



WEST VIRGINIA SECRETARY OF STATE

MAC WARNER

ADMINISTRATIVE LAW DIVISION

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Office of West Virginia
Secretary Of State

NOTICE OF RULE MODIFICATION OF A PROPOSED RULE

AGENCY: Health And Human Resources

RULE TYPE: Legislative

TITLE-SERIES: 69-12

RULE NAME: MEDICATION-ASSISTED TREATMENT
-- OFFICE-BASED MEDICATION-
ASSISTED TREATMENT

CITE AUTHORITY: 16-5Y-13

The above proposed Legislative rules, following review by the Legislative Rule Making Review Committee, is hereby modified as a result of review and comment by the Legislative Rule Making Review Committee. The attached modifications are filed with the Secretary of State.

BY CHOOSING 'YES', I ATTEST THAT THE PREVIOUS STATEMENT IS TRUE AND CORRECT.

Yes

April L Robertson -- By my signature, I certify that I am the person authorized to file legislative rules, in accordance with West Virginia Code §29A-3-11 and §39A-3-2.

TITLE 69
LEGISLATIVE RULE
DEPARTMENT OF HEALTH AND HUMAN RESOURCES

SERIES 12
MEDICATION-ASSISTED TREATMENT -- OFFICE-BASED MEDICATION-ASSISTED TREATMENT

§69-12-1. General.

1.1. Scope. -- This legislative rule establishes standards and procedures for the licensure and regulation of medication-assisted treatment - office-based medication-assisted treatment (OBMAT) programs.

1.2. Authority. -- W. Va. Code §16-5Y-1, *et seq.*

1.3. Filing Date. -- ~~May 1, 2019.~~

1.4. Effective Date. -- ~~July 30, 2019.~~

1.5. Sunset Provision. -- This rule shall terminate and have no further force or effect on ~~July 30, 2024~~ August 1, 2029.

1.6. Purpose. -- The purpose of this rule is to ensure that all West Virginia OBMAT programs conform to a common set of minimum standards and procedures to ensure the care, treatment, health, safety and welfare of patients therein.

1.7. Enforcement. -- This rule is enforced by the Secretary of the Department of Health and Human Resources or his or her designee.

§69-12-2. Definitions.

2.1. Definitions incorporated by reference. -- Those terms defined in W. Va. Code §§16-5Y-1, *et seq.* are incorporated herein by reference.

2.2. Administrative Detoxification or Administrative Withdrawal -- The detoxification from the approved medication-assisted treatment medication for the safety and well-being of the patient, other patients and staff of the OBMAT program.

2.3. Advanced Practice Registered Nurse -- A registered nurse who has acquired advanced clinical knowledge and skills preparing him or her to provide direct and indirect care to patients, completed a board approved graduate-level education program, passed a board-approved national certification examination, and has met all the requirements set forth by the West Virginia Board of Examiners for Professional Registered Nurses.

2.4. Adverse Event or Incident -- An event involving an immediate threat to the care or safety of an individual, either staff, patient, or visitor; the possibility of serious operational or personnel problems within the OBMAT program facility; or the potential to undermine public confidence in the OBMAT program.

2.5. Approved Authorities -- Programs or authorities that publish practice or treatment guidelines, standards, or protocols that the Secretary has approved for use by MAT programs. Approved authorities include, but are not limited to, the American Society of Addiction Medicine (ASAM); the Center for Substance Abuse Treatment (CSAT); the National Institute on Drug Abuse (NIDA); the American Association for the Treatment of Opioid Dependence (AATOD); the Federation of State Medical Boards (FSMB); and any other program or authority approved by the Secretary.

2.6. Case Management -- The process of coordinating and monitoring the services provided to a patient both within the program and in conjunction with other providers.

2.7. Clinical Staff -- The individuals employed by or associated with an OBMAT program who provide treatment, care, or rehabilitation to program patients or patients' families.

2.8. Co-Occurring Disorders -- The combination of current or former substance use disorders and any other mental disorders recognized in the current edition of the *Diagnostic and Statistical Manual of Mental Disorders* published by the American Psychiatric Association.

2.9. Coordination of Care Agreement -- An agreement signed by the physician, counsel, and patient allowing open communication and the exchange of health information between the indicated providers to ensure the patient is provided comprehensive and holistic treatment for substance use disorder, when medical treatment and counseling services are not being treated within the same program;

2.10. Counseling Session -- A face-to-face interaction, which may include telehealth, in a private location between a patient(s) and a primary counselor for a period of no less than 30 continuous minutes designated to address patient substance use disorder issues or coping strategies and individualized treatment plan of care.

2.11. Counselor -- A person who, by education, training, and experience, is qualified to provide psychosocial education, treatment, and guidance to patients enrolled with an OBMAT program and, if desired, to the families of such patients, in order to accomplish behavioral health, wellness, education, and other life goals.

2.12. Crisis -- A deteriorating or unstable situation often developing suddenly or rapidly that produces acute, heightened, emotional, mental, physical, medical or behavioral distress; or any situation or circumstance in which the individual perceives or experiences a sudden loss of his ability to use effective problem-solving and coping skills.

2.13. Critical Incident -- A life, safety, or health threat involving the staff or patients participating in a program, including, but not limited to, death or physical or sexual assault.

2.14. Detoxification or Medically Supervised Withdrawal Treatment -- The prescribing of a medication-assisted treatment medication to a patient in decreasing doses over time, under the supervision of a program physician, to alleviate adverse physical or psychosocial effects incident to withdrawal from the continuous or substantial use of an opioid drug.

2.15. Discharge Plan -- The written plan that establishes the criteria for a patient's discharge from a service and identifies and coordinates delivery of any services needed after discharge.

2.16. Diversion -- An activity involving the legitimate acquisition of pharmaceutical agents illegally diverted to entities not intended as the recipients by the initial supplier.

2.17. Diversion Control Plan -- A required plan developed and implemented by the OBMAT program, which may include, but is not limited to, the assigning of responsibilities to medical and administrative staff and other specific measures to reduce the possibility of diversion of controlled substances from legitimate treatment to illicit use.

2.18. For-Cause Inspection -- An inspection by any federal or state agency or accreditation body of an OBMAT program that may be operating in violation of 42 C.F.R. § 8 or state medication-assisted treatment rules, may be providing substandard treatment or may be serving as a possible source of diverted medications.

2.19. Grievance -- A written or oral complaint filed by a patient with a program administrator, medical director, or state agency alleging inadequate treatment by the OBMAT program.

2.20. Individualized Plan of Care or Treatment Strategy -- A plan or strategy of treatment and care developed by the patient's physician, counselors, and other health care professionals in conjunction with the patient that outlines attainable short-term treatment goals that are mutually acceptable to the patient and the OBMAT program and which specifies the services to be provided and the frequency and schedule for their provision.

2.21. Induction -- Initial treatment of a patient with medication-assisted treatment medication in order to suppress signs or symptoms of withdrawal or substance cravings; and generally, includes a gradual increase in medication-assisted treatment medication therapy until the symptoms are regularly and reliably suppressed or controlled.

2.22. Inspection or Survey -- Any examination by the Secretary or his or her designee of an OBMAT program including, but not limited to, the premises, staff, patients, and documents pertinent to initial and continued registration, so that the Secretary or his or her designee may determine whether a program is operating in compliance with registration. This includes any survey, monitoring visit, complaint investigation, or other inquiry conducted for the purposes of making a compliance determination with respect to registration requirements.

2.23. Long-Term Detoxification Treatment -- Detoxification or medically supervised withdrawal treatment for a period of more than 30 days.

2.24. Maintenance Treatment -- Treatment following induction and stabilization phases of treatment, and means the prescribing of a partial agonist treatment medication at stable dosage levels for a period in excess of twenty-one days in the treatment of an individual for opioid use disorder;

2.25. Maintenance Dose -- The level of medication-assisted treatment medication considered medically necessary to consistently suppress signs or symptoms of substance use disorders and substance cravings for individuals with a substance use disorder; and is generally administered at the end of the induction period and is individualized for each patient and may gradually change over time.

2.26. Medical and Rehabilitative Services -- Treatment and recovery services such as medical evaluations, counseling, and rehabilitative and other social programs intended to help patients in OBMAT programs become and remain productive members of society.

2.27. Medical or Patient Record -- Medical histories, records, reports, summaries, diagnoses, prognoses, records of treatments, and medication ordered and given, entries, x-rays, radiology interpretations, and other written electronic, or graphic data prepared, kept, made, or maintained in a facility that pertains to services rendered to patients.

2.28. Medical Withdrawal -- The medically managed, gradual, voluntary and therapeutic withdrawal of a patient from medication-assisted treatment, agreed upon by the patient and appropriate staff.

2.29. Medication Error -- An error in administering a medication to an individual and includes when any of the following occur: the wrong medication is given to an individual; the wrong individual is given the medication; the wrong dosage is given to an individual; medication is given to an individual at the wrong time or not at all; or the wrong method is used to administer the medication.

2.30. Mental Health Professional -- A person licensed under Chapter 30 of the West Virginia Code as a psychiatrist, a social worker, a psychologist, or a professional counselor.

2.31. Misuse or Non-Medical Use -- All uses of a prescription medication or substance other than those that are directed by a health care provider acting within his or her scope of practice and used by an intended patient within the law and the requirements of good medical practice.

2.32. Opioid Antagonist -- A drug that blocks opioids reception by attaching to the opioid receptors without activating them thereby causing no opioid effect and blocking full agonist opioids.

2.33. Opioid Drug -- Any substance or drug having an addiction-forming or addiction-sustaining liability similar to morphine or being capable of conversion into a drug or substance having such addiction-forming or addiction-sustaining liability including, but not limited to, heroin, morphine, codeine, oxycodone, hydrocodone, fentanyl, oxymorphone, hydromorphone, methadone, and any natural, semi-synthetic or synthetic drug that acts primarily through mu opioid receptor in the brain.

2.34. Opioid Treatment Services -- Treatment and services provided by an OBMAT program that uses medication-assisted treatment medications as a part of its treatment modality. Opioid treatment services may be provided through outpatient, residential, or hospital settings; and may include medical maintenance, medically supervised withdrawal, and detoxification, various levels of medical, psychosocial, and other types of care, detoxification treatment, and maintenance treatment.

2.35. Peer Recovery Support Services -- Non-clinical recovery support services that are recipient directed and delivered by peers who have life experience with recovery.

2.36. Pharmacotherapy -- The treatment of disease or medical condition through the administration of drugs.

2.37. Physical Dependence -- A state of biologic adaption that is evidenced by a class-specific withdrawal syndrome when the substance is abruptly discontinued or the dose rapidly reduced, or by the administration of an antagonist.

2.38. Physician Assistant -- A person who meets the qualifications set forth in W. Va. Code §§30-3E-1, *et seq.*, and is licensed pursuant to that article to practice medicine under the supervision of a physician or podiatrist licensed by the West Virginia Board of Medicine or the West Virginia Board of Osteopathic Medicine.

2.39. Physician Extender -- A medical staff person other than a program physician, functioning within his or her scope of practice to provide medical services to patients admitted to OBMAT programs. Physician extenders approved for employment at an OBMAT program include advanced practice registered nurses and physician assistants. Registered nurses and licensed practical nurses are not authorized to act as physician extenders in a MAT program, although they may work within the program in other capacities.

2.40. Plan of Correction -- A written description of the actions the OBMAT program intends to take to correct and prevent the reoccurrence of violations of a statute, rule, regulation or policy identified by the designated state oversight agency during an investigation or survey.

2.41. Plan of Education -- An approved continuing education plan that results in a physician, counselor or physician extender attaining professional competence in the field of substance use disorder treatment.

2.42. Positive Drug Screen -- A test that results in the presence of any drug or substance listed in this rule or any other drug or substance prohibited by the OBMAT program. The presence of medication which is part of the patient's individualized plan of care or treatment strategy shall not be considered a positive test.

2.43. Primary Counselor -- The individual designated by the OBMAT program to serve as a consultant and advisor to a patient on a regular basis. The primary counselor may be an addiction counselor and shall be included as a member of the patient's interdisciplinary team for opioid treatment programs.

2.44. Program Physician -- Any physician licensed in this state pursuant to Chapter 30 of the West Virginia Code, designated and approved by the medical director to prescribe and monitor medication-assisted treatment for patients admitted to an OBMAT program. The medical director may serve as a program physician.

2.45. Random Drug Testing -- Approved medical screening and testing of patients for drugs, alcohol, or other substances that shall be conducted so each patient of an OBMAT program has a statistically equal chance of being selected for testing at random, unscheduled times.

2.46. Recovery -- A process of change through which an individual improves his or her health and wellness, lives a self-directed life, and strives to achieve his or her full potential.

2.47. Relapse Prevention Plan -- A plan of action developed by a patient and his or her health and wellness, lives a self-directed life, and strives to achieve his or her full potential.

2.48. Titration -- The gradual increasing or decreasing of doses of a medication-assisted treatment medication to the minimal level clinically required for maintenance.

§69-12-3. State Opioid Treatment Authority.

3.1. The Secretary has designated the Bureau of Behavioral Health and Health Facilities as the state opioid treatment authority.

§69-12-4. State Oversight Authority; Powers and Duties.

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4.1. The Secretary has designated the Office of Health Facility Licensure and Certification (OHFLAC) within the Department of Health and Human Resources to act as the state oversight agency, as that agency is defined in this rule. OHFLAC shall provide regulatory oversight, regulation, and inspection of OBMAT programs.

4.2. The powers and duties of the state oversight agency include, but are not limited to, the following:

4.2.1. Develop and implement rules regarding the registration and oversight of OBMAT programs;

4.2.2. Accept applications and fees for registration of OBMAT programs and conduct all necessary reviews, inspections, or investigations in order to determine whether a registration should be issued;

4.2.3. Issue initial, amended, and renewed registration to an OBMAT program upon a determination that the program is qualified;

4.2.4. Perform both scheduled and unscheduled site visits to OBMAT programs when necessary and appropriate;

4.2.5. Monitor the activities of all OBMAT programs to ensure compliance with all state and federal requirements;

4.2.6. Receive and act upon complaints;

4.2.7. Inspect allegations of rule violations, unauthorized activities, or other conduct that may affect the health, safety, or well-being of patients or employees of an OBMAT program;

4.2.8. Assist an OBMAT program in developing a plan of correction in order to correct any noted violations or deficiencies;

4.2.9. Deny, revoke, or suspend the registration of an OBMAT program in accordance with the applicable administrative proceedings; and

4.2.10. Perform all other necessary actions related to the registration, monitoring, investigating, and oversight of OBMAT programs.

§69-12-5. Applicability.

5.1. Hospitals that are licensed under "Hospital Licensure," W. Va. Code R. §64-12-1, *et seq.*, and behavioral health facilities that are licensed under Behavioral Health Centers Licensure," W. Va. Code R. §64-11-1, *et seq.*, and which provide outpatient medication-assisted treatment as defined in W. Va. Code §16-5Y-2 are subject to the provisions of this rule and to all other relevant federal and state registration requirements as specified by the Secretary.

5.2. An OBMAT program directly operated by the Department of Veterans Affairs, the Indian Health Service or any other department or agency of the United States is not required to obtain a state registration.

5.3. Crisis Stabilization Units (CSU) are not required to obtain a state registration if the following conditions are met:

5.3.1. Treatment at the CSU is utilized only for detoxification or initiation of medication-assisted treatment, or both, or for treatment of a co-occurring disorder of an of an existing medication-assisted treatment client; and

5.3.2. The CSU must document the referral of the patient to an appropriate MAT program upon discharge from the CSU.

§69-12-6. Registration for OBMAT programs; Fees and Costs.

6.1. General Registration Provisions.

6.1.1. No person, partnership, association, or corporation may operate an OBMAT program in the state of West Virginia without first obtaining a registration pursuant to W. Va. Code §16-5Y-4 and this rule.

6.1.2. A registration is valid only for the location and persons named and described in the application.

6.1.3. Each OBMAT program location shall be registered separately, regardless of whether the program is operated under the same business name or management as another program.

6.1.4. Before operating an OBMAT program within the state of West Virginia, a program shall:

6.1.4.a. Be registered and qualified by the United States Department of Health and Human Services under the Controlled Substances Act, 21 U.S.C. §§ 801, *et seq.* (1970), as amended, to dispense medication-assisted treatment medications in the treatment of substance use disorder, if the OBMAT program dispenses MAT medications; and

6.1.4.b. Obtain from the Secretary a registration authorizing the operation of the OBMAT program and facility.

6.1.5. Each registered OBMAT program shall designate a medical director. The medical director shall be responsible for the operation of the program in accordance with the requirements of this rule. Nothing within this rule prevents an OBMAT program from designating two co-medical directors.

6.1.6. If the ownership of an OBMAT program changes, the new owner shall notify the Secretary within 10 days and immediately apply for a new registration. The new owner's application for a registration is valid for three months from the date the application is received by the director.

6.1.7. The OBMAT program shall notify the Secretary within 30 days prior to a change in name or physical address of the program and request an application form for a registration amendment.

6.1.8. If there is a change in the medical director, the OBMAT program must comply with provisions 6.1.5. and 7.3.4. of this rule.

6.1.9. If the OBMAT program is not in substantial compliance with this rule but does not pose a significant risk to the health, safety, or rights of the patients, a registration expiring in less than one year may be issued.

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6.1.10. The Secretary or his or her designee may enter the premises of any practice, office, or facility if the Secretary has reasonable belief that it is being operated or maintained as an OBMAT program without a registration.

6.1.11. If the owner, medical director, or other person in charge of a registered OBMAT program or of any other unregistered practice, office, or facility which the Secretary has reasonable belief is being operated as an OBMAT program refuses entry pursuant to this rule, the Secretary shall petition the Circuit Court of Kanawha County or the county in which the program is located for an inspection warrant.

6.1.12. If the Secretary finds on the basis of an inspection that any person, partnership, association, or corporation is operating as an OBMAT program without a registration, the OBMAT program shall apply for a registration within 10 days.

6.1.13. An OBMAT program that fails to apply for a registration is subject to the penalties established in this rule.

6.1.14. An OBMAT program shall surrender an expired, revoked, or otherwise invalid registration to the Secretary upon written demand.

6.2. Registration Application.

6.2.1. An OBMAT program shall submit an application for registration to the Secretary not less than 30 days and not more than 60 days prior to the anticipated initiation of services.

6.2.2. All applications for an initial, provisional, or renewal registration shall include and provide the documentation specified in W. Va. Code §16-5Y-4 in addition to the following:

6.2.2.a. Documentation of all current federal accreditations, certifications and authorizations;
and

6.2.2.b. A description of the organizational structure of the OBMAT program.

6.3. Registration Fees and Inspection Costs.

6.3.1. All applicants for an initial, provisional, or renewal registration shall be accompanied by a non-refundable fee in the amount required by this rule. In addition to the set fee, the annual renewal fee shall be adjusted on the first day of June of each year to correspond with increases in the consumer price index. The Office of Health Facility Licensure and Certification shall post the annual consumer price index increases on its website located at: <http://ohflac.wvdhhr.org/>. The base amounts for initial, provisional, and renewal fees are as follows:

6.3.1.a. Initial registration fee - \$250;

6.3.1.b. Provisional registration fee - only for existing programs as of the effective date of this rule seeking an initial registration of \$250; and

6.3.1.c. Renewal registration fee:

6.3.1.c.1. 1-50 patients - ~~\$260.56~~ \$250 plus adjustment;

6.3.1.c.2. 51-100 patients - ~~\$312.67~~ \$300 plus adjustment;

6.3.1.c.3. 101-200 patients - ~~\$416.89~~ \$400 plus adjustment; or

6.3.1.c.4. 201 or more patients - ~~\$521.12~~ \$500 plus adjustment.

6.3.2. An OBMAT program shall pay for the cost of the initial inspection prior to issuance of a registration. The fee for the initial inspection of an OBMAT program is \$250 plus the actual cost of the inspection and shall be billed to the applicant.

6.4. Initial Inspection and Issuance of Registration.

6.4.1. Upon receipt of an application for an initial registration to operate as an OBMAT program, the Secretary shall make an inspection of the program and facility in order to determine whether the program has satisfied all of the federal and state requirements for registration.

6.4.2. If the inspection reveals violations, deficiencies, or shortcomings on the part of the OBMAT program, the Secretary shall advise the program of the deficiencies. The program may submit one or more written plans of correction demonstrating compliance with the corrections required. The Secretary may conduct follow-up inspections if required.

6.4.3. Following an application review, onsite inspection or inspections, and approval of subsequent plans of correction as may be needed, if there is substantial compliance with the requirements of this rule and the cost of the inspection has been paid as required by this rule, the Secretary shall issue a registration in one of three categories:

6.4.3.a. An initial registration, valid for 12 months from the date of issuance, shall be issued to programs establishing a new service found to be in substantial compliance on initial review with regard to policy, procedure, facility, and recordkeeping regulations;

6.4.3.b. A provisional registration shall be issued when an OBMAT program seeks a renewal or is an existing program as of the effective date of this rule and is seeking an initial registration, and the OBMAT program is not in substantial compliance with this rule 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

6.4.3.c. A renewal registration shall be issued when an OBMAT program is in substantial compliance with this rule. A renewal registration shall expire not more than 12 months from the date of issuance.

6.4.4. A registration is valid for the OBMAT program named in the application and is not transferrable or assignable.

6.5. Denial of Registration.

6.5.1. The Secretary may deny an application for an initial, provisional, or renewal registration if:

6.5.1.a. The Secretary determines that the application is deficient in any respect;

6.5.1.b. The OBMAT program will not be or is not being operated in accordance with federal or state treatment standards, or federal or state standards, laws, and rules;

6.5.1.c. The OBMAT program will not permit an inspection or survey to proceed or will not permit timely access to records or information deemed relevant by the Secretary;

6.5.1.d. The OBMAT program has made misrepresentations in obtaining accreditation, certification, licensure, or registration;

6.5.1.e. The OBMAT program fails to designate a medical director at the program; or

6.5.1.f. The OBMAT program fails to have an established process for maintaining current, accessible patient records from admission through discharge.

6.5.2. If the Secretary determines not to issue a registration, the Secretary shall notify the applicant in writing of the denial and the basis for the decision. Following the denial, the program must follow closure procedures in this rule, including notification to existing patients.

6.5.3. An OBMAT program shall surrender an expired, revoked, or otherwise invalid registration to the Secretary upon written demand.

6.5.4. An OBMAT program may protest the denial of an initial, provisional, or renewal registration pursuant to the administrative procedures in this rule.

6.6. Renewal or Amended Registrations.

6.6.1. The OBMAT program shall submit an application for a renewal registration to the Secretary not less than 60 days prior to the expiration of the current registration. After the Secretary receives a complete renewal application with the required fee, the existing registration shall not expire until the new registration has been issued or denied.

6.6.2. The program shall notify the Secretary 30 days prior to a change in the name, geographic location or services of a program or a change in the substantial nature of the OBMAT program and simultaneously shall apply for an amended registration.

§69-12-7. Administrative Organization and Management of OBMAT Programs.

7.1. Each OBMAT program shall identify a program administrator, medical director, program physician(s), and, if applicable, counseling staff.

7.2. Program Administrator.

7.2.1. The administrator of an OBMAT program shall have at a minimum a bachelor's degree in an appropriate area of study and a minimum of two years of experience in the fields of substance use disorders, behavioral health, or health care administration; or a master's degree in an appropriate professional area of study; or six years of experience in the fields of substance use disorders, behavioral health, or health care administration; or be a program physician.

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7.2.2. The administrator is responsible for the day-to-day operation of the OBMAT program in a manner consistent with the laws and regulations of the United States Department of Health and Human Services, Drug Enforcement Administration (DEA), and the laws and rules of the state of West Virginia.

7.2.3. Duties of the administrator include:

7.2.3.a. Contribution to the development of policies and procedures for operation of the program;

7.2.3.b. Maintenance and security of the facility;

7.2.3.c. Employment, credentialing, evaluation, scheduling, training, and management of staff;

7.2.3.d. Protection of patient rights;

7.2.3.e. Conformity of the program with federal confidentiality regulations, namely, 42 C.F.R. Part 2;

7.2.3.f. Security of medication storage and safe handling of medications;

7.2.3.g. Contribution to the management of the facility budget;

7.2.3.h. Implementation of program policies and procedures;

7.2.3.i. Communication with the medical director; and

7.2.3.j. Maintenance of documentation regarding the medical director's training and experience in a file that is current and readily available at all times.

7.3. Medical Director.

7.3.1. Each OBMAT program shall have a designated medical director. The medical director shall

7.3.1.a. 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.

7.3.1.b. Complete the requirements for Drug Addiction Treatment Act of 2000, Pub. L. 106-310, 114 Stat. 1101, Title XXXV, §§ 3501, *et seq.*, (2000) if he or she prescribes partial opioid agonist; and

7.3.1.c. Demonstrate experience in substance use disorder treatment or medication-assisted treatment or have a written plan, not to exceed 12 months, to attain competence in substance use disorder treatment or medication-assisted treatment.

7.3.2. The medical director shall maintain authority over the medical aspects of treatment offered by the OBMAT program. The medical director is responsible for:

7.3.2.a. Operation of all medical aspects of the treatment program;

7.3.2.b. Administration and supervision of all medical services;

7.3.2.c. Compliance with all applicable federal, state, and local laws, rules, and regulations;

7.3.2.d. Maintenance of his or her continuing medical education in the field of substance use disorder treatment and medication-assisted treatment on a documented and ongoing basis;

7.3.2.e. Approval of the basic and continuing education programs of all staff employed by or volunteering at the OBMAT program; and

7.3.2.f. Determination of the ability of the program physicians and physician extenders to work independently within the applicable scope of practice.

7.3.3. The medical director shall ensure regulatory compliance and carry out those duties specifically assigned to the medical director. Nothing in this rule prohibits an OBMAT from designating co-medical directors.

7.3.4. Within 10 days after the withdrawal or termination of the medical director, the owner or owners of the program shall notify the Secretary of the identity of another medical director for the program. Another licensed physician shall assume the duties of the medical director on a temporary basis, not to exceed 60 days, until a new medical director is identified and begins work at the program. The interim physician may be another owner of the program or a program physician employed by or associated with the program.

7.4. Professional Medical Staff.

7.4.1. The OBMAT program may employ and use program physicians, physician extenders, and other health care professionals working within their scope of practice who have received sufficient education, training, experience, or any combination thereof, to enable that person to perform the assigned functions. All physicians, nurses, and other licensed professional care providers must comply with the credentialing requirements of their respective professions.

7.4.2. All physicians and physician extenders employed by the OBMAT program shall be actively licensed in West Virginia and shall have:

7.4.2.a. A minimum of one year of experience in substance use disorder treatment and medication-assisted treatment settings; or

7.4.2.b. Meet the following requirements:

7.4.2.b.1. Active enrollment in a plan of education for obtaining competence in medication-assisted treatment methods and substance use disorders that is approved by the medical director. The medical director shall certify the individual's completion of the plan of education when, in the discretion of the medical director, it is satisfactorily accomplished; and

7.4.2.b.2. Completion of the certification, training programs or continuing education programs recommended and approved by the medical director of the OBMAT program.

7.4.3. During all hours of operation, every OBMAT program shall have an actively licensed program physician on call and available for consultation with other staff members at any time.

7.4.4. During all hours of operation, when parties are being medically treated, every OBMAT program shall have present and on duty at the program at least one of the following actively-licensed health care professionals:

7.4.4.a. Physician;

7.4.4.b. Physician assistant;

7.4.4.c. Advanced practice registered nurse; or

7.4.4.d. Registered nurse.

7.4.5. Plans of Education.

7.4.5.a. Program physicians and physician extenders operating under a plan of education shall be supervised by the medical director at a frequency appropriate for the qualifications and experience of the employee.

7.4.5.b. The program administrator or his or her designee shall document when an employee undertakes a plan of education, maintain all records regarding plans of education for the professional medical staff, and ensure that the medical director monitors and certifies satisfactory completion of each plan of education.

7.4.5.c. The medical director shall approve each plan of education and the ability of a program physician or physician extender to work independently within his or her scope of practice. The medical director shall document an employee's successful completion of a plan of education and approval to provide services on an independent basis within his or her scope of practice.

7.4.5.d. The state opioid treatment authority may request periodic documentation of continuing education during the probationary period and afterward if the documentation provided at the end of that period is not satisfactory.

7.5. Counseling Staff.

7.5.1. Counseling through an OBMAT program shall be provided by counseling staff that meet the qualifications as described in W. Va. Code §16-5Y-5(d).

7.5.2. The OBMAT program shall assign or make referral to a primary counselor or counseling service for each patient to contribute to the appropriate treatment plan for the patient and to monitor patient progress.

7.5.3. Each OBMAT program's policies and procedures shall ensure sufficient counseling staff to meet the needs of the patient population and to comply with the requirements of this rule.

7.5.4. Any unlicensed or uncertified counseling staff employed or used on a referral basis by the program shall be directly supervised by a licensed or certified professional or advanced alcohol and drug

counselor, or both. At a minimum, the supervisor shall provide at least one hour of supervision per 20 hours of direct service. Supervision may be group in nature but must consist of case consultation and discussion or clinical training rather than administrative oversight.

7.5.5. Newly employed counselors and other non-physician clinical staff without experience in a recovery-based OBMAT program shall receive initial training lasting at least 12 hours as prescribed in a facility practice and procedures guide and consisting of, at a minimum, the following:

7.5.5.a. Substance use disorder overview;

7.5.5.b. Characteristics of the substance use disorder population;

7.5.5.c. Program policy and procedure;

7.5.5.d. Confrontation, de-escalation, and anger management;

7.5.5.e. Current strategies for identifying and treating alcohol, cocaine, and other substance use disorders; and

7.5.5.f. Identification of co-occurring behavioral health or developmental disorders.

7.5.6. An experienced counselor newly employed from another MAT program may be exempt from the mandatory initial training required by this rule, if the mandatory initial training has been received within the previous two years. If training was received more than two years prior to employment, six hours of training shall be provided.

7.5.7. Counselors with less than one year of full-time experience in the field of substance use disorder treatment and medication-assisted treatment shall accompany an experienced counselor at all times for a minimum of two weeks before seeing persons served without immediate and constant supervision.

7.6. Unlicensed Clinical Staff and Volunteers.

7.6.1. An OBMAT program may employ unlicensed clinical staff and utilize volunteers to assist in the operation of the program and facility. The program shall develop and implement policies and procedures which specify the roles and responsibilities of each unlicensed employee and volunteer. Documentation of the responsibilities, training, and other obligations of an unlicensed clinical staff employee or volunteer shall be included in the personnel file of the employee or volunteer.

7.6.2. All unlicensed clinical staff and volunteers shall receive direct on-site supervision and must be provided with assistance, directions for activity and support.

§69-12-8. Environment and Operation.

8.1. Service Operation Schedule.

8.1.1. Programs, especially sole practitioners of OBMAT programs, shall ensure that services are not interrupted due to staff vacations by having qualified, temporary coverage.

8.1.2. Except as otherwise provided herein, the program's days of operation shall meet the needs of the OBMAT program patients served.

8.1.3. The program shall notify the patients receiving medication-assisted treatment services in writing at least 30 days in advance of their intent to permanently change service hours.

8.2. Payments for services rendered may be made either by Medicare, West Virginia Medicaid, private insurance, or by cash as described in this rule. Prior to directly billing a patient for any MAT treatment, the OBMAT program must comply with the provisions of W. Va. Code §16-5Y-5(e).

8.3. Each OBMAT program facility shall have:

8.3.1. Sufficient space and adequate equipment for the provision of all services specified in the program's description of treatment services;

8.3.2. Clean, safe, and well-maintained patient and staff areas;

8.3.3. A secure room and lockable equipment for physical patient records or appropriate security mechanisms for electronic records, or both;

8.3.4. Private offices or areas for patient and group therapeutic meetings, sufficient in number to address the treatment needs of the population served;

8.3.5. Sufficient restrooms for the estimated patient population with areas for observation of specimen production, if necessary; and

8.3.6. Adequate parking areas.

8.4. Infection Control. The OBMAT program shall designate an infection control officer who shall develop, implement, and maintain an effective infection control program, based on a nationally recognized system of infection control guidelines, that protects the patients, their families and clinic personnel by early detection, prevention, and control of infections and communicable diseases.

§69-12-9. Life Safety Policies and Procedures.

9.1. All OBMAT program facilities must meet all other requirements of applicable federal or state regulatory or oversight agencies.

9.2. Life Safety Policies and Procedures.

9.2.1. Each OBMAT program shall develop, implement, and maintain policies and procedures regarding the appropriate and safe administration of medical treatment. The policies and procedures shall:

9.2.1.a. Establish a current emergency plan in case the program must be closed temporarily, including how patients will be informed of these emergency arrangements; and

9.2.1.b. Ensure that there is appropriately trained staff on duty at all times who are proficient in cardiopulmonary resuscitation and reversal of opiate overdose.

9.3. Each OBMAT program shall develop, implement, and maintain policies and procedures regarding safe and effective access to the facility and staff. The policies and procedures shall:

9.3.1. Provide 24-hour, seven day-per-week access to information so that patient emergencies may be immediately addressed;

9.3.2. Require the program to display in facility offices and waiting areas the names and telephone numbers of individuals or agencies who should be contacted in case of an emergency;

9.3.3. Include an up-to-date disaster plan that specifies emergency evacuation procedures, fire drills and maintenance of fire extinguishers; and

9.3.4. Address safety and security issues for patients and staff, including training staff to handle physical or verbal threats, acts of violence, inappropriate behavior, or other escalating and potentially dangerous situations, with emphasis on when security guards or police need to be summoned.

§69-12-10. For-Cause Inspections; Complaints.

10.1. The Secretary may conduct unannounced inspections of an OBMAT program for cause if the Secretary has received a complaint about the program or has reason to believe that the program may be operating in violation of federal or state statutes, rules, or regulations, may be providing substandard treatment or may be serving as possible source of diverted medications.

10.2. Any person may file a complaint with the Secretary alleging violation of applicable laws, rules, or policies by an OBMAT program. A complaint shall identify the OBMAT program by name and state the nature of the complaint.

10.3. At the time of any onsite investigation activities, the investigator shall notify the medical director or program administrator at the OBMAT program of the general reason for the investigation.

10.4. Within 15 working days of the investigation, the Secretary shall provide to the medical director or program administrator at an OBMAT program a written report of the results of the investigation. The report shall specify any deficiency found and the rule that forms the basis for the violation.

10.5. The Secretary may permit the OBMAT program to develop a plan of correction to address any noted violations or deficiencies. The Secretary may advise and consult with the medical director, program administrator, or other personnel at an OBMAT program to assist with a plan of correction.

10.6. The Secretary may impose a civil money penalty, suspend, or revoke a registration or take such other action as deemed appropriate to address any violations or deficiencies. In the event the Secretary determines that the continued operation of the OBMAT program is a threat to the health, welfare and safety of its patients or employees, the Secretary may issue an order immediately closing the facility pursuant to applicable administrative procedures.

10.7. Upon completion of the investigation, the Secretary shall notify the complainant whether the allegations have been substantiated and how to obtain a copy of the report.

10.8. The Secretary shall keep confidential any information that could reasonably lead to the identification of a complainant and of any patient involved in the complaint or investigation. The Secretary shall not disclose such information without the written consent of the complainant or patient. The Secretary shall delete any identifying information before disclosure of investigative information to the public.

10.9. If a complaint becomes the subject of a judicial proceeding, nothing in this rule prohibits the disclosure of information that would otherwise be disclosed in judicial proceedings.

§69-12-11. Plans of Correction.

11.1. Within 10 working days after receipt of the inspection report, the program administrator or medical director at an OBMAT program shall submit to the Secretary for approval a written plan to correct all deficiencies that are in violation of this rule or statute, unless a waiver or variance is requested by the OBMAT program and granted by the Secretary. The plan of correction shall specify:

11.1.1. Any action taken, or procedures proposed to correct the deficiencies and prevent their reoccurrence;

11.1.2. The date of completion or each action taken or to be taken; and

11.1.3. The signature of the medical director, or his or her designee, or other executive officer of the program.

11.2. The proposed plan of correction shall be approved, modified, or rejected by the Secretary in writing. The OBMAT program may make modifications to the plan at a later date in conjunction with the Secretary.

11.3. The Secretary shall state the reasons for rejection or modification of any plan of correction.

11.4. The program administrator or medical director shall submit a revised plan of correction to the Secretary within 10 working days of receipt of a rejection by the Secretary.

11.5. The OBMAT program shall immediately correct a violation that severely risks the health or safety of a patient or other person.

11.6. The Secretary shall determine if satisfactory corrections have been made and advise the program medical director of any compliance or continued deficiencies in writing.

11.7. The Secretary may provide consultation to the applicant in obtaining compliance with this rule.

§69-12-12. Waivers and Variances.

12.1. The Secretary may grant a waiver or variance to the provisions of this rule under any of the following circumstances:

12.1.1. A strict application of the rule clearly would be impractical and if any alternate arrangements are not detrimental to the health or safety of the patients or employees of the program;

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12.1.2. A waiver, variance, or extension of a provisional registration is necessary under extraordinary circumstances or otherwise to protect public health;

12.1.3. The waiver or variance serves the best interests of patient safety and quality of care; or

12.1.4. A variance is granted pursuant to W. Va. Code §16-5Y-5(e).

12.2. Any waiver or variance approved by the Secretary shall be in writing.

12.3. All waivers or variances shall be reviewed at least annually by the designated state oversight agency.

§69-12-13. Reports and Records.

13.1. Inspection Reports and Records.

13.1.1. The secretary shall keep on file a report of any inspection, survey, or investigation of an OBMAT program or any program sponsor, owner, employee, volunteer, or patient thereof.

13.1.2. Information in reports or records shall be available to the public except for the following:

13.1.2.a. Information regarding complaints and subsequent investigations that is deemed confidential by any provision of this rule or applicable state or federal laws;

13.1.2.b. Information of a personal nature from a patient or personnel file; or

13.1.2.c. Information required to be kept confidential by state or federal law.

13.1.3. A report of an inspection or investigation made public shall also state whether a plan of correction has been submitted to or approved by the secretary.

13.2. Statistical Reports and Records.

13.2.1. The OBMAT program shall file a quarterly statistical report with the secretary on a form prescribed by the secretary, which includes the following information:

13.2.1.a. The total number of patients receiving medication-assisted treatment, broken down by gender;

13.2.1.b. The numbers of in-state patients and out-of-state patients;

13.2.1.c. The number of patients admitted to the program;

13.2.1.d. The number of patients discharged from the program; and

13.2.1.e. The reason for discharge, including:

13.2.1.e.1. Termination or disqualification;

13.2.1.e.2. Voluntary withdrawal; or

13.2.1.e.3. An unexplained reason.

13.2.1.f. The number of pregnant patients.

13.3. Incident Reporting and Adverse Events.

13.3.1. Each OBMAT program shall develop and implement policies and procedures for documenting, investigating, taking corrective action, and tracking instances of known adverse events or incidents.

13.3.2. Incidents or adverse events may include:

13.3.2.a. Program medication errors or other known medication errors where a patient suffers an adverse effect;

13.3.2.b. Completed patient suicide and suicide attempts;

13.3.2.c. Drug or substance-related hospitalization of a patient related to the treatment being provided;

13.3.2.d. Patient death or serious injury due to trauma, suicide, medication error, or unusual circumstances;

13.3.2.e. Harm to family members or others from ingesting a patient's medication;

13.3.2.f. Selling drugs or substances on the premises;

13.3.2.g. Medication diversion;

13.3.2.h. Harassment or abuse, including physical, verbal, sexual, and emotional, of patients by staff;

13.3.2.i. Theft, burglary, break-in, or similar incident at the program;

13.3.2.j. Physical violence leading to injury;

13.3.2.k. Significant disruption of services due to disaster such as fire, storm, flood, or another occurrence; and

13.3.2.l. Incidents that result in negative community reaction.

13.3.3. Incidents or adverse events shall be reviewed on a quarterly basis by the medical director who may choose to make recommendations to the administration, governing body or owner or owners and a designated safety committee regarding the improvements in the process to prevent further incidents.

13.3.4. The program shall assure in the event of an incident or adverse event that:

13.3.4.a. The incident or adverse event is fully documented and appropriately reported to the correct state agencies as necessary;

13.3.4.b. There is prompt investigation and review of the situation surrounding the incident or adverse event;

13.3.4.c. Timely and appropriate corrective action is taken; and

13.3.4.d. Ongoing monitoring of any corrective action takes place until effectiveness of the action is established.

13.3.5. Within seven days of an incident or adverse event, the program shall file a report with the state oversight agency consisting of the following:

13.3.5.a. The action or actions implemented to prevent the reoccurrence of the incident or adverse event;

13.3.5.b. The time frames for the action or actions to be implemented;

13.3.5.c. The person or persons designated to implement and monitor the action or actions; and

13.3.5.d. The strategies for the measurements of effectiveness to be established.

§69-12-14. Staff Training and Credentialing.

14.1. Each OBMAT program shall ensure that all physicians, physician assistants, advanced practice registered nurses, registered nurses, licensed practical nurses, counselors, psychologists, marriage, and family therapists, social workers, and other licensed or certified professional care providers comply with the credentialing requirements of their respective professions, obtain and maintain a current license, and complete all continuing education requirements of the licensing board, W. Va. Code §16-5Y-5(d) and this rule.

14.2. Clinical staff of an OBMAT program may include employees, independent contractors, or both. The OBMAT program shall be responsible for ensuring that staff and contractors comply with all provisions of this rule. All clinical staff members and volunteers shall complete initial and continuing education and training that is specific to their job function, their interactions with patients, the pharmacotherapies to be used at the program, and the patient populations to be served.

14.3. Each OBMAT program shall maintain confidential individual personnel files for every clinical staff member or volunteer, that shall contain, at a minimum:

14.3.1. The application for employment, contract, or request to work as a volunteer;

14.3.2. Documentation of the date of employment;

14.3.3. Identifying information and emergency contacts;

14.3.4. Documentation of completion of program orientation, internal training, and a copy of the practitioner's active license;

14.3.5. Documentation of all licenses, certifications, or other credentials;

14.3.6. Documentation relating to performance evaluation, supervision of job performance, disciplinary actions, and termination summaries; and

14.3.7. Detailed job descriptions.

14.4. The OBMAT program shall have a policy that delineates procedures governing disciplinary actions and non-voluntary termination of staff or volunteers.

§69-12-15. Medication Security, Storage, Administration, and Documentation.

15.1. Medication Security. Each OBMAT program that chooses to obtain, and store medication shall develop and implement policies and procedures that comply with all relevant federal and state laws, rules, and regulations regarding the storage, administration, documentation, and management of medications kept at the facility, if applicable, including measures that:

15.1.1. Ensure responsible handling and secure storage of all medications kept at the program;

15.1.2. Ensure responsible documentation of all medications received, stored, administered, and dispensed at the program; and

15.1.3. Ensure that only authorized personnel may access the storage areas where any medications are kept.

15.2. Approved Medications.

An OBMAT program shall use only those medication-assisted treatment medications that are approved by the 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.

15.3. Prescriptions and Dosage.

The maintenance dose of medication prescribed for a patient shall be individually determined. Adjustments upward or downward in dosage shall not be made either as punishment or reward but shall be justified by the clinical documentation of the patient's condition, subjectively and objectively.

15.4. Prescriptions for medication-assisted treatment medications shall include full identifying information for the patient, including full name and physical address; diagnosis code for which the medication is being prescribed; drug name, strength, dosage form, quantity and directions for use; the OBMAT program's registration number; and the prescribing program physician's regular DEA number and DATA 2000 identification number, if applicable.

§69-12-16. Diversion Control Plan.

16.1. Each OBMAT shall have a plan to manage medication diversion as a result of its policy and procedures.

16.1.1. The diversion control plan shall be reviewed and approved by the medical director and program physicians at OBMAT programs at a minimum of every two years.

16.1.2. The diversion control plan shall minimize the diversion of medication-assisted treatment medications to illicit use. The plan shall include:

16.1.2.a. Continuous clinical and administrative monitoring of the potential for an actual diversion including an investigation, tracking, and monitoring system of incidents of diversion; and

16.1.2.b. Proactive planning and procedures for problem identification, correction, and prevention.

16.1.3. The diversion control plan shall contain, at a minimum, a random call-back program with mandatory compliance, which shall be in addition to the regular schedule of program visits.

§69-12-17. Patient Rights.

17.1. Each OBMAT program shall develop and implement policies and procedures which guarantee the following rights to patients:

17.1.1. To be informed, both verbally and in writing, of program rules and regulations and patients' rights and responsibilities;

17.1.2. To receive treatment provided in a fair and impartial manner free from unlawful discriminatory practices pursuant to W. Va. Code §5-11-9, including the right of a patient to choose a counselor who accepts the patient's insurance;

17.1.3. To receive an individualized plan of care or treatment strategy. The individualized plan of care or treatment strategy shall be maintained in the patient's chart;

17.1.4. To receive medications required by the individualized plan of care or treatment strategy on a schedule developed in accordance with applicable federal requirements and approved guidelines and protocols that is the most accommodating and least intrusive and disruptive method of treatment for most patients;

17.1.5. To be informed that random drug testing of all patients shall be conducted during the course of treatment as required in this rule, and that any refusal to participate in a random drug test shall be considered a positive test. The patient shall be informed of the consequences of having a positive drug screen result;

17.1.6. To be informed about potential interactions with and adverse reactions to other substances, including alcohol, other prescribed medications, over-the-counter pharmacological agents, other medical procedures, and food;

17.1.7. To be informed about the financial aspects of treatment, including the consequences of nonpayment of required fees;

17.1.8. To ensure confidentiality in accordance with federal regulations, 42 C.F.R. Part 2, and the Health Insurance Portability and Accountability Act of 1996, as amended;

17.1.9. To be informed of the extent of confidentiality, including the conditions under which information can be released without consent, the use of identifying information for the purpose of program evaluation, billing, and statutory requirements for reporting abuse;

17.1.10. To give informed consent prior to being involved in research projects and the right to retain a copy of the informed consent form;

17.1.11. To receive full disclosure of information about treatment and medication, including accommodation for those who do not speak English, or who are otherwise unable to read an informed consent form; and

17.1.12. Inform each patient about all treatment procedures, services, and other policies and procedures throughout the course of treatment.

17.2. The OBMAT program shall provide notice of how to file a complaint and grievance procedures which shall be displayed in the patient care area in a conspicuous place and easily available to patients. The notice should include program rules, consequences of noncompliance and procedures for filing a complaint or grievance.

17.3. It is the responsibility of the program to make every attempt before a patient is discharged to accommodate the patient's desire for medical withdrawal or to be referred to an alternative treatment program as appropriate. Administrative withdrawal shall be used only as a sanction of last resort.

17.4. Every person admitted to an OBMAT program shall receive program orientation. The orientation shall be made verbally within the first 30 days of treatment. Information provided in the orientation shall be given to the patient in writing at the time the decision is made to admit the patient, regardless of his or her condition, and shall include a formal agreement of informed consent to be signed by the patient.

17.5. Program orientation shall include the following:

17.5.1. An explanation of the rights and responsibilities of the patient.

17.5.2. An explanation of the services and activities provided by the OBMAT program, either onsite or by referral, including:

17.5.2.a. Expectations and rules;

17.5.2.b. Confidentiality policy;

17.5.2.c. Toxicological screening and random drug-testing policies;

17.5.2.d. Interventions; and

17.5.2.e. Various discharge criteria, including, but not limited to, administrative and medical withdrawal policies and procedures; and

17.5.3. A description of how the individualized plan of care or treatment strategy and coordination of care agreement will be developed and the patient's expected participation in the plan of care or treatment strategy.

17.6. Upon admission, each patient shall receive the following written information:

17.6.1. Signs and symptoms of overdose and when, where, and how to seek emergency assistance;

17.6.2. A formal agreement of informed consent to be signed by the patient;

17.6.3. A signed copy of the coordination of care agreement;

17.6.4. Patient's rights;

17.6.5. Confidentiality policies; and

17.6.6. Information on alternative methods available for treatment of substance use disorder and the potential benefits and risks. The state opioid treatment authority is responsible for providing informational materials to be used in discussing alternative treatments.

§69-12-18. Patient Records.

18.1. Each OBMAT program shall establish and maintain a recordkeeping system that is adequate to document and monitor patient care. The system shall comply with all federal and state reporting requirements relevant to medications approved for use in treatment of substance use disorder.

18.2. All patient records shall be maintained for a minimum of five years from the time that the documented treatment is provided. In the event a patient is a juvenile, the records shall be kept for a minimum of five years from the time the patient reaches the age of 18.

18.3. All patient records shall be kept confidential in accordance with all applicable federal and state requirements.

18.4. OBMAT program policies and procedures should ensure security of all records including electronic records, if any.

18.5. Individual patient records may include, but are not limited to:

18.5.1. Identifying and basic demographic data and the results of the screening process;

18.5.2. Documentation of program compliance with the program's policy regarding prevention of multiple admissions to any medication-assisted treatment programs;

18.5.3. All physical and biopsychosocial assessments during the course of treatment;

18.5.4. Medical reports including results of the physical assessment; family medical history; review of systems; laboratory reports, including results of required toxicology screens; results obtained from the Controlled Substances Monitoring Program (CSMP) database; and progress notes, including documentation of current dose and other dosage data;

18.5.5. Dated case entries of all significant contacts with patients;

18.5.6. The individualized plans of care or treatment strategies, and any amendments, reviews, or changes to the plans;

18.5.7. Coordination of care agreements signed by the patient, program physician and primary counselor;

18.5.8. Documentation from the Controlled Substance Monitoring Program or an out-of-state equivalent that the OBMAT program made a good faith effort to review whether the patient is enrolled in any other OBMAT program;

18.5.9. A record of correspondence with the patient, family members, and other individuals and a record of each referral for services and its results;

18.5.10. A record of correspondence with other health care providers of the patient;

18.5.11. Consent forms, releases of information, prescription documentation, travel, and employment; and

18.5.12. A closing summary, including reasons for discharge and any referral. In the case of death, the cause of death, if known, shall be documented.

18.6. Documentation of Patient Contact.

The primary counselor or medical staff, or both is responsible for documentation of significant contact with each patient, which shall be filed in the patient record and include a description of:

18.6.1. The reason for or nature of the contact;

18.6.2. The patient's current condition;

18.6.3. Significant events occurring since prior contact;

18.6.4. The assessment of patient status; and

18.6.5. A plan for action or further treatment.

§69-12-19. Admission Criteria and Admission Process.

19.1. Each OBMAT program shall develop, implement, and maintain policies and procedures designed to ensure that patients are admitted to maintenance treatment only after a determination has been made that the person meets the qualifications for admission.

19.2. Any patient seeking admittance to the OBMAT program shall undergo an initial medical assessment to determine whether the person meets the criteria for admission. The determination of admission eligibility shall be made using accepted medical and biopsychosocial criteria.

19.3. The patient desiring admission for treatment through the use of a medication-assisted treatment medication must be at least 16 years of age. For those patients who are unemancipated minors, consent for treatment is required from a parent or guardian.

19.4 Admission to the OBMAT program may be allowed to the following groups with a high risk of relapse without the necessity of a positive drug test or the presence of objective symptoms:

19.4.1. The patient is a pregnant woman with a history of substance use disorder;

19.4.2. The patient is a prisoner or has been released from a correctional facility within six months;

19.4.3. The patient is a former program patient who successfully completed treatment but believes that he or she is at risk of imminent relapse;

19.4.4. The patient is an HIV patient with a history of intravenous drug use; or

19.4.5. The patient has been deemed as high risk by the medical director or treating physician.

19.5. A patient enrolled in an OBMAT program shall not be permitted to obtain treatment in any other OBMAT program except in exceptional circumstances and only as provided in section 21 of these rules.

19.6. The program practitioner shall ensure that each patient voluntarily chooses maintenance treatment and that all relevant facts concerning the use of medication-assisted treatment medications are clearly and adequately explained to the patient. The program practitioner shall ensure that each newly admitted patient provides informed written consent to treatment.

19.7. If a patient was previously known to be discharged from treatment at another program, the admitting OBMAT program following patient consent shall contact the previous OBMAT program or programs for treatment history.

§69-12-20. Multiple Program Enrollments.

20.1. A patient enrolled in an OBMAT program shall not be permitted to obtain treatment in any other OBMAT program except in exceptional circumstances.

20.1.1. If the medical director or program physician of the OBMAT program in which the patient is enrolled determines that an exceptional circumstance exists, the patient may be granted permission to seek treatment at another OBMAT program.

20.1.2. The justification for finding exceptional circumstances shall be noted in the patient's individualized plan of care or treatment strategy and medical chart both at the OBMAT program in which the patient is enrolled and at the OBMAT program that provides the additional treatment.

20.2. When there is reason to believe a patient is receiving treatment at an opioid treatment program, the OBMAT program shall obtain a written consent for release of information from the patient to check the records of opioid treatment programs to ensure that the patient is not currently enrolled in those programs as well. The request for information may be made by telephone, fax, or e-mail. The release of information shall state that only prior admissions may be the subject of inquiry, not contacts without admission. The OBMAT program shall protect patient confidentiality at all times and with all procedures used in acquiring medical or health information.

20.3. Results of the multiple-program check shall be contained in the patient chart.

20.4. A multiple program enrollment check shall be repeated if the patient is discharged and readmitted at any time.

§69-12-21. Controlled Substances Monitoring Program Database.

21.1. Each OBMAT program shall comply with policies and procedures developed by the designated state oversight agency and the West Virginia Board of Pharmacy to allow physicians treating patients through an OBMAT program access to the Controlled Substances Monitoring Program database maintained by the West Virginia Board of Pharmacy.

21.2. Program practitioners shall access the database in accordance with the requirements of W. Va. Code §16-5Y-5(j).

§69-12-22. Required Services.

22.1. Each OBMAT program shall provide or make referral to medical, counseling, recovery, and other assessment and treatment services as necessary.

22.2. Each OBMAT program shall require every patient to undergo a documented biopsychosocial assessment by a program counselor or other qualified practitioner.

22.3. The OBMAT program shall complete a post-admission assessment, an initial individualized or plan of care or treatment strategy and, if applicable, a coordination of care agreement.

22.4. Random drug testing of all patients shall be conducted during the course of treatment as required in this rule. Each OBMAT program must provide adequate testing or analysis for drugs of abuse in accordance with generally accepted clinical practice.

22.5. Each OBMAT program must provide adequate substance use disorder counseling, either on-site or by referral, to each patient as clinically necessary and at the minimum levels as required by this rule.

22.6. Each OBMAT program shall maintain current policies and procedures that reflect the special needs of patients who are pregnant. Prenatal care and other gender-specific services of pregnant patients must be provided either by the OBMAT program or by referral to appropriate health care providers. Services rendered to pregnant patients shall comply with the requirements of this rule.

22.7. Each OBMAT program shall provide or make referrals for counseling on preventing exposure to, and the transmission of, HIV and hepatitis C for each patient admitted or re-admitted to maintenance or

detoxification treatment. Services rendered to patients with HIV and hepatitis C disease shall comply with the requirements of this rule.

22.8. Each OBMAT program that provides required services by referral or other agreement at offsite facilities or providers shall:

22.8.1. Establish a strong working relationship with several treatment providers offering different levels of treatment;

22.8.2. Be able to document a referral or other agreement with a local hospital, health care facility or other provider that provides offsite services for the OBMAT program;

22.8.3. Obtain a signed consent form from each patient to approve open communication with the offsite provider and the OBMAT program; and

22.8.4. Routinely provide and obtain updates from offsite providers to consistently monitor treatment attendance and progress.

22.9. Each OBMAT program shall provide or make referrals for each patient to obtain contraceptive drugs, devices, or procedures.

§69-12-23. Counseling.

23.1. Each OBMAT program shall provide substance use disorder counseling, by a counselor of the patient's choice, to every patient as is clinically appropriate. Counseling sessions should encourage and guide the patient to a lifestyle that does not include abuse or misuse of prescribed and illicit medications, drugs, or other substances. Counseling sessions are essential to promote and guide the patient to a more productive lifestyle of abstinence from illicit medications or drugs.

23.2. The counseling shall be provided by a professional as described in this rule, qualified by education or training to assess the biopsychosocial background of patients, to contribute to the appropriate individualized treatment plan for the patient, and to monitor patient progress. The primary counselor shall develop and implement the biopsychosocial portions of the patient's individualized plan of care or treatment strategy, in coordination with the medical staff and program physician.

23.3. Counseling sessions, which may be conducted via telehealth, shall be provided according to generally accepted best practices and shall be offered:

23.3.1. At least weekly during the first 90 days of treatment;

23.3.2. At least twice per month during the remainder of the first year of treatment; and

23.3.3. Thereafter, counseling sessions shall take place as indicated in the patient's individualized plan of care or treatment strategy.

23.4. All counseling sessions shall be documented in the OBMAT program's patient record and shall include a plan for action or further treatment that addresses the goals of the individualized plan of care or treatment strategy.

23.5. Where indicated, the OBMAT program will provide or document a referral for family members or significant others to counseling.

23.6. If counseling is not directly provided through the OBMAT program, the counselor(s) shall still meet the credentialing requirements pursuant to this rule and verification of all sessions must be documented in the MAT patient record.

§69-12-24. Post-Admission Assessment.

24.1. Each OBMAT program shall develop, implement, and maintain current policies and procedures, patient protocols, treatment plans, or treatment strategies, and profiles for the treatment of patients seeking treatment for medication-assisted treatment.

24.2. The program physician or physician extender shall conduct an assessment meeting the following requirements.

24.2.1. The assessment may include, but not limited to, an appropriate history and physical, mental status exam, substance use history, appropriate lab tests, pregnancy test for women of childbearing years, toxicology tests for drugs and alcohol, hepatitis B and hepatitis C screens, an inquiry to and report from the Controlled Substances Monitoring Program database, an inquiry whether the patient is being treated at any other opioid treatment OBMAT program, the diagnosis of all conditions, including a diagnosis of substance use disorder, including signs and symptoms, the dates, amounts, and dosage forms for any drugs prescribed, dispensed, and administered, and any other tests as necessary or appropriate in the treatment provider's discretion; and

24.2.2. For other than the toxicology tests for drugs and alcohol, appropriate history, substance abuse history, hepatitis B and hepatitis C screens, and the pregnancy test, the physician may satisfy the assessment requirements by reviewing records from a physical examination of the patient that was conducted by a physician within a reasonable period of time prior to the visit not to exceed 30 days and a copy of the report by the referring physician and any medical records from other providers, if applicable.

24.2.3. The post-admission assessment may include laboratory tests conducted by the OBMAT program or by other reliable sources.

24.3. Continuing Assessments.

Subsequent patient assessments shall include periodic patient evaluations. Patients shall be seen at reasonable intervals based upon the individual circumstance of the patient. Periodic assessment is necessary to determine compliance with the dosing regimen, effectiveness of treatment plan, and to assess how the patient is responding to the prescribed medication. Once a stable dosage is achieved and urine or other toxicology tests are free of illicit drugs, less frequent office visits may be initiated for patients on a stable dose of the prescribed medication who are making progress toward treatment objectives. Continuation or modification of therapy shall depend on the physician's evaluation of progress toward stated treatment objectives.

§69-12-25. Individualized Plan of Care or Treatment Strategy.

25.1. Delivery of patient care and treatment interventions shall be based on the needs identified in the individualized plan of care or treatment strategy.

25.2. Within 30 days after admission of a patient, the OBMAT program shall develop an individualized plan of care or treatment strategy and attach it to the patient's chart. The individualized plan of care or treatment strategy shall be developed pursuant to the guidelines and protocols established by the American Society of Addiction Medicine (ASAM), the Center for Substance Abuse Treatment (CSAT) and the National Institute on Drug Abuse (NIDA), the American Association for the Treatment of Opioid Dependence (AATOD), or such other nationally recognized authority approved by the Secretary. The individualized plan of care or treatment strategy shall include a recovery model based upon the generally approved guidelines and protocols.

25.3. The individualized plan of care or treatment strategy shall be reviewed by the program physician, primary counselor, and patient at least every 90 days and documented in the patient record. A revised plan of care or treatment strategy may be implemented with each review. After one year of successful treatment, the individualized plan of care or treatment strategy shall be reviewed annually, or more often based on the program physician and primary counselor's discretion and updated as appropriate.

25.4. The individualized plans of care or treatment strategies shall be developed by the patient, the program physician or physician extender and primary counselor, with input as appropriate from other health care providers.

25.5. All individualized plans of care or treatment strategies may include, but are not limited to:

25.5.1. Documentation of the patient's diagnoses; the proposed medical treatment and counseling; medication dosages and administration;

25.5.2. A requirement that the patient regularly attend and participate in the OBMAT program, both medical and counseling aspects, as determined necessary by the staff and patient;

25.5.3. The identification of triggers for misuse of substances;

25.5.4. The development and use of coping strategies for each trigger;

25.5.5. The development of a detailed relapse prevention plan;

25.5.6. Meaningful follow-up on any identified behavioral health issues;

25.5.7. Follow-up medical or physical issues as necessary;

25.5.8. Referral for a vocational evaluation, formal or informal, as appropriate;

25.5.9. A plan to achieve financial stability and independence, where appropriate;

25.5.10. A requirement that the patient abstain from use of illicit substances, abuse of prescription substances, or other substances of abuse;

25.5.11. Documentation of other patient or familial issues as relevant and appropriate and the proposed means of addressing such issues;

25.5.12. The success of the patient's treatment, initiatives and goals;

25.5.13. A description of services and their frequency to be provided for the patient and primarily directed to achieve the expected goals and outcomes;

25.5.14. The results from drug tests; and

25.5.15. Such other information as recommended by the guidelines and recovery model utilized for the patient.

25.6. With the patient's permission, the OBMAT program shall request complete medical records from other providers and maintain the records in the patient's medical record.

25.7. Coordination of Care Agreement.

25.7.1. If a coordination of care agreement is required, it shall be signed by the patient, program physician and primary counselor. If a change of program physician or primary counselor takes place, a new agreement must be signed.

25.7.2. The coordination of care agreement shall be reviewed and updated at least annually. If the coordination of care agreement is reviewed, but not updated, the review shall be documented in the patient's record.

25.7.3. The coordination of care agreement shall include the following:

25.7.3.a. An authorization allowing communication between the program physician and primary counselor so that the patient may receive comprehensive and quality medication-assisted treatment;

25.7.3.b. The name and contact information for the program physician and primary counselor;

25.7.3.c. The categories of records which may be shared;

25.7.3.d. A summary of treatment and goals, diagnoses, and services to be received onsite or by referral;

25.7.3.e. Current medications being prescribed, including dosage, frequency, and delivery; and

25.7.3.f. Date and prescription history for medication-assisted treatment medications.

§69-12-26. Administrative Withdrawal.

26.1. Administrative withdrawal is an involuntary withdrawal or administrative discharge from pharmacotherapy. Administrative withdrawal should be used as a last resort after the OBMAT program exhausts all efforts to address the patient's behavior or actions that would warrant administrative withdrawal. The schedule of withdrawal may be brief, less than 30 days, if necessary.

26.2. OBMAT programs shall develop and implement policies and procedures for the involuntary termination from treatment that includes and describes the rights of the patient and the responsibilities and rights of the program.

26.3. Administrative withdrawal may result from any of the following:

26.3.1. Non-payment of fees. The OBMAT program shall make every effort to consider all clinical data, including patient participation and compliance with treatment prior to initiating administrative withdrawal for non-payment. If the patient has a history of compliance and cooperation with treatment, the program shall document every effort to explore alternatives to administrative, withdrawal with the patient prior to onset of withdrawal. If necessary and unavoidable, the schedule of withdrawal shall follow protocols and guidelines of approved authorities.

26.3.2. Disruptive or adverse effect conduct. Disruptive conduct or behavior considered to have an adverse effect on the program, clinical staff, or patient population of such gravity as to justify the involuntary withdrawal and discharge of a patient. Such behaviors may include violence, threat of violence, dealing drugs, diversion of pharmacological agents, violation of peer confidentiality, repeated loitering, and failure to follow treatment plan objectives or noncompliance with program rules, policies and procedures resulting in an observable, negative impact on the program, staff, and other patients.

26.3.3. Incarceration or other confinement. The OBMAT program may work with law enforcement and corrections personnel in order to avoid mandatory withdrawal whenever possible.

26.4. The OBMAT program shall document in the patient's individualized plan of care or treatment strategy and chart all efforts regarding referral or transfer of the patient to a suitable, alternative treatment program.

26.5. Female patients shall have a negative pregnancy screen prior to the onset of administrative withdrawal. Patients withdrawn for not presenting to the program are not required to have a pregnancy test. A patient's refusal to take the test shall be documented. Refer to section 29.5. of this rule for administrative withdrawal for female patients with a positive pregnancy screen.

§69-12-27. Medical Withdrawal.

27.1. Medical withdrawal occurs as a voluntary and therapeutic withdrawal in accordance with approved national guidelines. In some cases, the withdrawal may be against the advice of clinical staff or against medical advice.

27.2. The OBMAT program shall supply a schedule of dose reduction well tolerated by the patient.

27.3. The program shall offer supportive treatment, including increased counseling sessions and referral to a self-help group or other counseling provider as appropriate.

27.4. The OBMAT program shall develop and implement policies and procedures for the continuing care of each patient following the last prescription given and for re-entry to maintenance treatment if relapse occurs or if the patient should reconsider withdrawal.

27.5. Female patients shall have a negative pregnancy screen prior to the onset of medically-supervised withdrawal. Refer to section 29.5. of this rule for medical withdrawal for female patients with a positive pregnancy screen.

27.6. The program shall have in place a detailed relapse prevention plan developed by the primary counselor in accordance with the approved national guidelines and in conjunction with the patient. The prevention plan shall be given to the patient in writing prior to the administration of the final dose of medication.

§69-12-28. Laboratory Services; Drug Screens.

28.1. All patients in the OBMAT program shall undergo monthly drug testing. Random drug testing of all patients shall be conducted during the course of treatment as required in this rule.

28.2. Collection and Testing.

28.2.1. OBMAT programs shall work carefully with toxicology testing kits or federally certified laboratories to ensure valid, appropriate results of toxicological screens.

28.2.2. Each OBMAT program shall have the capability of obtaining medication blood levels when clinically indicated or through random or monthly drug testing of all patients.

28.2.3. Urine drug screening and other adequately tested toxicological procedures shall be used as an aid in monitoring and evaluating a patient's progress in treatment.

28.2.4. Drug screening policies and procedures shall be determined on an individualized basis for each patient, subject to the following requirements:

28.2.4.a. A patient receiving medication-assisted treatment medication maintenance services must have at least two random urine drug screens per month for the first 12 months of medication-assisted treatment. After 12 months of medication-assisted treatment, and if the patient is compliant with program rules and treatment requirements, a patient is required to have one random urine drug screen every 90 days. After 36 months of medication-assisted treatment, and if the patient is compliant with program rules and treatment requirements, random drug screens shall be at the discretion of the provider but at least once per year.

28.2.4.b. A record of urine drug screens shall be kept in the patient record.

28.2.4.c. When using urine as a screening mechanism, each OBMAT program shall develop and implement policies and procedures which may include observed testing to minimize the chance of patient adulterating or substituting another individual's urine.

28.2.4.d. OBMAT programs shall develop and implement policies and procedures to minimize misidentification of urine specimens and to ensure that the tested specimens can be traced to the donor patient.

28.2.5. Drug screenings shall include toxicological analysis for drugs of abuse, including but not limited to:

28.2.5.a. Buprenorphine, including in ratio to Norbuprenorphine, if as clinically indicated;

28.2.5.b. Opiates including oxycodone at common levels of dosing;

28.2.5.c. Methadone, medication-assisted treatment medications or any other medication used by the program as an intervention for that patient;

28.2.5.d. Benzodiazepines;

28.2.5.e. Cocaine, including its metabolites, if clinically indicated;

28.2.5.f. Meth-amphetamine/amphetamines;

28.2.5.g. Tetrahydrocannabinol, delta-9-tetrahydrocannabinol, dronabinol, including its metabolites, if clinically indicated, or other similar substances; or

28.2.5.h. Other drugs or substances as determined by community standards, regional variation or clinical indication, such as carisoprodol or barbiturates.

28.2.6. Collection and testing shall be done in a manner that assures a method of confirmation for positive results and documents the chain of custody of the collection.

28.2.7. When necessary and appropriate, breathalyzers or other testing equipment may be used to screen for possible alcohol abuse.

28.2.8. Each OBMAT program shall document both the results of toxicological tests and the follow-up therapeutic action taken in the patient record.

28.2.9. Each OBMAT program shall ensure that program physicians demonstrate competence in the interpretation of "false negative" and "false positive" laboratory results as they relate to physiological issues, differences among laboratories and factors that impact the absorption, metabolism and elimination of substances.

28.2.10. The program physician or physician extender shall thoroughly evaluate a positive toxicological screen for any potentially licit substance such as benzodiazepines, carisoprodol, barbiturates, and amphetamines. The program shall verify that the patient has been prescribed these medications by a licensed physician or physician extender for a legitimate medical purpose; and

28.2.11. If a patient can produce prescriptions or other evidence of a legitimate prescription, such as current medication bottles that are fully labeled, the interdisciplinary team shall consider the patient's individual situation and the possibility that he or she may be dismissed from the care of his or her physician if the physician discovers that the patient is in an OBMAT program. The program physician shall make the ultimate decision as to the patient's continuing care in the program and the circumstances of that care.

28.2.12. Nothing contained in this rule shall preclude any OBMAT program from administering any additional drug tests it determines necessary.

28.3. Test Results.

28.3.1. Absence of medication-assisted treatment medication prescribed by the program for the patient is evidence of possible medication diversion. Whenever there is evidence of possible medication-assisted treatment medication diversion, the patient shall be re-evaluated by the program physician at the OBMAT program, and the individualized plan of care or treatment strategy shall be adjusted accordingly.

28.3.2. Special precautions shall be taken when a patient has both sedatives and buprenorphine in his or her urine. This requires immediate discussion with the patient about the dangers and shall be noted in the patient's record.

§69-12-29. Special Populations.

29.1. Concurrent Alcohol and Polysubstance Abuse.

29.1.1. Each OBMAT program shall address, where appropriate, misuse of alcohol and other non-opioid substances within the context of the medication-assisted therapy effort.

29.1.2. The OBMAT program shall ensure that its staff is fully trained and knowledgeable regarding current effective strategies for treating alcohol, illicit drug use, and other drug misuse.

29.1.3. Ongoing polysubstance use is not a reason for discharge unless the patient refuses recommended treatment. The interdisciplinary team shall consider the patient's condition and address the situation from a clinical perspective and in accordance with guidelines and protocols from approved authorities.

29.1.4. Each OBMAT program shall have a policy regarding treatment of comorbid disorders such as psychiatric and medical disorders. The goal of the treatment shall be to provide treatment for these disorders in as seamless a fashion as possible, maximizing patient convenience and compliance with appointments and recommendations.

29.2. Behavioral Health Needs.

29.2.1. Each OBMAT program shall ensure that patients with behavioral health needs are identified through the evaluation process and referred for appropriate treatment.

29.2.2. At all phases of treatment, the OBMAT program shall monitor patients during medical withdrawal and recovery for symptoms of behavioral illness.

29.2.3. Each OBMAT program shall establish linkages with licensed behavioral health providers in the community or in the program's facility.

29.2.4. Each OBMAT program may provide psychotropic medication management onsite by appropriately trained medical professionals. Individualized treatment plans of care shall describe the goals of psychotropic medication management, which shall be reviewed regularly. The patient's chart and individualized plan of care or treatment strategy shall document regular contact with the prescribing physician or physician extender, or both, for the distinct purpose of monitoring prescribed psychotropic medications if such medications are prescribed.

29.3. HIV Patients.

29.3.1. The OBMAT program shall educate all patients regarding HIV/AIDS, testing procedures, confidentiality, reporting, follow-up care, safer sex, social responsibilities and sharing of intravenous equipment.

29.3.2. The program shall establish linkages with HIV/AIDS treatment programs in the community.

29.4. Chronic Pain Patients.

29.4.1. Each OBMAT program shall ensure that physicians practicing at the facility are knowledgeable in the treatment and management of substance use disorder in the context of chronic pain and pain management. The program may not prohibit a patient diagnosed with chronic pain from receiving medication for either maintenance or withdrawal in a program setting.

29.4.2. Each OBMAT program shall ensure continuity of care and communication between programs or physicians regarding patients receiving treatment in both an OBMAT program and a facility or physician's office for purposes of pain management, with the patient's written permission. If a patient refuses permission for the two entities to communicate and coordinate care, the program shall document refusal and may make clinically appropriate decisions regarding continuation in treatment.

29.5. Pregnant Patients.

29.5.1. Pregnant women seeking and needing treatment shall be enrolled in the OBMAT program and provided treatment in accordance with guidelines and protocols from approved authorities.

29.5.2. The OBMAT program shall ensure referrals for every pregnant patient who does not have an obstetrical provider. Care for the pregnant patient with a substance use disorder should be co-managed by the OBMAT program and the patient's obstetrical provider. The OBMAT program shall have agreements in place with the patient's obstetrical provider, including informed consent procedures that ensure exchange of pertinent clinical information regarding compliance with the recommended plan of medical care.

29.5.3. With respect to pharmacotherapy for pregnant women with active opioid use disorder in medication-assisted therapy, the program shall ensure that:

29.5.3.a. Maintenance medication levels shall be maintained at the lowest possible dosage level that is a medically therapeutic dose as determined by the medical director or program physician taking the pregnancy into account.

29.5.3.b. The initial medication-assisted treatment dose for a newly admitted pregnant patient and the subsequent induction and maintenance dosing strategy reflect the same effective dosing protocols used for all other patients;

29.5.3.c. The dose is monitored carefully to supply increased or split dose if it becomes necessary; and

29.5.3.d. If a pregnant patient elects to withdraw from medication-assisted treatment against medical advice, the program shall inform the patient of the risks of withdrawal to the patient and the effects on the pregnancy.

29.5.4. The OBMAT program shall document referral for follow-up and primary care for the mother and infant.

29.5.5. If a pregnant patient is discharged, the OBMAT program shall identify the physician to whom the patient is being discharged. If a provider is not available, a referral shall be made to a Comprehensive Behavioral Health Center. Information regarding discharge for any reason, including an inability to refer, shall be retained in the clinical record.

§69-12-30. Registration Denials, Revocations, and Suspensions.

30.1. Grounds for Denial, Revocation or Suspension.

30.1.1. The Secretary may deny, revoke, or suspend a registration issued pursuant to this rule if any provisions of federal or state law or this rule are violated. The Secretary may revoke a registration and prohibit all program physicians associated with that OBMAT program from practicing at the program location based upon the findings and results of an annual, periodic, complaint, or other inspection and evaluation. The period of suspension for the registration of an OBMAT program shall be prescribed by the Secretary but may not exceed one year.

30.1.2. The Secretary may deny, revoke, or suspend an OBMAT program registration for one or more of the following reasons:

30.1.2.a. The Secretary makes a determination that fraud or other illegal action has been committed by any owner of the OBMAT program.

30.1.2.b. The OBMAT program has violated federal, state, or local law relating to registration, building, health, fire protection, safety, sanitation, or zoning;

30.1.2.c. The OBMAT program engages in practices that jeopardize the health, safety, welfare, or clinical treatment of a patient;

30.1.2.d. The OBMAT program has failed or refused to submit reports or makes records available as requested by the Secretary;

30.1.2.e. An OBMAT program has refused to provide access to its location or records as requested by the Secretary;

30.1.2.f. An OBMAT program's medical director has knowingly and intentionally misrepresented actions taken to correct a violation;

30.1.2.g. An owner or medical director of an OBMAT program concurrently operates an unregistered OBMAT program;

30.1.2.h. A program physician or any owner knowingly operates, owns, or manages an unregistered OBMAT program that is required to be registered;

30.1.2.i. The owners of an OBMAT program fail to apply for a new registration for the program upon a change of ownership and operate the program under the new ownership;

30.1.2.j. A program physician or any owner acquires or attempts to acquire a registration for an OBMAT program through misrepresentation or fraud or procures or attempts to procure a registration for an OBMAT program for any other person by making or causing to be made any false representation; or

30.1.2.k. The OBMAT program fails to have a medical director practicing at the program location as required by this rule.

30.2. Effect of Denial, Revocation, or Suspension.

30.2.1. If a registration for an OBMAT program has been revoked, the Secretary may stay the effective date of the revocation if the medical director, owner or owners, and administrator of the program can show that the stay is necessary to ensure appropriate referral and placement of patients.

30.2.2. If the registration of an OBMAT program is denied, revoked, or suspended, no person, firm, association, or corporation may operate the program as an OBMAT program as of the effective date of the denial, revocation, or suspension. The owners of the OBMAT program are responsible for removing all signs and symbols identifying the premises as an OBMAT program within 30 days form the date of the denial, revocation, or suspension.

30.2.3. If a registration for an OBMAT program has been denied, revoked, or suspended the program must supply, at a minimum, a copy of the following information to the Secretary;

30.2.3.a. A closure notice to be mailed to all active patients meeting the guidelines set forth by its respective medical board;

30.2.3.b. The date the closure letter will be mailed to all active patients;

30.2.3.c. The number of active patients to receive the closure notice;

30.2.3.d. A Class II legal advertisement that complies with the requirements of article 3, chapter 59 of the West Virginia Code regarding the program closure, including the dates the notice will appear and the name of the newspaper; and

30.2.3.e. Contact information the program has supplied to patients who may need help locating a new treating physician or program.

30.2.4. Upon the effective date of the denial, revocation, or suspension the medical director of the OBMAT program shall advise the Secretary and the West Virginia Board of Pharmacy of the disposition of all drugs located on the premises. The disposition is subject to the supervision and approval of the Secretary and the DEA. Drugs that are purchased or held by an unregistered OBMAT program may be deemed adulterated.

30.2.5. If the registration of an OBMAT program is revoked or suspended, no person named in the registration documents of the program, including persons owning or operating the OBMAT program,

may apply to own, register, or operate another OBMAT program for five years after the date of revocation or suspension, either individually or as part of a group practice, firm, association, or corporation.

30.2.6. If an OBMAT program registration is denied or revoked, a new application for registration shall be considered by the Secretary, if, when and after the conditions upon which denial or revocation was based have been corrected and evidence of this fact has been furnished. A new registration may then be granted after proper inspection has been made and the Secretary makes a written finding that all provisions of this article and rules promulgated pursuant to this article have been satisfied.

§69-12-31. Penalties and Equitable Relief.

31.1. Grounds for Penalties and Injunctions.

31.1.1. Any person, partnership, association, or corporation which establishes, conducts, manages, or operates an OBMAT program without first obtaining a registration therefore or which violates any provisions of this law or rule shall be assessed a civil money penalty by the Secretary in accordance with this rule.

31.1.2. Each day of continuing violation after notification of the infraction shall be considered a separate violation.

31.1.3. If the OBMAT program fails to timely file reports required by section 13 of this rule, the Secretary may impose a civil monetary penalty not to exceed \$1,000 per day.

31.1.4. If the OBMAT program's owner or owners, medical director, and administrator knowingly and intentionally misrepresents actions taken to correct a violation, the Secretary may impose a civil money penalty not to exceed \$10,000 and revoke or deny the OBMAT program's registration.

31.1.5. If an owner or owners or medical director of an OBMAT program concurrently operates an unregistered OBMAT program, the Secretary may impose a civil money penalty upon the owner or owners or medical director, or both, not to exceed \$5,000 per day.

31.1.6. If the owner of an OBMAT program that requires a registration under this article fails to apply for a new registration for the program upon a change of ownership and operates the program under the new ownership, the Secretary may impose a civil money penalty not to exceed \$5,000.

31.1.7. If a program physician knowingly operates, owns or manages an unregistered OBMAT program that is required to be registered pursuant to this article; knowingly prescribes or dispenses or causes to be prescribed or dispensed, controlled substances in an unregistered OBMAT program that is required to be registered; or obtains a registration to operate an OBMAT program through misrepresentation or fraud; procures or attempts to procure a registration for an OBMAT 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.

31.2. The Secretary may deny an OBMAT program's application for registration or application for renewal registration; revoke or suspend a registration; order an admissions ban or reduction in patient census for one or more of the following reasons:

31.2.1. The Secretary makes a determination that fraud or other illegal action has been committed;

31.2.2. The program has violated federal, state, or local law relating to building, health, fire protection, safety, sanitation, or zoning;

31.2.3. The program conducts practices that jeopardize the health, safety, welfare, or clinical treatment of a patient;

31.2.4. The program has failed or refused to submit reports, comply with the documentation requirements of this rule, or make records available as requested by the Secretary or his or her designee; or

31.2.5. A program has refused to provide access to its location or records as requested by the Secretary, or his or her designee.

31.3. 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 OBMAT program or violation of any provisions of this rule without first obtaining a registration therefore in the manner hereinbefore provided.

31.3.1. The Secretary may also seek injunctive relief if the establishment, conduct, management, or operation of any OBMAT program, whether registered or not, jeopardizes the health, safety, or welfare of any or all of its patients.

31.3.2. In determining whether a penalty is to be imposed and in fixing the amount of the penalty, the Secretary shall consider the following factors:

31.3.2.a. 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 OBMAT program's actions or the actions of the medical director or any treating physician employed by or associated with the program, the severity of the action or potential harm, and the extent to which the provisions of the applicable laws or rules were violated.

31.3.2.b. What actions, if any, the medical director or treating physician took to correct the violations;

31.3.2.c. Whether there were any previous violations at the OBMAT program; and

31.3.2.d. The financial benefits that the OBMAT program derived from committing or continuing to commit the violation.

31.4. Upon finding that a physician has violated the provisions of this rule, the Secretary shall provide notice of the violation to the applicable professional licensing board.

§69-12-32. Administrative Due Process.

32.1. Before any OBMAT program registration is denied, suspended, or revoked, written notice shall be given to the owner or owners of the program, stating the grounds of the denial, suspension, revocation, or penalty and the date set for any enforcement action.

32.1.1. The notice shall be sent by certified mail to the owner or owners at the address where the OBMAT program concerned is located.

32.1.2. Within 30 days of receipt of the notice, the owner or owners may submit a request for an administrative hearing or an informal meeting to address and resolve the findings.

32.1.3. The OBMAT program and its owner or owners shall be entitled to be represented by legal counsel at the informal meeting or at the hearing at their own expense.

32.1.4. All of the pertinent provisions of W. Va. Code §§29A-5-1, *et seq.*, and W. Va. Code R. §69-1-1, *et seq.*, shall apply to and govern any hearing authorized by this rule.

32.1.5. If an owner fails to request a hearing within the time frame specified, he or she shall be subject to the full penalty imposed.

32.1.6. The filing of a request for a hearing does not stay or supersede enforcement of the final decision or order of the Secretary. The Secretary may, upon good cause shown, stay such enforcement.

§69-12-33. Administrative Appeals and Judicial Review.

33.1. Any owner of an OBMAT program who disagrees with the final administrative decision as a result of the hearing may, within 30 days after receiving notice of the decision, appeal the decision of the Circuit Court of Kanawha County or in the county where the petitioner resides or does business.

33.1.1. The filing of a petition for appeal does not stay or supersede enforcement of the final decision or order of the Secretary. An appellant may apply to the circuit court for a stay of or to supersede the final decision or order.

33.1.2. The Circuit Court may affirm, modify, or reverse the final administrative decision. The owner or owners, or the Secretary may appeal the court's decision to the Supreme Court of Appeals.