

WEST VIRGINIA LEGISLATURE

2018 REGULAR SESSION

Introduced

Senate Bill 615

BY SENATORS DRENNAN AND WOELFEL

[Introduced February 19, 2018; Referred
to the Committee on Health and Human Resources;
and then to the Committee on Government
Organization]

1 A BILL to amend and reenact §16-5Y-3 and §16-5Y-4 of the Code of West Virginia, 1931, as
2 amended, all relating to licensing and registering opioid treatment programs and office-
3 based, medication-assisted treatment programs; and establishing a deemed-qualified
4 status for renewal when the provider is also licensed by the state as a behavioral health
5 center and the provider has a federally approved accredited and registered opioid
6 treatment program.

Be it enacted by the Legislature of West Virginia:

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

§16-5Y-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 secretary in accordance with the provisions of
3 this 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 secretary 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 provide a recommendation to the secretary whether to approve or deny
11 the application for a license. The secretary shall issue a license if the facility is in compliance with
12 the provisions of this article and with the rules lawfully 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
15 a 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 secretary on forms furnished by the secretary.
28 A license shall be renewed if the secretary determines that the applicant is in compliance with this
29 article and with all rules promulgated pursuant to this article. A state-licensed behavioral health
30 facility that is also accredited and registered as required by the federal agency responsible for
31 oversight of opioid treatment programs is deemed in compliance with the requirements of this
32 article and shall not be required to submit the information listed in subsection (f) of this section,
33 with the exception of the full operating name of the program, the program's physical and mailing
34 addresses, evidence of program's behavioral health center license, and evidence of the federal
35 opioid treatment program accreditation and registration. A license issued to one program location
36 pursuant to this article is not transferrable or assignable. Any change of ownership of a licensed
37 medication-assisted treatment program requires submission of a new application. The
38 medication-assisted treatment program shall notify the secretary of any change in ownership
39 within ten days of the change and must submit a new application within the time frame prescribed
40 by the secretary.

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

- 44 (1) Full operating name of the program as advertised;
- 45 (2) Legal name of the program as registered with the West Virginia Secretary of State;
- 46 (3) Physical address of the program;
- 47 (4) Preferred mailing address for the program;
- 48 (5) Email address to be used as the primary contact for the program;
- 49 (6) Federal Employer Identification Number assigned to the program;
- 50 (7) All business licenses issued to the program by this state, the state Tax Department,
- 51 the Secretary of State and all other applicable business entities;
- 52 (8) Brief description of all services provided by the program;
- 53 (9) Hours of operation;
- 54 (10) Legal Registered Owner Name – name of the person registered as the legal owner
- 55 of the program. If more than one legal owner (i.e., partnership, corporation, etc.) list each legal
- 56 owner separately, indicating the percentage of ownership;
- 57 (11) Medical director's full name, medical license number, Drug Enforcement
- 58 Administration registration number, and a list of all current certifications;
- 59 (12) For each employee of the program, provide the following:
- 60 (A) Employee's role and occupation within the program;
- 61 (B) Full legal name;
- 62 (C) Medical license, if applicable;
- 63 (D) Drug Enforcement Administration registration number, if applicable;
- 64 (E) Drug Enforcement Administration identification number to prescribe buprenorphine for
- 65 addiction, if applicable; and
- 66 (F) Number of hours per week worked at program;
- 67 (13) Name and location address of all programs owned or operated by the applicant;
- 68 (14) Notarized signature of applicant;
- 69 (15) Check or money order for licensing fee and inspection fee;

70 (16) Verification of education and training for all physicians, counselors and social workers
71 practicing at or used by referral by the program such as fellowships, additional education,
72 accreditations, board certifications and other certifications;

73 (17) Board of Pharmacy Controlled Substance Prescriber Report for each prescriber
74 practicing at the program for the three months preceding the date of application; and

75 (18) If applicable, a copy of a valid Certificate of Need or a letter of exemption from the
76 West Virginia Health Care Authority.

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

81 (h) The opioid treatment program shall display the current license in a prominent location
82 where services are provided and in clear view of all patients.

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

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

**§16-5Y-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 secretary 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
8 as the secretary 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 then provide a recommendation to the secretary whether to approve or deny the application
12 for registration. The secretary shall issue a registration if the facility is in compliance with the
13 provisions of this article and with the rules lawfully promulgated 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
24 consumer. It shall expire not more than six months from the date of issuance, and may not be
25 consecutively reissued; or

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

29 of issuance.

30 (e) At least sixty days prior to the registration expiration date, an application for renewal
31 shall be submitted by the office based medication-assisted treatment program to the secretary on
32 forms furnished by the secretary. A registration shall be renewed if the secretary determines that
33 the applicant is in compliance with this article and with all rules promulgated pursuant to this
34 article. A state-licensed behavioral health facility that is also accredited and registered as required
35 by the federal agency responsible for oversight of opioid treatment programs is deemed in
36 compliance with the requirements of this article and shall not be required to submit the information
37 listed in subsection (f) of this section, with the exception of the full operating name of the program,
38 the program's physical and mailing addresses, evidence of program's behavioral health center
39 license, and evidence of the federal opioid treatment program accreditation and registration. A
40 registration issued to one program location pursuant to this article is not transferrable or
41 assignable. Any change of ownership of a registered medication-assisted treatment program
42 requires submission of a new application. The medication-assisted treatment program shall notify
43 the secretary of any change in ownership within ten days of the change and must submit a new
44 application within the time frame prescribed by the secretary.

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

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

- 55 the Secretary of State and all other applicable business entities;
- 56 (8) Brief description of all services provided by the program;
- 57 (9) Hours of operation;
- 58 (10) Legal Registered Owner Name – name of the person registered as the legal owner
59 of the program. If more than one legal owner (i.e., partnership, corporation, etc.) list each legal
60 owner separately, indicating the percentage of ownership;
- 61 (11) Medical director's full name, medical license number, Drug Enforcement
62 Administration registration number, and a listing of all current certifications;
- 63 (12) For each physician, counselor or social worker of the program, provide the following:
- 64 (A) Employee's role and occupation within the program;
- 65 (B) Full legal name;
- 66 (C) Medical license, if applicable;
- 67 (D) Drug Enforcement Administration registration number, if applicable;
- 68 (E) Drug Enforcement Administration identification number to prescribe buprenorphine for
69 addiction, if applicable; and
- 70 (F) Number of hours worked at program per week;
- 71 (13) Name and location address of all programs owned or operated by the applicant;
- 72 (14) Notarized signature of applicant;
- 73 (15) Check or money order for registration fee;
- 74 (16) Verification of education and training for all physicians, counselors and social workers
75 practicing at or used by referral by the program such as fellowships, additional education,
76 accreditations, board certifications and other certifications;
- 77 (17) Board of Pharmacy Controlled Substance Prescriber Report for each prescriber
78 practicing at the program for the three months preceding the date of application; and
- 79 (18) If applicable, a copy of a valid Certificate of Need or a letter of exemption from the
80 West Virginia Health Care Authority.

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

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

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

91 (j) Any person, partnership, association or corporation operating a medication-assisted
92 treatment program shall be permitted to continue operation until the effective date of the new rules
93 promulgated pursuant to this article. At that time a person, partnership, association or corporation
94 shall file for registration within six months pursuant to the licensing procedures and requirements
95 of this section and the new rules promulgated hereunder. The existing procedures of the person,
96 partnership, association or corporation shall remain effective until receipt of the registration.

NOTE: The purpose of this bill is to reduce redundancy in regulatory requirements by allowing a medication-assisted treatment program to be relicensed if it is also licensed as a behavioral health center and has a federally accredited and registered opioid treatment program. Accredited programs will not be required to submit burdensome and potentially redundant paperwork to be licensed or registered.

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