

WEST VIRGINIA LEGISLATURE

2019 REGULAR SESSION

Introduced

House Bill 3005

BY DELEGATE KESSINGER, BY REQUEST

[Introduced February 12, 2019; Referred
to the Committee on Health and Human Resources.]

1 A BILL to amend and reenact §16-5Y-5 of the Code of West Virginia, 1931, as amended, relating
2 to requiring patients who are pregnant while undergoing medication-assisted treatment to
3 receive prenatal care.

Be it enacted by the Legislature of West Virginia:

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

§16-5Y-5. Operational requirements.

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

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

7 (c) Each medication-assisted treatment program shall designate a medical director. If the
8 medication-assisted treatment program is accredited by a Substance Abuse and Mental Health
9 Services Administration approved accrediting body that meets nationally accepted standards for
10 providing medication-assisted treatment, including the Commission on Accreditation of
11 Rehabilitation Facilities or the Joint Commission on Accreditation of Healthcare Organizations,
12 then the program may designate a medical director to oversee all facilities associated with the
13 accredited medication-assisted treatment program. The medical director shall be responsible for
14 the operation of the medication-assisted treatment program, as further specified in the rules
15 promulgated pursuant to this article. He or she may delegate the day-to-day operation of a
16 medication-assisted treatment program as provided in rules promulgated pursuant to this article.
17 Within 10 days after termination of a medical director, the medication-assisted treatment program
18 shall notify the director of the identity of another medical director for that program. Failure to have
19 a medical director practicing at the program may be the basis for a suspension or revocation of
20 the 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
24 not under any probationary restrictions;

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

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

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

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

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

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

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

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

- 47 (1) Be a licensed psychiatrist;
- 48 (2) Certification as an alcohol and drug counselor;
- 49 (3) Certification as an advanced alcohol and drug counselor;
- 50 (4) Be a counselor, psychologist, marriage and family therapist, or social worker with a
51 master's level education with a specialty or specific training in treatment for substance use
52 disorders, as further described in the rules promulgated pursuant to this article;
- 53 (5) Under the direct supervision of an advanced alcohol and drug counselor, be a
54 counselor with a bachelor's degree in social work or another relevant human services field:
55 Provided, That the individual practicing with a bachelor's degree under supervision applies for
56 certification as an alcohol and drug counselor within three years of the date of employment as a
57 counselor; or
- 58 (6) Be a counselor with a graduate degree actively working toward licensure or certification
59 in the individual's chosen field under supervision of a licensed or certified professional in that field
60 and/or advanced alcohol and drug counselor.
- 61 (e) The medication-assisted treatment program shall be eligible for, and not prohibited
62 from, enrollment with West Virginia Medicaid and other private insurance. Prior to directly billing
63 a patient for any medication-assisted treatment, a medication-assisted treatment program must
64 receive either a rejection of prior authorization, rejection of a submitted claim, or a written denial
65 from a patient's insurer or West Virginia Medicaid denying coverage for such treatment: *Provided,*
66 That the secretary may grant a variance from this requirement pursuant to §15-5Y-6 of this code.
67 The program shall also document whether a patient has no insurance. At the option of the
68 medication-assisted treatment program, treatment may commence prior to billing.
- 69 (f) The medication-assisted treatment program shall apply for and receive approval as
70 required from the United States Drug Enforcement Administration, Center for Substance Abuse
71 Treatment, or an organization designated by Substance Abuse and Mental Health and Mental
72 Health Administration.

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

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

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

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

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

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

93 (j) A person may not dispense any medication-assisted treatment medication, including a
94 controlled substance as defined by §60A-1-101 of this code, on the premises of a licensed
95 medication-assisted treatment program, unless he or she is a physician or pharmacist licensed in
96 this state and employed by the medication-assisted treatment program unless the medication-
97 assisted treatment program is a federally certified narcotic treatment program. Prior to dispensing
98 or prescribing medication-assisted treatment medications, the treating physician must access the

99 Controlled Substances Monitoring Program Database to ensure the patient is not seeking
100 medication-assisted treatment medications that are controlled substances from multiple sources
101 and to assess potential adverse drug interactions, or both. Prior to dispensing or prescribing
102 medication-assisted treatment medications, the treating physician shall also ensure that the
103 medication-assisted treatment medication utilized is related to an appropriate diagnosis of a
104 substance use disorder and approved for such usage. The physician shall also review the
105 Controlled Substances Monitoring Program Database no less than quarterly and at each patient's
106 physical examination. The results obtained from the Controlled Substances Monitoring Program
107 Database shall be maintained with the patient's medical records.

108 (k) A medication-assisted treatment program responsible for medication administration
109 shall comply with:

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

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

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

- 120 (1) When a physician diagnoses an individual as having a substance use disorder, the
121 physician may treat the substance use disorder by managing it with medication in doses not
122 exceeding those approved by the United States Food and Drug Administration as indicated for
123 the treatment of substance use disorders and not greater than those amounts described in the
124 rules promulgated pursuant to this article. The treating physician and treating counselor's

125 diagnoses and treatment decisions shall be made according to accepted and prevailing standards
126 for medical care;

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

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

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

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

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

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

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

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

148 (4) A prescriber authorized to prescribe a medication-assisted treatment medication who
149 practices at a medication-assisted treatment program is responsible for maintaining the control
150 and security of his or her prescription blanks and any other method used for prescribing a

151 medication-assisted treatment medication. The prescriber shall comply with all state and federal
152 requirements for tamper-resistant prescription paper. In addition to any other requirements
153 imposed by statute or rule, the prescriber shall notify the secretary and appropriate law-
154 enforcement agencies in writing within 24 hours following any theft or loss of a prescription blank
155 or breach of any other method of prescribing a medication-assisted treatment medication; and

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

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

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

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

167 (q) If a physician is not the patient's obstetrical or gynecological provider, the physician
168 shall consult with the patient's obstetrical or gynecological provider to the extent possible to
169 determine whether the prescription is appropriate for the patient. If a patient is, or becomes
170 pregnant while undergoing medication-assisted treatment therapy, the coordination of care
171 agreement shall contain a provision that the patient receive prenatal care as a condition of
172 continuation of treatment.

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

175 (s) The physician shall follow the recommended manufacturer's tapering schedule for the
176 medication-assisted treatment medication. If the schedule is not followed, the physician shall

177 document in the patient's medical record and the clinical reason why the schedule was not
178 followed. The secretary may investigate a medication-assisted treatment program if a high
179 percentage of its patients are not following the recommended tapering schedule.

NOTE: The purpose of this bill is to require patients who are pregnant while undergoing medication-assisted treatment to receive prenatal care.

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