WEST VIRGINIA LEGISLATURE

2016 REGULAR SESSION

Committee Substitute

for

Committee Substitute

for

Senate Bill 460

BY SENATORS COLE (MR. PRESIDENT) AND KESSLER

(BY REQUEST OF THE EXECUTIVE)

[Originating in the Committee on The Judiciary;

reported on February 27, 2016]

A BILL to amend and reenact §16-1-4 of the Code of West Virginia, 1931, as amended; to amend said code by adding thereto a new article, designated §16-5Y-1, §16-5Y-2, §16-5Y-3, §16-5Y-4, §16-5Y-5, §16-5Y-6, §16-5Y-7, §16-5Y-8, §16-5Y-9, §16-5Y-10, §16-5Y-11, §16-5Y-12 and §16-5Y-13; and to amend and reenact §60A-9-5 of said code, all relating to licensing and regulation of medication-assisted treatment programs for substance use disorders; repealing regulation of opioid treatment programs; setting out purpose; providing definitions; creating licenses for opioid treatment programs; creating categories of licenses; setting out licensing requirements; providing for registration of office-based medication-assisted programs; providing for application, fees and inspections of office-based medication-assisted programs; setting operational requirements for medication-assisted treatment programs; providing for a program sponsor and medical director; setting forth staffing requirements; providing for regulation and oversight by Office of Health Facility Licensure and Certification; designating necessity for a medical director and prescribing minimum training and performance requirements; allowing enrollment as a Medicaid provider; providing billing requirements; setting forth minimum certification requirements; mandating state and federal criminal background checks; designating who may prescribe and dispense medication-assisted treatment medications; setting certain minimum practice standards and patient treatment standards for any medication-assisted treatment program prescribing or dispensing medication-assisted treatment medications; requiring review of the Controlled Substances Monitoring Database for each patient at least quarterly; setting compliance requirements for a medication-assisted treatment program; providing for patient protocols, treatment plans and profiles; allowing liquid methadone to be prescribed and dispensed only as allowed by legislative rule; setting notification requirements of operation changes; restricting location of medication-assisted treatment programs; allowing for waivers and variances from certification or licensure standards; permitting inspection warrants; providing for an administrative review and appeal process; allowing civil monetary penalties; designating license limitations for

deviation for accepted practice or patient treatment standards; permitting the secretary to promulgate rules, including emergency rules; providing advertisement requirements; creating a moratorium on new opioid treatment programs; establishing state authority and state oversight authority for medication-assisted treatment programs; mandating data collection; and granting Office of Health Facility Licensure and Certification access to the Controlled Substances Monitoring Database for use in certification, licensure and regulation of health facilities.

Be it enacted by the Legislature of West Virginia:

That §16-1-4 of the Code of West Virginia, 1931, as amended, be amended and reenacted; that said code be amended by adding thereto a new article, designated §16-5Y-1, §16-5Y-2, §16-5Y-3, §16-5Y-4, §16-5Y-5, §16-5Y-6, §16-5Y-7, §16-5Y-8, §16-5Y-9, §16-5Y-10, §16-5Y-11, §16-5Y-12 and §16-5Y-13; and that §60A-9-5 of said code be amended and reenacted, all to read as follows:

CHAPTER 16. PUBLIC HEALTH.

ARTICLE 1. STATE PUBLIC HEALTH SYSTEM.

§16-1-4. Proposal of rules by the secretary.

(a) The secretary may propose rules in accordance with the provisions of article three, chapter twenty-nine-a of this code that are necessary and proper to effectuate the purposes of this chapter. The secretary may appoint or designate advisory councils of professionals in the areas of hospitals, nursing homes, barbers and beauticians, postmortem examinations, mental health and intellectual disability centers and any other areas necessary to advise the secretary on rules.

(b) The rules may include, but are not limited to, the regulation of:

(1) Land usage endangering the public health: *Provided,* That no rules may be promulgated or enforced restricting the subdivision or development of any parcel of land within which the individual tracts, lots or parcels exceed two acres each in total surface area and which

individual tracts, lots or parcels have an average frontage of not less than one hundred fifty feet even though the total surface area of the tract, lot or parcel equals or exceeds two acres in total surface area, and which tracts are sold, leased or utilized only as single-family dwelling units. Notwithstanding the provisions of this subsection, nothing in this section may be construed to abate the authority of the department to:

(A) Restrict the subdivision or development of a tract for any more intense or higher density occupancy than a single-family dwelling unit;

(B) Propose or enforce rules applicable to single-family dwelling units for single-family dwelling unit sanitary sewerage disposal systems; or

(C) Restrict any subdivision or development which might endanger the public health, the sanitary condition of streams or sources of water supply;

(2) The sanitary condition of all institutions and schools, whether public or private, public conveyances, dairies, slaughterhouses, workshops, factories, labor camps, all other places open to the general public and inviting public patronage or public assembly, or tendering to the public any item for human consumption and places where trades or industries are conducted;

(3) Occupational and industrial health hazards, the sanitary conditions of streams, sources of water supply, sewerage facilities and plumbing systems and the qualifications of personnel connected with any of those facilities, without regard to whether the supplies or systems are publicly or privately owned; and the design of all water systems, plumbing systems, sewerage systems, sewage treatment plants, excreta disposal methods and swimming pools in this state, whether publicly or privately owned;

(4) Safe drinking water, including:

(A) The maximum contaminant levels to which all public water systems must conform in order to prevent adverse effects on the health of individuals and, if appropriate, treatment techniques that reduce the contaminant or contaminants to a level which will not adversely affect the health of the consumer. The rule shall contain provisions to protect and prevent contamination

of wellheads and well fields used by public water supplies so that contaminants do not reach a level that would adversely affect the health of the consumer;

(B) The minimum requirements for: Sampling and testing; system operation; public notification by a public water system on being granted a variance or exemption or upon failure to comply with specific requirements of this section and rules promulgated under this section; record keeping; laboratory certification; as well as procedures and conditions for granting variances and exemptions to public water systems from state public water systems rules; and

(C) The requirements covering the production and distribution of bottled drinking water and may establish requirements governing the taste, odor, appearance and other consumer acceptability parameters of drinking water;

(5) Food and drug standards, including cleanliness, proscription of additives, proscription of sale and other requirements in accordance with article seven of this chapter as are necessary to protect the health of the citizens of this state;

(6) The training and examination requirements for emergency medical service attendants and emergency medical care technician-paramedics; the designation of the health care facilities, health care services and the industries and occupations in the state that must have emergency medical service attendants and emergency medical care technician-paramedics employed and the availability, communications and equipment requirements with respect to emergency medical service attendants and to emergency medical care technician-paramedics. Any regulation of emergency medical service attendants and emergency medical care technician- paramedics may not exceed the provisions of article four-c of this chapter;

(7) The health and sanitary conditions of establishments commonly referred to as bed and breakfast inns. For purposes of this article, “bed and breakfast inn” means an establishment providing sleeping accommodations and, at a minimum, a breakfast for a fee. The secretary may not require an owner of a bed and breakfast providing sleeping accommodations of six or fewer rooms to install a restaurant-style or commercial food service facility. The secretary may not

require an owner of a bed and breakfast providing sleeping accommodations of more than six rooms to install a restaurant-type or commercial food service facility if the entire bed and breakfast inn or those rooms numbering above six are used on an aggregate of two weeks or less per year;

(8) Fees for services provided by the Bureau for Public Health including, but not limited to, laboratory service fees, environmental health service fees, health facility fees and permit fees;

(9) The collection of data on health status, the health system and the costs of health care.

~~(10) Opioid treatment programs duly licensed and operating under the requirements of chapter twenty-seven of this code.~~

~~(A) The Health Care Authority shall develop new certificate of need standards, pursuant to the provisions of article two-d of this chapter, that are specific for opioid treatment program facilities.~~

~~(B) No applications for a certificate of need for opioid treatment programs may be approved by the Health Care Authority as of the effective date of the 2007 amendments to this subsection.~~

~~(C) There is a moratorium on the licensure of new opioid treatment programs that do not have a certificate of need as of the effective date of the 2007 amendments to this subsection, which shall continue until the Legislature determines that there is a necessity for additional opioid treatment facilities in West Virginia.~~

~~(D) The secretary shall file revised emergency rules with the Secretary of State to regulate opioid treatment programs in compliance with the provisions of this section. Any opioid treatment program facility that has received a certificate of need pursuant to article two-d, of this chapter by the Health Care Authority shall be permitted to proceed to license and operate the facility.~~

~~(E) All existing opioid treatment programs shall be subject to monitoring by the secretary. All staff working or volunteering at opioid treatment programs shall complete the minimum education, reporting and safety training criteria established by the secretary. All existing opioid treatment programs shall be in compliance within one hundred eighty days of the effective date~~

~~of the revised emergency rules as required herein. The revised emergency rules shall provide at a minimum:~~

~~(i) That the initial assessment prior to admission for entry into the opioid treatment program shall include an initial drug test to determine whether an individual is either opioid addicted or presently receiving methadone for an opioid addiction from another opioid treatment program.~~

~~(ii) The patient may be admitted to the opioid treatment program if there is a positive test for either opioids or methadone or there are objective symptoms of withdrawal, or both, and all other criteria set forth in the rule for admission into an opioid treatment program are met. Admission to the program may be allowed to the following groups with a high risk of relapse without the necessity of a positive test or the presence of objective symptoms: Pregnant women with a history of opioid abuse, prisoners or parolees recently released from correctional facilities, former clinic patients who have successfully completed treatment but who believe themselves to be at risk of imminent relapse and HIV patients with a history of intravenous drug use.~~

~~(iii) That within seven days of the admission of a patient, the opioid treatment program shall complete an initial assessment and an initial plan of care.~~

~~(iv) That within thirty days after admission of a patient, the opioid treatment program shall develop an individualized treatment plan of care and attach the plan to the patient's chart no later than five days after the plan is developed. The opioid treatment program shall follow guidelines established by a nationally recognized authority approved by the secretary and include a recovery model in the individualized treatment plan of care. The treatment plan is to reflect that detoxification is an option for treatment and supported by the program; that under the detoxification protocol the strength of maintenance doses of methadone should decrease over time, the treatment should be limited to a defined period of time, and participants are required to work toward a drug-free lifestyle.~~

~~(v) That each opioid treatment program shall report and provide statistics to the Department of Health and Human Resources at least semiannually which includes the total~~

~~number of patients; the number of patients who have been continually receiving methadone treatment in excess of two years, including the total number of months of treatment for each such patient; the state residency of each patient; the number of patients discharged from the program, including the total months in the treatment program prior to discharge and whether the discharge was for:~~

~~(A) Termination or disqualification;~~

~~(B) Completion of a program of detoxification;~~

~~(C) Voluntary withdrawal prior to completion of all requirements of detoxification as determined by the opioid treatment program;~~

~~(D) Successful completion of the individualized treatment care plan; or~~

~~(E) An unexplained reason.~~

~~(vi) That random drug testing of all patients shall be conducted during the course of treatment at least monthly. For purposes of these rules, "random drug testing" means that each patient of an opioid treatment program facility has a statistically equal chance of being selected for testing at random and at unscheduled times. Any refusal to participate in a random drug test shall be considered a positive test. Nothing contained in this section or the legislative rules promulgated in conformity herewith will preclude any opioid treatment program from administering such additional drug tests as determined necessary by the opioid treatment program.~~

~~(vii) That all random drug tests conducted by an opioid treatment program shall, at a minimum, test for the following:~~

~~(A) Opiates, including oxycodone at common levels of dosing; (B) Methadone and any other medication used by the program as an intervention;~~

~~(C) Benzodiazepine including diazepam, lorazepan, clonazepam and alprazolam;~~

~~(D) Cocaine;~~

~~(E) Methamphetamine or amphetamine;~~

~~(F) Tetrahydrocannabinol, delta-9-tetrahydrocannabinol or dronabinol or other similar substances; or~~

~~(G) Other drugs determined by community standards, regional variation or clinical indication.~~

~~(viii) That a positive drug test is a test that results in the presence of any drug or substance listed in this schedule and any other drug or substance prohibited by the opioid treatment program. A positive drug test result after the first six months in an opioid treatment program shall result in the following:~~

~~(A) Upon the first positive drug test result, the opioid treatment program shall:~~

~~(1) Provide mandatory and documented weekly counseling of no less than thirty minutes to the patient, which shall include weekly meetings with a counselor who is licensed, certified or enrolled in the process of obtaining licensure or certification in compliance with the rules and on staff at the opioid treatment program;~~

~~(2) Immediately revoke the take home methadone privilege for a minimum of thirty days; and~~

~~(B) Upon a second positive drug test result within six months of a previous positive drug test result, the opioid treatment program shall:~~

~~(1) Provide mandatory and documented weekly counseling of no less than thirty minutes, which shall include weekly meetings with a counselor who is licensed, certified or enrolled in the process of obtaining licensure or certification in compliance with the rules and on staff at the opioid treatment program;~~

~~(2) Immediately revoke the take-home methadone privilege for a minimum of sixty days; and~~

~~(3) Provide mandatory documented treatment team meetings with the patient.~~

~~(C) Upon a third positive drug test result within a period of six months the opioid treatment program shall:~~

~~(1) Provide mandatory and documented weekly counseling of no less than thirty minutes, which shall include weekly meetings with a counselor who is licensed, certified or enrolled in the process of obtaining licensure or certification in compliance with the rules and on staff at the opioid treatment program;~~

~~(2) Immediately revoke the take-home methadone privilege for a minimum of one hundred twenty days; and~~

~~(3) Provide mandatory and documented treatment team meetings with the patient which will include, at a minimum: The need for continuing treatment; a discussion of other treatment alternatives; and the execution of a contract with the patient advising the patient of discharge for continued positive drug tests.~~

~~(D) Upon a fourth positive drug test within a six-month period, the patient shall be immediately discharged from the opioid treatment program or, at the option of the patient, shall immediately be provided the opportunity to participate in a twenty- one day detoxification plan, followed by immediate discharge from the opioid treatment program: *Provided,* That testing positive solely for tetrahydrocannabinol, delta-9-tetrahydrocannabinol or dronabinol or similar substances shall not serve as a basis for discharge from the program.~~

~~(ix) That the opioid treatment program must report and provide statistics to the Department of Health and Human Resources demonstrating compliance with the random drug test rules, including:~~

~~(A) Confirmation that the random drug tests were truly random in regard to both the patients tested and to the times random drug tests were administered by lottery or some other objective standard so as not to prejudice or protect any particular patient;~~

~~(B) Confirmation that the random drug tests were performed at least monthly for all program participants;~~

~~(C) The total number and the number of positive results; and~~

~~(D) The number of expulsions from the program.~~

~~(x) That all opioid treatment facilities be open for business seven days per week; however, the opioid treatment center may be closed for eight holidays and two training days per year. During all operating hours, every opioid treatment program shall have a health care professional as defined by rule promulgated by the secretary actively licensed in this state present and on duty at the treatment center and a physician actively licensed in this state available for consultation.~~

~~(xi) That the Office of Health Facility Licensure and Certification develop policies and procedures in conjunction with the Board of Pharmacy that will allow physicians treating patients through an opioid treatment program access to the Controlled Substances Monitoring Program database maintained by the Board of Pharmacy at the patient's intake, before administration of methadone or other treatment in an opioid treatment program, after the initial thirty days of treatment, prior to any take-home medication being granted, after any positive drug test, and at each ninety-day treatment review to ensure the patient is not seeking prescription medication from multiple sources. The results obtained from the Controlled Substances Monitoring Program database shall be maintained with the patient records.~~

~~(xii) That each opioid treatment program shall establish a peer review committee, with at least one physician member, to review whether the program is following guidelines established by a nationally recognized authority approved by the secretary. The secretary shall prescribe the procedure for evaluation by the peer review. Each opioid treatment program shall submit a report of the peer review results to the secretary on a quarterly basis.~~

~~(xiii)~~ (c) The secretary shall propose a rule for legislative approval in accordance with the provisions of article three, chapter twenty-nine-a of this code for the distribution of state aid to local health departments and basic public health services funds.

The rule shall include the following provisions:

Base allocation amount for each county;

Establishment and administration of an emergency fund of no more than two percent of the total annual funds of which unused amounts are to be distributed back to local boards of health at the end of each fiscal year;

A calculation of funds utilized for state support of local health departments;

Distribution of remaining funds on a per capita weighted population approach which factors coefficients for poverty, health status, population density and health department interventions for each county and a coefficient which encourages counties to merge in the provision of public health services;

A hold-harmless provision to provide that each local health department receives no less in state support for a period of four years beginning in the 2009 budget year.

The Legislature finds that an emergency exists and, therefore, the secretary shall file an emergency rule to implement the provisions of this section pursuant to the provisions of section fifteen, article three, chapter twenty-nine-a of this code. The emergency rule is subject to the prior approval of the Legislative Oversight Commission on Health and Human Resources Accountability prior to filing with the Secretary of State.

~~(xiv)~~ (d) The secretary may propose rules for legislative approval that may include the regulation of other ~~Other~~ health-related matters which the department is authorized to supervise and for which the rule-making authority has not been otherwise assigned.

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

§16-5Y-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 Department of Health and Human Resources. 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.

§16-5Y-2. Definitions.

(a) "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.

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

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

(d) "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.

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

(f) "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.

(g) "Controlled substances monitoring program database" means the database maintained by the West Virginia Board of Pharmacy pursuant to section three, article nine, chapter

sixty-a of this code that monitors and tracks certain prescriptions written or dispensed by dispensers and prescribers in West Virginia.

(h) "Director" means the Director of the Office of Health Facility Licensure and Certification.

(i) "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.

(j) "Governing body" means the person or persons identified as being legally responsible for the 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.

(k) "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.

(l) "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.

(m) "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.

(n) "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 and is listed on the schedule of controlled substances in article two, chapter sixty-a of this code.

(o) "Office-based medication-assisted treatment" means all publicly or privately owned medication-assisted treatment programs in clinics, facilities, offices or programs that treat 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 or other medication-assisted medication approved for use in office-based medication-assisted treatment setting.

(p) "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.

(q) "Opioid treatment program" means all publicly or privately owned medication-assisted treatment programs in clinics, facilities, offices or programs that treat individuals with substance use disorders through on-site administration or dispensing of a medication-assisted treatment medication in the form of an opioid agonist or partial opioid agonist.

(r) "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.

(s) "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.

(t) "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.

(u) "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.

(v) “Program sponsor” means the person named in the application for the certification and licensure of a 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.

(w) “Secretary” means the Secretary of the West Virginia Department of Health and Human Resources or his or her designee.

(x) “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.

(y) “State oversight agency” means the agency or office of state government identified by the secretary to provide regulatory oversight of medication-assisted treatment programs on behalf of the State of West Virginia.

(z) “Substance” means the following:

(1) Alcohol;

(2) Controlled substances defined by sections two hundred four, two hundred six, two hundred eight and two hundred ten, article two, chapter sixty-a 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.

(aa) “Substance Abuse and Mental Health Services Administration” means the agency under the 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.

(bb) "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.

(cc) "Variance" means written permission granted by the secretary 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.

(dd) "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.

§16-5Y-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 secretary 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 secretary 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 provide a recommendation to the secretary whether to approve or deny the application for a license. The secretary 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 twelve-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 sixty days prior to the license expiration date, an application for renewal shall be submitted by the opioid treatment program to the secretary on forms furnished by the secretary. A license shall be renewed if the secretary 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 secretary of any change in ownership within ten days of the change and must submit a new application within the time frame prescribed by the secretary.

(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 secretary 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;

(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 secretary 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 secretary 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.

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

§16-5Y-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 secretary 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 secretary 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 then provide a recommendation to the secretary whether to approve or deny the application for registration. The secretary 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 twelve-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 sixty days prior to the registration expiration date, an application for renewal shall be submitted by the office-based medication-assisted treatment program to the secretary on forms furnished by the secretary. A registration shall be renewed if the secretary 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 medication-assisted treatment program requires submission of a new application. The medication-assisted treatment program shall notify the secretary of any change in ownership within ten days of the change and must submit a new application within the time frame prescribed by the secretary.

(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 secretary 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

(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;

(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 secretary 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 secretary 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 a 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.

§16-5Y-5. Operational requirements.

(a) The medication-assisted treatment program shall be licensed and registered in this state with the secretary, 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 medication-assisted treatment program as provided in rules promulgated pursuant to this article. Within ten 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;

(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 secretary; and

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

(d) Each medication-assisted treatment program shall designate counseling staff, either employee 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) A licensed psychiatrist;

(2) Certification as an alcohol and drug counselor;

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

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

(6) 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.

(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 such treatment. 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 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 article forty-nine, chapter sixteen of this code and subsequent rules promulgated thereunder.

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

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

(2) Whose 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) Whose 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 section one hundred one, article one, chapter sixty-a 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. 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 such 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 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 State 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 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 secretary;

(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 physician, physician assistant or advanced practice registered nurse shall perform a physical examination of a patient on the same day that the prescriber initially prescribes, dispenses or administers a medication-assisted treatment medication to a patient and at intervals as required in the rules promulgated pursuant to this article;

(5) An alcohol and drug abuse counselor, an advanced alcohol and drug abuse counselor or other qualified counselor, psychiatrist, psychologist or social worker shall perform a biopsychosocial assessment, including, but not limited to, a mental status examination of a patient on the same day or no more than seven days prior to the day that the physician initially prescribes, dispenses or administers a medication-assisted treatment medication to a patient and at intervals as required in the rules promulgated pursuant to this article; and

(6) 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 secretary and appropriate law-enforcement agencies in writing within twenty-four hours following any theft or loss of a prescription blank or breach of any other method of prescribing a medication-assisted treatment medication.

(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 secretary, 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.

§16-5Y-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 article five-h, chapter sixteen 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.

(1) 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 secretary 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 secretary 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 secretary 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 secretary 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.

(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 secretary for the duration of such waiver or variance.

§16-5Y-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 secretary, licensed in this state, and a law-enforcement officer shall 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 secretary, 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 secretary 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.

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

(a) The secretary 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 secretary 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 secretary 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 ten working days after receipt of the secretary'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 secretary shall proceed in accordance with the provisions of article five, chapter twenty-nine-a 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 secretary 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 secretary as a result of the hearing provided in this section may, within thirty 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 court may affirm, modify or reverse the decision of the secretary and either the applicant, licensee or registrant, or the secretary 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 thirty 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 secretary 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 secretary. 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 secretary may grant a variance pursuant to section six of this article 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 secretary, but may not exceed one year.

§16-5Y-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 secretary 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 secretary 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 secretary 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 secretary 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 secretary 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 secretary 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 secretary or any other board, court or entity.

(b) Notwithstanding the existence or pursuit of any other remedy, the secretary 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 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 secretary 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 secretary shall provide notice of the violation to the applicable licensing board.

§16-5Y-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.

§16-5Y-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) Review 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 approved by the secretary;

(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.

§16-5Y-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.

§16-5Y-13. Rules; minimum standards for medication-assisted treatment programs.

(a) The secretary shall promulgate rules in accordance with the provisions of chapter twenty-nine-a 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 secretary determines are appropriate.

(b) The Legislature finds that an emergency exists and, therefore, the secretary shall file an emergency rule to implement the provisions of this section pursuant to the provisions of section fifteen, article three, chapter twenty-nine-a of this code.

CHAPTER 60A. UNIFORM CONTROLLED SUBSTANCES ACT.

ARTICLE 9. CONTROLLED SUSBTANCES MONITORING.

§60A-9-5. Confidentiality; limited access to records; period of retention; no civil liability for required reporting.

(a) (1) The information required by this article to be kept by the board is confidential and not subject to the provisions of chapter twenty-nine-b of this code or obtainable as discovery in

civil matters absent a court order and is open to inspection only by inspectors and agents of the board, members of the West Virginia State Police expressly authorized by the Superintendent of the West Virginia State Police to have access to the information, authorized agents of local law-enforcement agencies as members of a federally affiliated drug task force, authorized agents of the federal Drug Enforcement Administration, duly authorized agents of the Bureau for Medical Services, duly authorized agents of the Office of the Chief Medical Examiner for use in post-mortem examinations, duly authorized agents of the Office of Health Facility Licensure and Certification for use in certification, licensure and regulation of health facilities, duly authorized agents of licensing boards of practitioners in this state and other states authorized to prescribe Schedules II, III, and IV controlled substances, prescribing practitioners and pharmacists and persons with an enforceable court order or regulatory agency administrative subpoena: *Provided*, That all law-enforcement personnel who have access to the Controlled Substances Monitoring Program database shall be granted access in accordance with applicable state laws and the board's legislative rules, shall be certified as a West Virginia law-enforcement officer and shall have successfully completed training approved by the board. All information released by the board must be related to a specific patient or a specific individual or entity under investigation by any of the above parties except that practitioners who prescribe or dispense controlled substances may request specific data related to their Drug Enforcement Administration controlled substance registration number or for the purpose of providing treatment to a patient: *Provided, however,* That the West Virginia Controlled Substances Monitoring Program Database Review Committee established in subsection (b) of this section is authorized to query the database to comply with said subsection.

(2) Subject to the provisions of subdivision (1) of this subsection, the board shall also review the West Virginia Controlled Substance Monitoring Program database and issue reports that identify abnormal or unusual practices of patients who exceed parameters as determined by the advisory committee established in this section. The board shall communicate with prescribers

and dispensers to more effectively manage the medications of their patients in the manner recommended by the advisory committee. All other reports produced by the board shall be kept confidential. The board shall maintain the information required by this article for a period of not less than five years. Notwithstanding any other provisions of this code to the contrary, data obtained under the provisions of this article may be used for compilation of educational, scholarly or statistical purposes, and may be shared with the West Virginia Department of Health and Human Resources for those purposes, as long as the identities of persons or entities and any personally identifiable information, including protected health information, contained therein shall be redacted, scrubbed or otherwise irreversibly destroyed in a manner that will preserve the confidential nature of the information. No individual or entity required to report under section four of this article may be subject to a claim for civil damages or other civil relief for the reporting of information to the board as required under and in accordance with the provisions of this article.

(3) The board shall establish an advisory committee to develop, implement and recommend parameters to be used in identifying abnormal or unusual usage patterns of patients in this state. This advisory committee shall:

(A) Consist of the following members: A physician licensed by the West Virginia Board of Medicine, a dentist licensed by the West Virginia Board of Dental Examiners, a physician licensed by the West Virginia Board of ~~Osteopathy~~ Osteopathic Medicine, a licensed physician certified by the American Board of Pain Medicine or subspecialty certified by the American Osteopathic Association in Pain Medicine or Pain Management, a licensed physician board certified in medical oncology recommended by the West Virginia State Medical Association or West Virginia Osteopathic Medical Association, a licensed physician board certified in palliative care recommended by the West Virginia Center on End of Life Care, a pharmacist licensed by the West Virginia Board of Pharmacy, a licensed physician member of the West Virginia Academy of Family Physicians, an expert in drug diversion and such other members as determined by the board.

(B) Recommend parameters to identify abnormal or unusual usage patterns of controlled substances for patients in order to prepare reports as requested in accordance with subdivision (2), subsection (a) of this section.

(C) Make recommendations for training, research and other areas that are determined by the committee to have the potential to reduce inappropriate use of prescription drugs in this state, including, but not limited to, studying issues related to diversion of controlled substances used for the management of opioid addiction.

(D) Monitor the ability of medical services providers, health care facilities, pharmacists and pharmacies to meet the 24-hour reporting requirement for the Controlled Substances Monitoring Program set forth in section three of this article and report on the feasibility of requiring real-time reporting.

(E) Establish outreach programs with local law enforcement to provide education to local law enforcement on the requirements and use of the Controlled Substances Monitoring Program Database established in this article.

(b) The board shall create a West Virginia Controlled Substances Monitoring Program Database Review Committee of individuals consisting of two prosecuting attorneys from West Virginia counties, two physicians with specialties which require extensive use of controlled substances and a pharmacist who is trained in the use and abuse of controlled substances. The review committee may determine that an additional physician who is an expert in the field under investigation be added to the team when the facts of a case indicate that the additional expertise is required. The review committee, working independently, may query the database based on parameters established by the advisory committee. The review committee may make determinations on a case-by-case basis on specific unusual prescribing or dispensing patterns indicated by outliers in the system or abnormal or unusual usage patterns of controlled substances by patients which the review committee has reasonable cause to believe necessitates further action by law enforcement or the licensing board having jurisdiction over the prescribers

or dispensers under consideration. The review committee shall also review notices provided by the chief medical examiner pursuant to subsection (h), section ten, article twelve, chapter sixty-one of this code and determine on a case-by-case basis whether a practitioner who prescribed or dispensed a controlled substance resulting in or contributing to the drug overdose may have breached professional or occupational standards or committed a criminal act when prescribing the controlled substance at issue to the decedent. Only in those cases in which there is reasonable cause to believe a breach of professional or occupational standards or a criminal act may have occurred, the review committee shall notify the appropriate professional licensing agency having jurisdiction over the applicable prescriber or dispenser and appropriate law-enforcement agencies and provide pertinent information from the database for their consideration. The number of cases identified shall be determined by the review committee based on a number that can be adequately reviewed by the review committee. The information obtained and developed may not be shared except as provided in this article and is not subject to the provisions of chapter twenty-nine-b of this code or obtainable as discovering in civil matters absent a court order.

(c) The board is responsible for establishing and providing administrative support for the advisory committee and the West Virginia Controlled Substances Monitoring Program Database Review Committee. The advisory committee and the review committee shall elect a chair by majority vote. Members of the advisory committee and the review committee may not be compensated in their capacity as members but shall be reimbursed for reasonable expenses incurred in the performance of their duties.

(d) The board shall promulgate rules with advice and consent of the advisory committee, in accordance with the provisions of article three, chapter twenty-nine-a of this code. The legislative rules must include, but shall not be limited to, the following matters:

(1) Identifying parameters used in identifying abnormal or unusual prescribing or dispensing patterns;

(2) Processing parameters and developing reports of abnormal or unusual prescribing or dispensing patterns for patients, practitioners and dispensers;

(3) Establishing the information to be contained in reports and the process by which the reports will be generated and disseminated; and

(4) Setting up processes and procedures to ensure that the privacy, confidentiality and security of information collected, recorded, transmitted and maintained by the review committee is not disclosed except as provided in this section.

(e) All practitioners, as that term is defined in section one hundred one, article two of this chapter who prescribe or dispense Schedule II, III or IV controlled substances shall have online or other form of electronic access to the West Virginia Controlled Substances Monitoring Program database;

(f) Persons or entities with access to the West Virginia Controlled Substances Monitoring Program Database pursuant to this section may, pursuant to rules promulgated by the board, delegate appropriate personnel to have access to said database;

(g) Good faith reliance by a practitioner on information contained in the West Virginia Controlled Substances Monitoring Program Database in prescribing or dispensing or refusing or declining to prescribe or dispense a Schedule II, III or IV controlled substance shall constitute an absolute defense in any civil or criminal action brought due to prescribing or dispensing or refusing or declining to prescribe or dispense; and

(h) A prescribing or dispensing practitioner may notify law enforcement of a patient who, in the prescribing or dispensing practitioner's judgment, may be in violation of section four hundred ten, article four of this chapter based on information obtained and reviewed from the controlled substances monitoring database. A prescribing or dispensing practitioner who makes a notification pursuant to this subsection is immune from any civil, administrative or criminal liability that otherwise might be incurred or imposed because of the notification if the notification is made in good faith.

(i) Nothing in the article may be construed to require a practitioner to access the West Virginia Controlled Substances Monitoring Program database except as provided in section five-a of this article.

(j) The board shall provide an annual report on the West Virginia Controlled Substance Monitoring Program to the Legislative Oversight Commission on Health and Human Resources Accountability with recommendations for needed legislation no later than January 1 of each year.

NOTE: The purpose of this bill is to repeal the regulation of opioid treatment programs, to create licenses for all medication-assisted treatment programs, including opioid treatment programs and office based medication-assisted treatment programs, and provide for regulation and oversight by the Office of Health Facility Licensure and Certification and to grant the Office Health Facility Licensure and Certification access to the Controlled Substance Monitoring Database for use in certification, licensure and regulation of health facilities.

Chapter 16, Article 5X is a new article. Strike-throughs indicate language that would be stricken from a heading or the present law and underscoring indicates new language that would be added.