WEST VIRGINIA CODE: §16B-13-5

§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

WV Legislature

those duties specifically assigned to the medical director as further described in the rules promulgated pursuant to this article;

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

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

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

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

(1) Be a licensed psychiatrist;

(2) 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

WV Legislature

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 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

WV Legislature

physician must access the Controlled Substances Monitoring Program Database to ensure the patient is not seeking medication-assisted treatment medications that are controlled substances from multiple sources and to assess potential adverse drug interactions, or both. Prior to dispensing or prescribing medication-assisted treatment medications, the treating physician shall also ensure that the medication-assisted treatment medication utilized is related to an appropriate diagnosis of a substance use disorder and approved for 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

WV Legislature

modification to the plan of treatment;

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

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

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

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

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

(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;

WV Legislature

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

(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.

WV Legislature