, modify or reverse the decision of the secretary and either the
36 applicant, licensee or registrant, or the secretary may appeal from the court's decision to the

37 Supreme Court of Appeals.

38 (h) If the license or registration of a medication-assisted treatment program is denied,
39 suspended or revoked, the medical director of the program, any owner of the program or owner or
40 lessor of the medication-assisted treatment program property shall cease to operate the clinic,
41 facility, office or program as a medication-assisted treatment program as of the effective date of
42 the denial, suspension or revocation. The owner or lessor of the medication-assisted treatment
43 program property is responsible for removing all signs and symbols identifying the premises as a
44 medication-assisted treatment program within thirty days. Any administrative appeal of such
45 denial, suspension or revocation shall not stay the denial, suspension or revocation.

46 (i) Upon the effective date of the denial, suspension or revocation, the medical director of
47 the medication-assisted treatment program shall advise the secretary and the Board of Pharmacy
48 of the disposition of all medications located on the premises. The disposition is subject to the
49 supervision and approval of the secretary. Medications that are purchased or held by a
50 medication-assisted treatment program that is not licensed may be deemed adulterated.

51 (j) If the license or registration of a medication-assisted treatment program is suspended or
52 revoked, any person named in the licensing or registration documents of the program, including
53 persons owning or operating the medication-assisted treatment program, may not, as an
54 individual or as part of a group, apply to operate another medication-assisted treatment program
55 for up to five years after the date of suspension or revocation. The secretary may grant a variance
56 pursuant to section six of this article to the prohibition of this subsection.

57 (k) The period of suspension for the license or registration of a medication-assisted
58 treatment program shall be prescribed by the secretary, but may not exceed one year.

§16-5Y-10.

Advertisement

disclosure.

1 Any advertisement made by or on behalf of a medication-assisted treatment program or
2 inpatient substance use disorder treatment facility through public media, such as a telephone
3 directory, medical directory, newspaper or other periodical, outdoor advertising, radio or television,

- 4 or through written or recorded communication, concerning the treatment of substance use
- 5 disorders, as defined in section two of this article, shall include the name of, at a minimum, the
- 6 medical director responsible for the content of the advertisement.

NOTE: The purpose of this bill is to establish licensing requirements required for inpatient substance use disorder treatment facilities.

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