WEST VIRGINIA CODE CHAPTER 16b ARTICLE 13

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§16B-13-1. Purpose.

The purpose of this act is to establish licensing and registration requirements for facilities and physicians that treat patients with substance use disorders to ensure that patients may be lawfully treated by the use of medication and drug screens, in combination with counseling and behavioral therapies, to provide a holistic approach to the treatment of substance use disorders and comply with oversight requirements developed by the Inspector General. The Legislature recognizes the problem of substance use disorders in West Virginia and the need for quality, safe treatment of substance use disorders to adequately protect the people of West Virginia.

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§16B-13-2. Definitions.

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

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

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

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

"Biopsychosocial" means relating to, or concerned with, biological, psychological, and social aspects in contrast to the strictly biomedical aspects of disease.

"Center for Substance Abuse Treatment" means the center under the Substance Abuse and Mental Health Services Administration that promotes community-based substance abuse 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

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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 and treat substance use disorders, as those terms are defined in this article.

"Medication-assisted treatment medication" means any medication 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 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

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administration or dispensing of a medication-assisted treatment medication in the form of an opioid agonist or 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 responsibilities at work, school, or home.

"Substance Abuse and Mental Health Services Administration" means the agency under the

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United States Department of Health and Human Services responsible for the accreditation and certification of medication-assisted treatment programs and that provides leadership, resources, programs, policies, information, data, contracts, and grants for the purpose of reducing the impact of substance abuse and mental or behavioral illness.

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

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

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

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

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

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

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

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

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

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

(2) A provisional license shall be issued when an opioid treatment program seeks a renewal license, or is an existing program as of the effective date of this article and is seeking an initial license, and the opioid treatment program is not in substantial compliance with this article and with all rules promulgated 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 license shall be issued when an opioid treatment program is in substantial compliance with this article and with all rules promulgated pursuant to this article. A renewal license shall expire not more than one year from the date of issuance.

(e) At least 60 days prior to the license expiration date, an application for renewal shall be submitted by the opioid treatment program to the director on forms furnished by the director. A license 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 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.

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(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;

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(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.

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

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

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

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

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

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

(2) A provisional registration shall be issued when an office-based, medication-assisted treatment program seeks a renewal registration, or is an existing program as of the effective date of this article and is seeking an initial registration, and the office-based, medication-assisted treatment program is not in substantial compliance with this article and with all rules promulgated 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

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(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 dispense drugs indicated and approved by the United States Food and Drug Administration for the treatment of substance use disorders.

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

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

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

(k) A person, partnership, association, or corporation providing office-based, medication-assisted treatment to no more than 30 patients of their practice or program 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 counselling and drug screens, has implemented diversion control measures, has completed medical education training on addiction treatment encompassing all forms of medication-assisted treatment, will provide patient numbers upon request, and will provide any other

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information required by the director related to patient health and safety; and

(2) Is prohibited from establishing an office-based, medication-assisted treatment at any other location or facility after the submission of an attestation submitted pursuant to §16-5Y-4(k)(2) 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.

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§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 Services Administration-approved accrediting body that meets nationally accepted standards for providing medication-assisted treatment, including the Commission on Accreditation of Rehabilitation Facilities or the Joint Commission on Accreditation of Healthcare Organizations, then the program may designate a medical director to oversee all facilities associated with the accredited medication-assisted treatment program. The medical director shall be responsible for the operation of the medication-assisted treatment program, as further specified in the rules promulgated pursuant to this article. He or she may delegate the day-to-day operation of a medication-assisted treatment program as provided in rules promulgated pursuant to this article. Within 10 days after termination of a medical director, the medication-assisted treatment program shall notify the director of the identity of another medical director for that program. Failure to have a medical director practicing at the program may be the basis for a suspension or revocation of the program license. The medical director shall:

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

(2) Meet both of the following training requirements:

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

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

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

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(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) Be certified as an alcohol and drug counselor;

(3) Be certified 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) Be a counselor with a bachelor's degree in social work or another relevant human services field under the direct supervision of an advanced alcohol and drug counselor: *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;

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

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

(e) The medication-assisted treatment program shall be eligible for, and not prohibited from, enrollment with West Virginia Medicaid and other private insurance. Prior to directly billing a patient for any medication-assisted treatment, a medication-assisted treatment program must receive either a rejection of prior authorization, rejection of a submitted claim, or a written denial from a patient’s insurer or West Virginia Medicaid denying coverage for that

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treatment: *Provided*, That the director, in consultation with the Inspector General, may grant a variance from this requirement pursuant to §16B-13-6 of this code. The program shall also document whether a patient has no insurance. At the option of the medication-assisted treatment program, treatment may commence prior to billing.

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

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

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

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

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

(2) 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) 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.

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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 that 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

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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;

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

(6) The medication-assisted treatment program shall offer long-acting reversible contraception to patients recovering from addiction; such offerings shall be provided in accordance with the following provisions:

(A) Contraceptive Counseling Requirement:

(i) The medication-assisted treatment program shall provide shared decision-making contraceptive counseling;

(ii) Counseling shall be non-coercive and tailored to the patient's lifestyle, health needs, and personal preferences, ensuring informed choice in contraceptive options;

(iii) Counseling services shall be available to both male and female patients; and

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(iv) Medical eligibility screening for potential contraindications;

(B) Medical Assessment & Referral Process:

(i) The medication-assisted treatment program may not place or insert a long-acting reversible contraception unless they have a licensed healthcare provider on staff who is trained; and

(ii) If the medication-assisted treatment program lacks a qualified provider or necessary medical equipment, it shall establish a referral system to direct patients to a licensed healthcare provider or clinic capable of full contraceptive service delivery.

(n) Medication-assisted treatment programs shall only 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 it 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.

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§16B-13-6. Restrictions; variances and waivers.

(a) A medication-assisted treatment program shall not be located, operated, managed or owned at the same location where a chronic pain management clinic licensed and defined in §16B-7-1 *et seq*. of this code is located.

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

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

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

(d) The director, in consultation with the Inspector General, may grant a waiver or a variance from any licensure or registration standard, or portion thereof, for the period during which the license or registration is in effect.

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

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

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

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

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

(2) The director, in consultation with the Inspector General, shall issue a written statement to the medication-assisted treatment program granting or denying a request for a waiver or variance of program licensure or registration standards.

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

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

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§16B-13-7. Inspection; inspection warrant.

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

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

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

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

(e) 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 inspection warrant against any person, partnership, association, or corporation to allow any inspection or seizure of records in order to complete any inspection allowed by this article or the rules promulgated pursuant to this article, or to meet any other purpose of this article or the rules promulgated pursuant to this article.

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

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§16B-13-8. License and registration limitation; denial; suspension; revocation.

(a) The director, in consultation with the Inspector General, may, by order, impose a ban on the admission of patients or reduce the patient capacity of the medication-assisted treatment program, or any combination thereof, when he or she finds upon inspection of the medication-assisted treatment program that the licensee or registrant is not providing adequate care under the medication-assisted treatment program's existing patient quota, and that a reduction in quota or imposition of a ban on admissions, or any combination thereof, would place the licensee or registrant in a position to render adequate care. Any notice to a licensee or registrant of reduction in quota or ban on new admissions shall include the terms of the order, the reasons therefor and the date set for compliance.

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

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

(d) An applicant, licensee or registrant has 10 working days after receipt of the director's order denying, suspending, or revoking a license or registration to request a formal hearing contesting such denial, suspension, or revocation of a license or registration under this article. If a formal hearing is requested, the applicant, licensee or registrant and the director shall proceed in accordance with the provisions of §29A-5-1 *et seq*. of this code.

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

(f) Any applicant, licensee or registrant who is dissatisfied with the decision of the director as a result of the hearing provided in this section may, within 30 days after receiving notice of the decision, petition the circuit court of Kanawha County, in term or in vacation, for judicial review of the decision.

(g) The West Virginia Intermediate Court of Appeals may affirm, modify or reverse the decision of the Board of Review and either the applicant, licensee or registrant, or the

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director may appeal from the court's decision to the Supreme Court of Appeals.

(h) If the license or registration of a medication-assisted treatment program is denied, suspended, or revoked, the medical director of the program, any owner of the program or owner or lessor of the medication-assisted treatment program property shall cease to operate the clinic, facility, office, or program as a medication-assisted treatment program as of the effective date of the denial, suspension, or revocation. The owner or lessor of the medication-assisted treatment program property is responsible for removing all signs and symbols identifying the premises as a medication-assisted treatment program within 30 days. Any administrative appeal of such denial, suspension or revocation shall not stay the denial, suspension, or revocation.

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

(j) If the license or registration of a medication-assisted treatment program is suspended or revoked, any person named in the licensing or registration documents of the program, including persons owning or operating the medication-assisted treatment program, may not, as an individual or as part of a group, apply to operate another medication-assisted treatment program for up to five years after the date of suspension or revocation. The director, in consultation with the Inspector General, may grant a variance pursuant to §16B-13-6 of this code to the prohibition of this subsection.

(k) The period of suspension for the license or registration of a medication-assisted treatment program shall be prescribed by the director, in consultation with the Inspector General, but may not exceed one year.

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§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 registration;

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

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

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

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

(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

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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.

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§16B-13-10. Advertisement disclosure.

Any advertisement made by or on behalf of a medication-assisted treatment program through public media, such as a telephone directory, medical directory, newspaper or other periodical, outdoor advertising, radio or television, or through written or recorded communication, concerning the treatment of substance use disorders, as defined in section two of this article, shall include the name of, at a minimum, the medical director responsible for the content of the advertisement.

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§16B-13-11. State Opioid Treatment Authority.

(a) Prior to establishing, operating, maintaining, or advertising a medication-assisted treatment program within this state, a medication-assisted treatment program shall be approved by the state opioid treatment authority for operation of a medication-assisted treatment program in this state.

(b) The state opioid treatment authority shall act as the state's coordinator for the development and monitoring of medication-assisted treatment programs and it shall serve as a liaison with the appropriate federal agencies.

(c) The designated state oversight agency is responsible for licensing, monitoring, and investigating complaints and grievances regarding medication-assisted treatment programs.

(d) The powers and duties of the state opioid treatment authority include, but are not limited to, the following:

(1) Facilitate the development and implementation of rules, regulations, standards and best practice guidelines to ensure the quality of services delivered by medication-assisted treatment programs;

(2) Act as a liaison between relevant state and federal agencies;

(3) Be available for consultation regarding medication-assisted treatment guidelines, rules, regulations and recovery models for individualized treatment plans of care developed by the federal government and other nationally recognized authorities;

(4) Ensure delivery of technical assistance and informational materials to medication-assisted treatment programs as needed;

(5) Perform both scheduled and unscheduled site visits to medication-assisted treatment programs in cooperation with the identified state oversight agency when necessary and appropriate;

(6) Consult with the federal government regarding approval or disapproval of requests for exceptions to federal regulations, where appropriate;

(7) Review and approve exceptions to federal and state dosage policies and procedures;

(8) Receive and refer patient appeals and grievances to the designated state oversight agency when appropriate; and

(9) Work cooperatively with other relevant state agencies to determine the services needed and the location of a proposed medication-assisted treatment program.

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§16B-13-12. Moratorium; certificate of need.

There is a moratorium on the licensure of new opioid treatment programs which do not have a certificate of need as of the effective date of the enactment of this section during the 2016 regular session of the Legislature which shall continue until the Legislature determines that there is a necessity for additional opioid treatment programs in West Virginia.

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§16B-13-13. Rules; minimum standards for medication-assisted treatment programs.

(a) The Inspector General shall promulgate rules in accordance with the provisions of §29A-1-1 *et seq*. of this code for the licensure of medication-assisted treatment programs to ensure adequate care, treatment, health, safety, welfare, and comfort of patients at these facilities. These rules shall include, at a minimum:

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

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

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

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

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

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

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

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

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

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

(11) Data collection and reporting requirements;

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

(13) Such other standards or requirements as the Inspector General determines are appropriate.

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

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