WEST VIRGINIA SECRETARY OF STATE

NATALIE E. TENNANT

ADMINISTRATIVE LAW DIVISION

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OFFICE OF WEST VIRGINIA SECRETARY OF STATE

FORM 3 -- NOTICE OF AGENCY APPROVAL OF A PROPOSED RULE AND FILING WITH THE LEGISLATIVE RULE-MAKING REVIEW COMMITTEE

AGENCY **Health And Human Resources**

RULE TYPE **Legislative** AMENDMENT TO EXISTING RULE **No** TITLE-SERIES **69-12**

RULE NAME **Medication - Assisted Treatment - Office - Based Medication Assisted Treatment**

CITE AUTHORITY **16-5Y-1 et seq**

THE ABOVE PROPOSED LEGISLATIVE RULE HAVING GONE TO A PUBLIC HEARING OR A PUBLIC COMMENT PERIOD IS HEREBY APPROVED BY THE PROMULGATING AGENCY FOR FILING WITH THE SECRETARY OF STATE AND THE LEGISLATIVE RULE-MAKING REVIEW COMMITTEE FOR THEIR REVIEW.

BY CHOOSING 'YES', I ATTEST THAT THE PREVIOUS STATEMENTS ARE TRUE AND CORRECT.

Yes

Melanie A Pagliaro -- 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-Series: 69-12

Rule Id: 10220

Document: 28903

WEST VIRGINIA SECRETARY OF STATE

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OFFICE OF
WEST VIRGINIA SECRETARY OF STATE

FORM 10 -- LEGISLATIVE QUESTIONNAIRE (Page 1)

AGENCY **Health And Human Resources**
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RULE NAME **Medication - Assisted Treatment - Office - Based Medication Assisted Treatment**

CITE AUTHORITY **16-5Y-1 et seq**

PRIMARY CONTACT

M. Kathy Lawson
Building 6, Room 817-B
State Capitol Complex
Charleston, STATE ZIP

SECONDARY CONTACT

Melanie A. Pagliaro, OCS
One Davis Square
Suite 100, East
Charleston, STATE SECONDARY ZIP SECONDARY

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CITE AUTHORITY **16-5Y-1 et seq**

AUTHORIZING STATUTE(S) CITATION
§ 16-5Y-1 et seq

DATE FILED IN STATE REGISTER WITH NOTICE OF HEARING OR PUBLIC COMMENT PERIOD
Friday, July 08, 2016

WHAT OTHER NOTICE, INCLUDING ADVERTISING, DID YOU GIVE OF THE HEARING?
internal and external stakeholders meetings were held, rule was posted to website, rule was emailed to stakeholders once published.

DATE OF PUBLIC HEARING(S) OR PUBLIC COMMENT PERIOD ENDED
Sunday, August 07, 2016

Melanie A Pagliaro -- 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.

WEST VIRGINIA SECRETARY OF STATE

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FORM 10 -- LEGISLATIVE QUESTIONNAIRE (Page 2)

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CITE AUTHORITY **16-5Y-1 et seq**

ATTACH LIST OF PERSONS WHO APPEARED AT HEARING, COMMENTS RECEIVED, AMENDMENTS, REASONS FOR AMENDMENTS.

Attached

DATE YOU FILED IN STATE REGISTER THE AGENCY APPROVED PROPOSED LEGISLATIVE RULE FOLLOWING PUBLIC HEARING: (BE EXACT)

Friday, August 26, 2016

Melanie A Pagliaro -- 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-Series: 69-12

Rule Id: 10220

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FORM 10 -- LEGISLATIVE QUESTIONNAIRE (Page 3)

AGENCY **Health And Human Resources**

RULE TYPE **Legislative** AMENDMENT TO EXISTING RULE **No** TITLE-SERIES **69-12**

RULE NAME **Medication - Assisted Treatment - Office - Based Medication Assisted Treatment**

CITE AUTHORITY **16-5Y-1 et seq**

IF THE STATUTE UNDER WHICH YOU PROMULGATED THE SUBMITTED RULES REQUIRES CERTAIN FINDINGS AND DETERMINATIONS TO BE MADE AS A CONDITION PRECEDENT TO THE PROMULGATION, GIVE THE DATE UPON WHICH YOU FILED IN THE STATE REGISTER A NOTICE OF THE TIME AND PLACE OF A HEARING FOR THE TAKING OF EVIDENCE AND A GENERAL DESCRIPTION OF THE ISSUES TO BE DECIDED.

Melanie A Pagliaro -- 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.

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FORM 10 -- LEGISLATIVE QUESTIONNAIRE (Page 4)

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CITE AUTHORITY **16-5Y-1 et seq**

DATE OF HEARING OR COMMENT PERIOD

ON WHAT DATE DID YOU FILE IN THE STATE REGISTER THE FINDINGS AND DETERMINATIONS REQUIRED TOGETHER WITH THE REASONS THEREFOR?

ATTACH FINDINGS AND DETERMINATIONS AND REASONS

None

BY CHOOSING 'YES', I ATTEST THAT THE PREVIOUS STATEMENTS ARE TRUE AND CORRECT.

Yes

Melanie A Pagliaro -- 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.

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FORM 11 -- FISCAL NOTE FOR PROPOSED RULES (Page 1)

AGENCY **Health And Human Resources**
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CITE AUTHORITY **16-5Y-1 et seq**

PRIMARY CONTACT
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SECONDARY CONTACT
Melanie A. Pagliaro, OCS
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CITE AUTHORITY **16-5Y-1 et seq**

SUMMARIZE IN A CLEAR AND CONCISE MANNER WHAT IMPACT THIS MEASURE WILL HAVE ON COSTS AND REVENUES OF STATE GOVERNMENT.

the department expects $0 in FY 2017 and approximately $256,576 in subsequent years depending on the number of clinics and providers ultimately subject to regulation.

Melanie A Pagliaro -- 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.

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FORM 11 -- FISCAL NOTE FOR PROPOSED RULES (Page 2)

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FISCAL NOTE DETAIL -- SHOW OVER-ALL EFFECT IN ITEM 1 AND 2 AND, IN ITEM 3, GIVE AN EXPLANATION OF BREAKDOWN BY FISCAL YEAR, INCLUDING LONG-RANGE EFFECT.

Effect Of Proposal	Current Increase/Decrease (use ' - ')	Next Increase/Decrease (use ' - ')	Fiscal Year (Upon Full Implementation)
ESTIMATED TOTAL COST	0.00	0.00	256,576.00
PERSONAL SERVICES			170,820.00
CURRENT EXPENSES			85,756.00
REPAIRS AND ALTERATIONS			
ASSETS			
OTHER			
ESTIMATED TOTAL REVENUES	0.00	17,100.00	60,000.00

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CITE AUTHORITY **16-5Y-1 et seq**

3. EXPLANATION OF ABOVE ESTIMATES (INCLUDING LONG-RANGE EFFECT). PLEASE INCLUDE ANY INCREASE OR DECREASE IN FEES IN YOUR ESTIMATED TOTAL REVENUES.

In subsequent years, OHFLAC will need additional 4 Surveyor FTEs (average salary and benefits is $42,705). Total personal service cost for OHFLAC is esitmated $170,820 upon full program implementation. Current expense is estimated at $55,972 oer year- travel, training and office supplies. Rent and Utilities for the new staff is estimated at $9,004 per year and the one time cost for computer equipment is $6,580. The need to for vehicles of a cost of $14,200.

Revenues is from license fees.

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PLEASE IDENTIFY ANY AREAS OF VAGUENESS, TECHNICAL DEFECTS, REASONS THE PROPOSED RULE WOULD NOT HAVE A FISCAL IMPACT, AND OR ANY SPECIAL ISSUES NOT CAPTURED ELSEWHERE ON THIS FORM.

SB 454 created a regulatory program for medication assisted treatment programs. it was determined that two rules were needed for the program.

BY CHOOSING 'YES', I ATTEST THAT THE PREVIOUS STATEMENTS ARE TRUE AND CORRECT.

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FORM 12 -- BRIEF SUMMARY AND STATEMENT OF CIRCUMSTANCES (Page 1)

AGENCY **Health And Human Resources**
RULE TYPE **Legislative** AMENDMENT TO EXISTING RULE **No** TITLE-SERIES **69-12**
RULE NAME **Medication - Assisted Treatment - Office - Based Medication Assisted Treatment**

CITE AUTHORITY **16-5Y-1 et seq**

SUMMARIZE IN A CLEAR AND CONCISE MANNER CONTENTS OF CHANGES IN RULE AND STATEMENT OF CIRCUMSTANCES REQUIRING THE RULE.

BRIEF SUMMARY
This rule applies to any publicly or privately owned medication-assisted treatment program in physicians offices that treat individuals with substance use disorders through the prescription, administration or dispensing of medication-assisted treatment medication in the form of opioid agonist, partial opioid agonist or other medication-assisted treatment medication as defined in W. Va. Code § 16-5Y-2 and further described in this rule.
STATEMENT OF CIRCUMSTANCES
Through the passage of SB 454 during the 2016 Regular Session of the West Virginia Legislature, the Secretary of the Department of Health and Human Resources is mandated to promulgate legislative rules establishing specific standards and procedures to provide for the licensure or registration and regulation of two types of medication-assisted treatment programs, including office-based medication-assisted treatment programs. The other type of medication-assisted treatment program authorized by SB 454 will be addressed in a separate rule, 69 CSR 11.

BY CHOOSING 'YES', I ATTEST THAT THE PREVIOUS STATEMENTS ARE TRUE AND CORRECT.

Yes
Melanie A Pagliaro -- 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-Series: 69-12

Rule Id: 10220

Document: 28903

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. --

1.4. Effective Date. --

1.5. Sunset Date. -- This rule will expire five years after the effective date.

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 Registered Nurses Board.

2.4. Adverse Event or Incident -- An event involving an immediate threat to the care or safety of an individual, either staff or patient; 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 OBMAT programs. Approved

authorities include the American Society of Addiction Medicine (ASAM); the Center for Substance Abuse Treatment (CSAT); the Substance Abuse and Mental Health Services Administration (SAMHSA); the National Institute on Drug Abuse (NIDA); the American Association for the Treatment of Opioid Dependence (AATOD); the Federation of State Medical Boards; 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 a 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. Counseling Session -- A face-to-face interaction in a private location between a patient(s) and a primary counselor for a period of no less than 30 minutes designated to address patient substance use disorder issues or coping strategies and individualized plan of care or treatment strategy.

2.10. 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.

2.11. 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.

2.12. 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.

2.13. Detoxification or Medically Supervised Withdrawal Treatment -- The dispensing 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.

2.14. 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.

2.15. Dispense -- The preparation and delivery of a medication-assisted treatment medication in an appropriately labeled and suitable container to a patient by an OBMAT program, but does not include the preparation and delivery of medications by a pharmacy licensed pursuant to the provisions of W. Va. Code §§ 30-5-1, *et seq.*

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 federal or state medication-assisted treatment standards, 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. Initial Assessment -- An assessment conducted prior to or at admission and initial screening of a proposed patient that focuses on the individual's eligibility or need for admission and treatment; and provides indicators for initial dosage level and forms the basis for the individualized plan of care or treatment strategy.

2.23. 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.

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

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 treatment 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 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, buprenorphine and any natural, semi-synthetic or synthetic drug that acts primarily through the mu opioid receptor in the brain.

2.33. 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.

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

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

2.36. 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.

2.37. 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 supervision.

2.38. 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.

2.39. 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.

2.40. 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.

2.41. 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. Any refusal to participate in a random drug test shall be considered a positive drug test.

2.42. 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.

2.43. Program Physician -- Any physician 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.

2.44. 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.

2.45. 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.

2.46. Relapse Prevention Plan -- A plan of action developed by a patient and his or her primary counselor to help the patient anticipate and prepare for situations or environmental stimuli that were previously associated with substance abuse or addiction in order to avoid a return to use of opioids or other inappropriate or addictive substances.

2.47. 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.

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

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

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

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

4.2.f. Receive and act upon complaints;

4.2.g. Inspect allegations of rule or regulation 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.h. Assist an OBMAT program in developing a plan of correction in order to correct any noted violations or deficiencies;

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

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

§69-12-5. Certification; Approval and Exemptions.

5.1. Hospitals that are licensed under "Hospital Licensure," 64 C.S.R § 12, and behavioral health facilities that are licensed under "Behavioral Health Centers Licensure," 64 C.S.R. § 11, 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.a. Treatment at the CSU is for no more than 14 days; and

5.3.b. 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.a. 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.

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

6.1.c. 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.d. Before establishing, operating, maintaining or advertising an OBMAT program within the state of West Virginia, a program shall:

6.1.d.1. Be registered and qualified by the United States Department of Health and Human Services under the Controlled Substances Act to dispense medication-assisted treatment medications in the treatment of substance use disorder, if the OBMAT program dispenses MAT medications; and

6.1.d.2. Obtain from the secretary a registration authorizing the operation of the OBMAT program and facility.

6.1.e. 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 will prevent an OBMAT program from designating two co-medical directors.

6.1.f. 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.g. The OBMAT program shall notify the secretary in writing 30 days prior to a change in name or location of the program and request an application form for a registration amendment.

6.1.h. If there is a change in the medical director, the OBMAT program must comply with the provisions of this rule.

6.1.i. 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.

6.1.j. 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.k. 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.l. 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.m. An OBMAT program that fails to apply for a registration is subject to the penalties established in this rule.

6.1.n. An OBMAT program shall surrender an expired, revoked or otherwise invalid registration to the secretary upon written demand.

6.2. Registration Application.

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

6.2.b.1. Documentation of all current federal accreditations, certifications and authorizations; and

6.2.b.2. A description of the organizational structure of the OBMAT program.

6.3. Registration Fees and Inspection Costs.

6.3.a. All applicants for an initial, provisional or renewed 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 base amounts for initial, provisional and renewal fees are as follows:

6.3.a.1. Initial registration fee – $250;

6.3.a.2. Provisional registration fee – only for existing programs as of the effective date of this rule seeking an initial registration of $250; and

6.3.a.3. Renewal registration fee:

6.3.a.3.A. 1-50 patients - $250;

6.3.a.3.B. 51-100 patients - $300;

6.3.a.3.C. 101-200 patients - $400;

6.3.a.3.D. 201 or more patients - $500;

6.3.b. 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 by the secretary.

6.4. Initial Inspection and Issuance of Registration.

6.4.a. 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.b. 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.c. 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.c.1. 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.c.2. 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.c.3. 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.d. 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.a. The secretary may deny an application for an initial, provisional or renewal registration if:

6.5.a.1. The secretary determines that the application is deficient in any respect;

6.5.a.2. 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.a.3. 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.a.4. The OBMAT program has made misrepresentations in obtaining accreditation, certification, licensure or registration;

6.5.a.5. The OBMAT program fails to designate a medical director at the program; or

6.5.a.6. The OBMAT program fails to have an established process for maintaining current, accessible patient records from admission through discharge.

6.5.b. 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.c. An OBMAT program shall surrender an expired, revoked or otherwise invalid registration to the secretary upon written demand.

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

6.6. Renewed or Amended Registrations.

6.6.a. 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.b. 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.a. 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.

7.2.b. 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.c. Duties of the administrator include:

7.2.c.1. Contribution to the development of policies and procedures for operation of the program;

7.2.c.2. Maintenance and security of the facility;

7.2.c.3. Employment, credentialing, evaluation, scheduling, training and management of staff;

7.2.c.4. Protection of patient rights;

7.2.c.5. Conformity of the program with federal confidentiality regulations, namely, 42 C.F.R. Part 2;

7.2.c.6. Security of medication storage and safe handling of medications;

7.2.c.7. Contribution to the management of the facility budget;

7.2.c.8. Implementation of program policies and procedures;

7.2.c.9. Communication with the medical director; and

7.2.c.10. 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.a. Each OBMAT program shall have a designated medical director. The medical director shall

7.3.a.1. Have a full, active and unencumbered license to practice allopathic medicine or surgery from the West Virginia Board of Medicine or to practice osteopathic medicine or surgery from the West Virginia Board of Osteopathic Medicine in this state.

7.3.a.2. Complete the requirements for the Drug Addiction Treatment Act of 2000, if he or she prescribes partial opioid agonist; and

7.3.a.3. 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.b. 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.b.1. Operation of all medical aspects of the treatment program;

7.3.b.2. Administration and supervision of all medical services;

7.3.b.3. Compliance with all applicable federal, state and local laws, rules and regulations;

7.3.b.4. 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.b.5. Approval of the basic and continuing education programs of all staff employed by or volunteering at the OBMAT program; and

7.3.b.6. Determination of the ability of the program physicians and physician extenders to work independently within the applicable scope of practice.

7.3.c. 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.d. 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.a. 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.b. All physicians and physician extenders employed by the OBMAT program shall be actively licensed in West Virginia and shall have:

7.4.b.1. A minimum of one year of experience in substance use disorder treatment and medication-assisted treatment settings; or

7.4.b.2 Meet the following requirements:

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

7.4.c. 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.d. During all hours of operation, when patients 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.d.1. Physician;

7.4.d.2. Physician assistant;

7.4.d.3. Advanced practice registered nurse; or

7.4.d.4. Registered nurse.

7.4.e. Plans of Education.

7.4.e.1. 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.e.2. 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.e.3. 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.e.4. 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.a. 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.b. The OBMAT program shall assign or make referral to a primary counselor for each patient to contribute to the appropriate treatment plan for the patient and to monitor patient progress.

7.5.c. 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.d. 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.e. The program administrator is responsible for documentation of supervision, which shall be available for review at all times.

7.5.f. Newly employed counselors and other non-physician clinical staff without experience in a recovery-based OBMAT program shall receive initial training lasting at least 20 hours and consisting of, at a minimum, the following:

7.5.f.1. Substance use disorder overview;

7.5.f.2. Opioid treatment, detoxification protocols, recovery models and basic pharmacology and dosing;

7.5.f.3. Characteristics of the substance use disorder population;

7.5.f.4. Toxicology screening and observation of sample collection;

7.5.f.5. Program policy and procedure;

7.5.f.6. Confrontation, de-escalation and anger management;

7.5.f.7. Cultural sensitivity as necessary and appropriate;

7.5.f.8. Current strategies for identifying and treating alcohol, cocaine and other substance use disorders;

7.5.f.9. Identification of co-occurring behavioral health or developmental disorders; and

7.5.f.10. Other clinical issues as appropriate for the population served.

7.5.g. 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. The program administrator shall document in the personnel file any exemption granted and the basis for the exemption.

7.5.h. 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.a. 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.b. All unlicensed clinical staff and volunteers shall receive direct on-site supervision and be provided with assistance, directions for activity and support.

§69-12-8. Environment and Operation.

8.1. Service Operation Schedule.

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

8.1.c. The program shall develop and implement the following for days not in operation, if applicable:

8.1.c.1. 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; and

8.1.c.2. The program shall establish procedures for emergency access to prescription and dose information 24 hours a day, seven days a week. This information may be provided via an answering service or other electronic means.

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.

8.2.a. Prior to directly billing a patient for any MAT treatment, the OBMAT program shall document in the patient's record the receipt of any rejection of prior authorization, rejection of a submitted claim, or written denial from a patient's insurer, Medicare or West Virginia Medicaid denying coverage for opioid treatment. The OBMAT program shall also clearly document in the patient's record if the patient has no insurance or has voluntarily and with full knowledge of the financial obligations, including all treatment costs, requested a claim not be submitted to their insurer, Medicare or West Virginia Medicaid. When any instance described in this section regarding direct billing and acceptance of

cash payments from a patient occurs, the OBMAT program shall clearly document in the patient's record the rationale and medical necessity for acceptance into the program.

8.2.b. The OBMAT program may directly bill and accept cash payments from a patient only after the requirements of this rule herein, have been fulfilled and documented.

8.2.c. At the option of the OBMAT program, treatment may commence prior to billing.

8.3 Each OBMAT program facility shall have:

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

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

8.3.c. A secure room and lockable equipment for physical patient records and appropriate security mechanisms for electronic records;

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

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

8.3.f. Adequate parking areas.

8.4. The OBMAT program facility may provide security personnel in lobby and parking areas, either clinic staff or contracted, if the population served or clinic environment warrants such an arrangement. If contracted staff is used for security, the staff must be trained in patient confidentiality.

8.5. Infection Control.

8.5.a. The OBMAT program shall develop, implement and maintain an effective infection control program that protects the patients, their families and clinic personnel by preventing and controlling infections and communicable diseases.

8.5.b. The program shall include the implementation of a nationally recognized system of infection control guidelines.

8.5.c. The OBMAT program shall have an active surveillance and education program for the prevention, early detection, control and investigation of infections and communicable diseases.

8.5.d. The OBMAT program shall designate a person or persons, with appropriate education and training, as infection control officer to develop and implement policies governing control of infections and communicable diseases for patients and personnel.

§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.a. 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.a.1. 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.a.2. 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.a. Provide 24 hour, seven day-per-week access to information, as described in this rule, so that patient emergencies may be immediately addressed;

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

9.3.d. 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 a 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 programs 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.a. Any action taken or procedures proposed to correct the deficiencies and prevent their reoccurrence;

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

11.1.c. The signature of the head of the governing body or his or her designee.

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 persons.

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.a. 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; or

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

12.1.c. The waiver or variance serves the best interests of patient safety and quality of care.

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

13.1.b.1. Information regarding complaints and subsequent investigations that is deemed confidential by any provision of this rule or applicable state or federal laws;

13.1.b.2. Information of a personal nature from a patient or personnel file; or

13.1.b.3. Information required to be kept confidential by state or federal law.

13.1.c. 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.a. 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.a.1. The total number of patients receiving medication-assisted treatment;

13.2.a.2. The numbers of WV patients and out-of-state patients;

13.2.a.3. The number of patients discharged from the program;

13.2.a.4. The reason for discharge, including:

13.2.a.4.A. Termination or disqualification;

13.2.a.4.B. Voluntary withdrawal; or

13.2.a.4.C. An unexplained reason.

13.3. Incident Reporting and Adverse Events.

13.3.a. 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.b. Adverse events or incidents are defined as an event which may involve:

13.3.b.1. Immediate threat to the care or safety of an individual, whether staff member, visitor, patient or other patient;

13.3.b.2. The possibility of serious operational or personnel problems; or

13.3.b.3. The potential to undermine public confidence in the OBMAT program.

13.3.c. Incidents or adverse events may include:

13.3.c.1. Program medication errors or other known medication errors;

13.3.c.2. Potentially lethal patient suicide attempts;

13.3.c.3. Drug or substance-related hospitalization of a patient;

13.3.c.4. Patient death or serious injury due to trauma, suicide, medication error or unusual circumstances;

13.3.c.5. Harm to family members or others from ingesting a patient's medication;

13.3.c.6. Selling drugs or substances on the premises;

13.3.c.7. Medication diversion;

13.3.c.8. Harassment or abuse, including physical, verbal, sexual and emotional, of patients by staff;

13.3.c.9. Theft, burglary, break-in or similar incident at the program;

13.3.c.10. Violence;

13.3.c.11. Significant disruption of services due to disaster such as fire, storm, flood or other occurrence; and

13.3.c.12. The potential for negative community reaction or which the program director or medical director believes may lead to community concern.

13.3.d. 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 regarding the improvements in the process to prevent further incidents.

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

13.3.e.1. The incident or adverse event is fully documented and appropriately reported to the correct state agencies as necessary;

13.3.e.2. There is prompt investigation and review of the situation surrounding the incident or adverse event;

13.3.e.3. Timely and appropriate corrective action is taken; and

13.3.e.4. Ongoing monitoring of any corrective action takes place until effectiveness of the action is established.

13.3.f. 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.f.1. The action or actions implemented to prevent the reoccurrence of the incident or adverse event;

13.3.f.2. The time frames for the action or actions to be implemented;

13.3.f.3. The person or persons designated to implement and monitor the action or actions; and

13.3.f.4. The strategies for the measurements of effectiveness to be established.

13.3.g. The OBMAT program shall report any known death involving drug overdose or drug-related complications to the state opioid treatment authority and the state oversight agency within 24 hours of the program receiving notification of the mortality.

§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 develop detailed job descriptions for credentialed and non-credentialed staff and volunteers that clearly define the education, training, qualifications and competencies needed to provide specific services. The job descriptions shall be provided to and reviewed with all employees or volunteers at the time of the initial interview, upon employment and whenever there are significant changes in job assignment or a modification of the employee or volunteer's job description or responsibilities.

14.4. Within 10 days of the date any new clinical staff member or volunteer begins working at an OBMAT program, the program shall provide the staff member or volunteer with an orientation as to the person's primary job responsibilities and requirements. All clinical staff members and volunteers shall receive formal training in confidentiality issues and requirements prior to working at the program.

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

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

14.5.b. Documentation of the date of employment;

14.5.c. Identifying information and emergency contacts;

14.5.d. Documentation of completion of orientation, internal and external training and continuing education;

14.5.e. Documentation of all licenses, certifications or other credentials;

14.5.f. Documentation relating to performance, supervision, disciplinary actions and termination summaries; and

14.5.g. Detailed job descriptions.

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

§69-12-15. Risk Management.

15.1. Each OBMAT program shall:

15.1.a. Obtain a voluntary, written, program-specific informed consent to treatment from each patient at admission;

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

15.1.c. Obtain voluntary, written, informed consent to the prescribed therapy from each patient before receiving a prescription; and

15.1.d. Inform each patient that:

15.1.d.1. The goal of medication-assisted treatment is recovery, stabilization of functioning and establishment of a recovery-oriented lifestyle;

15.1.d.2. Detoxification from opioids or other substances is a treatment alternative to an ongoing, recovery-oriented plan of care or treatment strategy.

15.1.d.3. At each review of the individualized plan of care or treatment strategy, in full consultation with the patient, the program will discuss present level of functioning, course of treatment and future long-term recovery goals; and

15.1.d.4. A patient may choose to withdraw from or be maintained on the medication as he or she desires, unless medically contraindicated.

15.2. Each OBMAT program shall inform every patient regarding legal requirements and program policies concerning the report of suspected child abuse and neglect as well as other forms of abuse, such as violence against women.

15.3. Each OBMAT program shall inform every patient as to federal confidentiality regulations, 42 C.F.R. Part 2, and the Health Insurance Portability and Accountability Act of 1996, as amended.

15.4. Each OBMAT program shall:

15.4.a. Promulgate and make available a written description of patient rights and responsibilities;

15.4.b. Follow due process procedures and observe any applicable medical protocols for any involuntary terminations of patients;

15.4.c. Ensure that family members of employees do not receive special privileges; and

15.4.d. Monitor credentialing of all staff to ensure that they maintain current credentials for performing their assigned job duties.

§69-12-16. Medication Security, Storage, Administration and Documentation.

16.1. Medication Security.

16.1.a. 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:

16.1.a.1. Ensure responsible handling and secure storage of all medications kept at the program;

16.1.a.2. Ensure responsible documentation of all medications received, stored, administered and dispensed at the program; and

16.1.a.3. Ensure that only authorized personnel may access the storage areas where any medications are kept.

16.2. Approved Medications.

16.2.a. 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.

16.2.b. The state opioid treatment authority is responsible for reviewing, monitoring, and approving, when applicable, practice guidelines for alternative treatments as they become available. The guidelines shall be in conformance with any nationally recognized guidelines approved by the secretary. The OBMAT program is responsible for remaining in conformity with practice guidelines as issued or approved by the state opioid treatment authority.

16.3. Prescriptions and Dosage.

16.3.a. Each OBMAT program shall have a procedure through which the patient can discuss the prescriptions and dosages of medication he or she receives with appropriate staff members regularly and upon request. This procedure shall be clearly described to the patient. A written explanation of the prescription dosing procedures shall be initialed and dated by the patient and maintained in the patient chart and individualized plan of care or treatment strategy.

16.3.b. 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.

16.3.c. Dosages of medication shall be adjusted so that they ultimately:

16.3.c.1. Prevent the onset of subjective and objective signs of opioid or substance abstinence syndrome for 24 hours or more;

16.3.c.2. Reduce or eliminate drug cravings; and

16.3.c.3. Block the effects of illicitly acquired opioids without inducing persistent euphoric or other undesirable effects.

16.4. An OBMAT program and its physicians shall not dispense or administer medication-assisted treatment drugs on site.

16.5. All prescriptions for medication-assisted treatment medications may be issued by electronic prescribing, whenever possible.

16.6. 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.

§69-12-17. Continuous Quality Improvement Policies; Diversion Control Plan.

17.1. Each OBMAT program shall develop, implement and maintain current quality assurance and quality control plans that include provisions for:

17.1.a. Regular and continuous staff education;

17.1.b. A service delivery assessment which, at a minimum, shall evaluate appropriateness of the individualized treatment plan and services delivered, completeness of documentation in patients; records and quality of and participation in staff training programs, linkage to a utilization of primary care and other out-of-program services, and availability of services and medications for other conditions;

17.1.c. An ongoing assessment, measurement and monitoring of patient outcomes, treatment outcomes and the various processes including, but not limited to:

17.1.c.1. Reduction or elimination of the patient's use of illicit opioids, illicit drugs and the problematic use of licit drugs;

17.1.c.2. Reduction or elimination of associated criminal activities;

17.1.c.3. Reduction of the patient's behaviors contributing to the spread of infectious diseases;

17.1.c .4. Improvement of quality of life through the restoration of physical and behavioral health and functional status, including employment or volunteerism, as may be appropriate; and

17.1.c.5. Assessment of medication-related issues, including, but not limited to, security, inventory and prescription dosage issues.

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

17.2.a. The diversion control plan shall be reviewed and approved by the medical director and program physicians at OBMAT programs at a minimum of every 2 years.

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

17.2.b.1. Continuous clinical and administrative monitoring of the potential for and actual diversion including an investigation, tracking and monitoring system of incidents of diversion; and

17.2.b.2. Proactive planning and procedures for problem identification, correction and prevention.

17.2.c. 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.

§69-12-18. Patient Rights.

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

18.1.a. To be informed, both verbally and in writing, of program rules and regulations and patients' rights and responsibilities. The rights and responsibilities shall be posted prominently and reviewed with the patient at admission, at the end of a stabilization period, at the time of an annual treatment review and at any time changes in the rights and responsibilities occur;

18.1.b. To receive treatment provided in a fair and impartial manner regardless of race, sex, age, sexual orientation or religion;

18.1.c. To receive an individualized plan of care or treatment strategy developed according to guidelines established by a nationally recognized authority and approved by the secretary. The individualized plan of care or treatment strategy shall include a recovery model, shall be reviewed periodically by the program physician and counselor at OBMAT programs, and shall be maintained in the patient's chart;

18.1.d. 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;

18.1.e. 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;

18.1.f. To be entitled to participate in an OBMAT program that provides an adequate number of competent, qualified and experienced professional staff to implement and supervise the individualized plan of care or treatment strategy;

18.1.g. 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;

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

18.1.i. To be given a copy of the initial assessment, written acceptance into the program; or, in the case of denial of admission a referral to an appropriate treatment program based upon the results of the initial assessment;

18.1.j. 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;

18.1.k. 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 purposes of program evaluation, billing and statutory requirements for reporting abuse;

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

18.1.m. 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

18.1.n. To be entitled to protection from other patients' disruptive actions or behavior. The program shall attempt to determine the cause of that behavior so that an appropriate referral to an alternative method of care can be made.

18.2. The OBMAT program shall have patient grievance procedures which shall be displayed in the patient care area in a conspicuous place and easily available to patients. They should include program rules, consequences of noncompliance and procedures for filing a complaint or grievance. The procedures shall inform the patients of the following:

18.2.a. The right of a patient to express verbally or in writing his or her dissatisfaction with or complaints about treatment received;

18.2.b. The right of a patient to initiate grievance procedures without fear of reprisal;

18.2.c. The right of a patient to be informed of the grievance procedure in a manner that can be understood by the patient; and

18.2.d. The right of a patient to receive a decision in writing with the reasoning articulated.

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

§69-12-19. Patient Records.

19.1. 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.

19.2. 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.

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

19.4. All patient records shall be updated in a timely manner.

19.5. Information in the patient medical records shall be entered by designated program staff and approved by the program physician. Entries shall be legible and organized in an effective manner, allowing materials to be easily retrieved.

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

19.7. Individual patient records shall contain:

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

19.7.b. Documentation of program compliance with the program's policy regarding prevention of multiple admissions;

19.7.c. An initial assessment report;

19.7.d. A narrative biopsychosocial history;

19.7.e. All physical and biopsychosocial assessments;

19.7.f. 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 database; and progress notes, including documentation of current dose and other dosage data;

19.7.g. Dated case entries of all significant contacts with patients, including a record of each counseling session in chronological order;

19.7.h. Dates and results of case conferences for patients;

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

19.7.j. Documentation that the services listed in the individualized plan of care or treatment strategy are available and have been provided or offered;

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

19.7.l. Documentation that the OBMAT program made a good faith effort to review whether the patient is enrolled in any other OBMAT program;

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

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

19.7.o. Documentation that the patient was provided with a copy of the program's rules and regulations; a copy of the patient's rights and responsibilities; a copy of the detoxification treatment plan option, if applicable; a copy of the patient's individualized plan of care or treatment strategy; a copy of the patient's goals; and documentation that each of these items was discussed with the patient;

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

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

19.8. Documentation of Patient Contact.

19.8.a. 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:

19.8.a.1. The reason for or nature of the contact;

19.8.a.2. The patient's current condition;

19.8.a.3. Significant events occurring since prior contact;

19.8.a.4. The assessment of patient status; and

19.8.a.5. A plan for action or further treatment.

19.8.b. Each entry shall be completed by the next business day, but no longer than three business days following the contact and shall be clearly dated and initialed or signed by the staff person involved.

19.9. An OBMAT program that closes or discontinues OBMAT program services shall arrange for continued management of all patient records as follows:

19.9.a. The owner of the OBMAT program shall notify the secretary in writing of the address where records will be stored and specify the individual who will be managing records and that individual's contact information.

19.9.b. The owner of the OBMAT program shall arrange for the storage of each record through one or more of the following measures:

19.9.b.1. The owner of the OBMAT program shall continue to manage the records and give written assurance to the secretary that it will respond to authorized requests for copies of patient records within 10 working days.

19.9.b.2. The owner of the OBMAT program shall transfer records of patients who have given written consent to another OBMAT program; or

19.9.b.3. The owner of the OBMAT program shall enter into an agreement with another OBMAT program to store and manage the patient records.

§69-12-20. Initial Assessment; Admission Criteria and Admission Process.

20.1. Each OBMAT program shall develop, implement and maintain policies and procedures designed to ensure that patients are admitted to maintenance treatment only after assessment by qualified personnel who have determined that the person meets the qualifications for admission.

20.2. Any patient seeking admittance to the OBMAT program shall undergo an initial assessment to determine whether the person meets the criteria for admission. The initial assessment shall be conducted by the medical director, an approved program physician or a supervised physician extender. The initial assessment shall focus on the patient's eligibility and need for treatment and shall provide indicators for initial dosage level, if required, and if admission is determined appropriate. The determination of admission eligibility shall be made using accepted medical criteria such as those listed in the latest approved version of the Diagnostic and Statistical Manual for Mental Disorders.

20.3. The initial physical assessment shall include documentation of:

20.3.a. A brief assessment;

20.3.b. The patient's immediate relevant history, including, but not limited to, determination of chronic or acute medical conditions such as diabetes, renal disease, hepatitis, sickle cell anemia, tuberculosis, human immunodeficiency virus (HIV) exposure, sexually transmitted disease, chronic cardiopulmonary disease and pregnancy;

20.3.c. A determination of currently prescribed medication or over-the-counter substances;

20.3.d. An evaluation of the patient's use of other substances of abuse and alcohol;

20.3.e. Determination of current substance use disorder;

20.3.f. Determination of length of substance use disorder;

20.3.g. An initial drug test and full drug screen to identify whether the patient is using other drugs;

20.3.h. An inquiry to and report from the Controlled Substances Monitoring Program database;

20.3.i. An inquiry whether the patient is enrolled in any other OBMAT program;

20.3.j. Identification of comorbid medical and psychiatric conditions or disorders and to determine how, when and where they will be addressed;

20.3.k. Screen for communicable diseases and address them as needed and evaluate patient's level of physical, psychological and social functioning or impairment;

20.3.l. Assessment of the patient's access to social supports, family, friends, employment, housing, finances and whether any legal problems exist; and

20.3.m. Determination of the patient's readiness to participate in treatment.

20.4. The patient desiring admission for treatment through the use of a medication-assisted treatment medication must be at least 18 years of age. Exceptions may be made on extremely rare occasions by application with parental consent through the treating physician to the state opioid treatment authority.

20.5. All admissions shall include documentation regarding medical necessity and program eligibility for medication-assisted treatment that includes:

20.5.a. Objective evidence, such as a positive drug test, of current physical dependence or tolerance to opioids or methadone;

20.5.b. Objective symptoms of withdrawal, with documentation of the signs and symptoms of withdrawal, or both; or

20.5.c. Evidence from the patient of the following:

20.5.c.1. An onset of opioid physical dependence prior to admission with continuous use the greater part of the year; and

20.5.c.2. Evidence of multiple and daily self-administration of an opioid.

20.6. The following behavioral signs which support the diagnosis of substance use disorder shall be discussed and documented, although none are considered required for admission:

20.6.a. Unsuccessful efforts to control use;

20.6.b. Time spent obtaining drugs or recovering from the effects of abuse;

20.6.c. Continual use despite harmful consequences;

20.6.d. Obtaining opiates illegally;

20.6.e. Inappropriate use of prescribed opiates;

20.6.f. Giving up or reducing important social, occupational or recreational activities;

20.6.g. Continuing use of the opiate despite known adverse consequences to self, family or society; and

20.6.h. One or more unsuccessful attempts at gradual removal of physical dependence on opioids or detoxification using methadone, buprenorphine or other appropriate medications.

20.7. The absence of physiological dependence should not be an exclusion criterion, and admission may be clinically justified. The initial assessment may recognize that patients in some populations may be susceptible to relapse to substance use disorder, leading to high-risk behaviors with potentially life threatening consequences.

20.8. After thorough review of the information acquired through the initial assessment, a patient may be admitted to the OBMAT program if, using accepted medical criteria, a determination is made that one or more of the following factors is met:

20.8.a. The patient is currently addicted to an opioid drug, as evidenced by a positive drug test for either opioids or methadone;

20.8.b. There are objective symptoms of withdrawal, or both; or

20.8.c. There is objective evidence that the patient qualifies under the provisions of this rule.

20.9. 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:

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

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

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

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

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

20.10. 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.

20.11. The program physician or physician extender shall review the accumulated data directly with the patient and confirm a diagnosis of substance use disorder of sufficient severity to warrant admission to the OBMAT program. The program practitioner shall document that treatment is medically necessary. The admission and initial dosing decisions ultimately rest with the medical director or the designated program practitioner.

20.12. 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.

20.13. Admission of patients with no opioid tolerance shall require careful monitoring and documentation during the induction phase of treatment.

20.14. The physician or physician extender and patient shall each sign and date the verification that the initial assessment and review occurred and that the patient received all applicable information, policies and procedures.

20.15. Exceptions to admission policy shall be reviewed and tracked by the medical director at an OBMAT program and be made available to regulatory bodies.

20.16. If a patient was previously discharged from treatment at another program, the admitting OBMAT program with patient consent shall contact the previous OBMAT program or programs for treatment history.

20.17. Non-admissions. The program shall maintain written logs that identify persons who were considered for admission or initially screened for admission but were not admitted. This log shall identify the reasons why the patients were not admitted and what referrals were made for them by the program.

20.18. Patient Transfers.

20.18.a. OBMAT programs may accept patients transferring from another OBMAT program within the state of West Virginia, if:

20.18.a.1. The OBMAT program accepting a patient voluntarily transferring from another OBMAT program shall provide documentation that the patient's medical record and reasons for the transfer was sought from the patient's previous OBMAT program; and

20.18.a.2. The patient is in compliance with readmission policies for patients who have been administratively detoxified.

20.18.b. In order for the patient to transfer to another OBMAT program, the following requirements shall be met:

20.18.b.1. The OBMAT program that the patient is leaving shall forward all relevant patient records to the OBMAT program where the patient is transferring; and

20.18.b.2. The OBMAT program shall provide documentation that the patient's medical record and reason for transfer was sought from the patient's previous OBMAT program and shall meet the admission criteria of this rule.

20.18.c. Patients who are West Virginia residents and wish to transfer to another West Virginia-based program shall be reviewed by the new program's admission program physician or medical director on an individual basis to determine their placement on the receiving program's patient listing. The review shall determine the patient's need, program placement availability and the circumstances for the transfer request.

20.18.d. Patients who are not West Virginia residents shall transfer to a West Virginia program as a new admission in accordance with this rule.

§69-12-21. Multiple Program Enrollments.

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

21.1.a. 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.

21.1.b. 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.

21.2. When practicable, the OBMAT program shall obtain a written consent for release of information from the patient in order to check the records of every opioid treatment program within 100 miles of the program site so as 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.

21.3. Results of the multiple-program check shall be contained in the clinical record, the patient chart and the individualized plan of care or treatment strategy.

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

§69-12-22. Controlled Substances Monitoring Program Database.

22.1. 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.

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

22.3. The program practitioners shall access the Controlled Substances Monitoring Program database in order to ensure that the patient is not seeking prescription medication from multiple sources. The results obtained from the database shall be maintained with the patient records.

§69-12-23. Orientation.

23.1. Every person admitted to an OBMAT program shall receive program orientation. The orientation shall be made verbally at the earliest opportunity. 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.

23.2. Orientation shall include the following:

23.2.a. An explanation of the rights and responsibilities of the patient.

23.2.b. An explanation of the patient's right to file a grievance and applicable appeal procedures.

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

23.2.c.1. Expectations and rules;

23.2.c.2. Hours of operation;

23.2.c.3. Access to after-hours services;

23.2.c.4. Confidentiality policy;

23.2.c.5. Toxicological screening and random drug-testing policies;

23.2.c.6. Sanctions, restrictions and other penalties;

23.2.c.7. Interventions;

23.2.c.8. Incentives; and

23.2.c.9. Various discharge criteria, including, but not limited to, administrative and medical withdrawal policies and procedures.

23.2.d. An explanation about obtaining reports from the Controlled Substances Monitoring Program database; how the reports are used to treat and monitor the patient and the requirement that the reports be maintained in the patient files.

23.2.e. An explanation of any and all financial obligations of the patient; all fees charged by the OBMAT program; and any financial arrangements for services provided by the OBMAT program, including the requirements stated in W. Va. Code § 16-5Y-5(e).

23.2.f. Familiarization with the OBMAT program facility and premises.

23.2.g. A description of the OBMAT program's policies regarding:

23.2.g.1. Use of alcohol on or prior to entering the facility and premises;

23.2.g.2. Smoking;

23.2.g.3. Illicit or licit drugs brought into the program or onto the premises; and

23.2.g.4. Weapons brought into the program or onto the premises.

23.2.h. Identification of the counselor assigned to the patient and contact information for that counselor.

23.2.i. A copy of the OBMAT program rules identifying the following:

23.2.i.1. Any restrictions the program may place on the patient;

23.2.i.2. Events, behaviors or attitudes that may lead to the loss of rights or privileges for the patient; and

223.2.i.3. Means by which the patient may regain rights or privileges that have been restricted;

23.2.j. An explanation of the purpose and process of the initial and subsequent physical and biopsychosocial assessments;

23.2.k. 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; and

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

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

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

23.3.c. A signed copy of the coordination of care agreement;

23.3.d. Patient's rights;

23.3.e. Confidentiality policies; and

23.3.f. 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.

23.4. As soon as the patient is stable and capable of understanding, the patient shall receive group or individual education, or both, on the following:

23.4.a. The nature of substance use disorder, including the great likelihood that substance use disorder is a relapsing disease and is likely to have grave medical and social consequences if not treated on an ongoing basis;

23.4.b. The anticipated benefits of treatment;

23.4.c. The nature of the recovery process;

23.4.d. HIV spectrum and other infectious diseases;

23.4.e. Potential drug interactions;

23.4.f. Self-help groups;

23.4.g. Medical issues related to detoxification from medication-assisted treatment medications;

234.4.h. The special risk of withdrawal from the medication-assisted treatment medication prescribed to the individual patient and detoxification to pregnant women and the fetus, as appropriate;

23.4.i. Characteristics of the medications or prescribed by the program;

23.4.j. Drug safety issues; and

23.4.k. Side effects of medications administered or prescribed by the program.

23.5. Documentation that the patient has completed the orientation shall be completed and signed by the patient and maintained in the patient's chart and individualized plan of care or treatment strategy.

§69-12-24. Required Services.

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

24.2. Each OBMAT program shall require every patient to undergo a documented biopsychosocial assessment by a program counselor or other qualified practitioner. The biopsychosocial assessment shall be completed at the time of admission or prior to the first dose of medication-assisted treatment medication.

24.3. Within 14 days of the admission of a patient, 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.

24.4. 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.

24.5. 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.

24.6. 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.

24.7. 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 disease shall comply with the requirements of this rule.

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

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

24.8.b. 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;

24.8.c. Review psychosocial treatment expectations and responsibilities with the patient;

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

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

24.9. Services provided by an OBMAT program should adhere to recovery initiatives promoted by federal and state laws, rules and regulations and the protocols and guidelines of approved authorities. Recovery initiatives include assistance in overcoming or managing a patient's substance use disorder or other diseases; encouraging a patient to live in a physically and emotionally healthy manner in a stable

and safe place; encouraging the patient to engage in meaningful daily activities, such as job, school, volunteerism, family caretaking or creative endeavors; and assisting the patient in obtaining the independence, income and resources to participate in society and in developing relationships and supportive social networks.

24.10. The program shall complete a physical and biopsychosocial assessments, or refer the patient to an outside provider for same, which shall be used to develop the long-term individualized plan of care or treatment strategy. The physical and biopsychosocial assessments shall integrate information obtained in all treatment of the patient at the OBMAT program.

§69-12-25. Counseling.

25.1. Each OBMAT program shall provide substance use disorder counseling 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.

25.2. The counseling shall be provided by a professional as described in this rule, qualified by education or training to assess the psychological and sociological 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 psychological and social portions of the patient's individualized plan of care or treatment strategy, in coordination with the medical staff and program physician. The individualized plan of care or treatment strategy shall address the social, environmental, psychological, social and familial issues relative to recognizing, correcting and eliminating the patient's maladaptive patterns of drug consumption and other high risk or destructive behaviors.

25.3. The primary counselor is responsible for assisting the patient in altering lifestyles and patterns of behavior in order to improve the patient's ability to function adaptively in his or her family and community.

25.4. Each OBMAT program shall provide counseling on matters indirectly related to substance use disorder, including, but not limited to:

25.4.a. Preventing exposure to, and the transmission of, HIV and hepatitis C for each patient admitted or readmitted to maintenance or detoxification treatment; and

25.4.b. Domestic violence, sexual abuse and anger management.

25.5. Each OBMAT program shall develop and implement policies and procedures which ensure that single sex groups or same sex counselors will be available to all patients, as warranted or requested and clinically indicated.

25.6. Counseling sessions shall be provided according to generally accepted best practices and shall be offered:

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

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

25.6.c. Thereafter, for subsequent 90-day periods of treatment, counseling sessions shall take place as needed or indicated in the patient's individualized plan of care or treatment strategy.

25.7. The counseling program shall provide for additional counseling, as clinically indicated, of any patient who has a positive drug test. The counseling sessions may consist of group counseling sessions. However, the patient must attend at least one individual, private session per month.

25.8. 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.

25.9. Each counseling session shall be documented and completed within three business days of each session and shall be clearly dated and initialed or signed by the counselor providing the counseling session.

25.10. Counseling session opportunities for family or significant others involvement in counseling shall be provided and documented referral made and documented.

25.11. 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.

§69-12-26. Post-Admission Assessment and Initial Plan of Care or Treatment Strategy.

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

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

26.2.a. The assessment shall include, at a minimum, 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

26.2.b. For other than the toxicology tests for drugs and alcohol, appropriate history, substance abuse history, hepatitis "B" and "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.

26.2.c. A program physician or physician extender shall perform an assessment of the patient on the same day that the program practitioner initially prescribes a medication-assisted treatment medication to a patient. All assessments shall be performed according to accepted and prevailing standards for medical care.

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

26.2.d.1. Laboratory tests that are not directly conducted by the OBMAT program may be provided by the patient's primary care physician, other health care providers or by a medical clinic.

26.2.d.2. The OBMAT program is responsible for obtaining and maintaining documentation of required laboratory tests performed by an alternative provider. Alternative providers may not supply toxicology screens unless they meet the required quality guidelines, content and timelines.

26.2.d.3. Tests not directly conducted by the OBMAT program at admission shall have been conducted within the 30 days prior to the admission in order to be considered a valid assessment of the patient.

26.3. Continuing Assessments.

26.3.a. Subsequent patient assessments shall include the following:

26.3.a.1. Periodic Patient Evaluation. 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 does 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 such as:

26.3.a.1.A. Absence of toxicity;

26.3.a.1.B. Absence of medical or behavioral adverse effects;

26.3.a.1.C. Responsible handling of medications;

26.3.a.1.D. Compliance with all elements of the treatment plan including recovery-oriented activities, psychotherapy and/or other psychosocial modalities; and

26.3.a.1.E. Abstinence from illicit drug use. If reasonable treatment goals are not being achieved, the physician shall re-evaluate the appropriateness of continued treatment or modification.

26.3.b. Consultation. The physician shall refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives. The physician shall pursue a team approach to the treatment of opioid addiction, including referral for counseling and other ancillary services. Ongoing communication between the physician and other treatment professionals is necessary to ensure appropriate compliance with the treatment plan. The management of addiction in patients with comorbid psychiatric disorders requires extra care, monitoring, documentation and consultation with or referral to a mental health professional.

26.4. Initial Plan of Care or Treatment Strategy.

26.4.a. The treating program physician and other health care professionals, working within their scope of practice, directly involved in the care of the patient shall develop a written initial plan of care or treatment strategy for every patient.

26.4.b. The initial plan of care or treatment strategy shall include, at a minimum:

26.4.b.1. Information required for the initial assessment;

26.4.b.2. Documentation of the patient's diagnoses, the proposed medical and medication-assisted treatment, medication dosages and administration;

26.4.b.3. Documentation of the patient's current physical condition and whether the patient requires other health care;

26.4.b.4. Laboratory test results;

26.4.b.5. Follow-up on any identified medical, physical or behavioral health issues;

26.4.b.6. Documentation of any education regarding the OBMAT program's policies and procedures, substance use disorder or counseling sessions and resolution of other issues unique to the needs of the individual patient;

26.4.b.7. Such other information as recommended by the guidelines and treatment model utilized for the patient;

26.4.b.8. Specific goals and outcomes to improve or maintain the optimal health of the patient which are based on the assessment of the patient; and

26.4.b.9. A description of services and their frequency to be provided for the patient and primarily directed to achieve the expected goals and outcomes.

§69-12-27. Individualized Plan of Care or Treatment Strategy.

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

27.2. Within 30 days after admission of a patient, the OBMAT program shall develop a more comprehensive individualized plan of care or treatment strategy and attach it to the patient's chart no later than five days after the plan is developed. 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.

27.3. 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. If a new plan of care or treatment strategy is not implemented, the reasons for such decision should be documented in the patient's record. Physical and electronic plans of care, including all reviews and updates, must be acknowledged by the patient.

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

27.5. All individualized plans of care or treatment strategies shall include, at a minimum:

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

27.5.b. 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;

27.5.c. The identification of triggers for misuse of substances;

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

27.5.e. The development of a detailed relapse prevention plan;

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

27.5.g. Follow-up medical or physical issues as necessary;

27.5.h. A vocational evaluation, formal or informal;

27.5.i. A plan to achieve financial stability and independence;

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

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

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

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

27.5.n. The results from initial, monthly and random drug tests; and

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

27.6. The individualized plan of care or treatment strategy shall reflect the patient's current physical health condition and whether the patient requires other health care services. OBMAT programs without primary care services onsite shall refer patients for appropriate laboratory tests and additional medical treatment and follow up on the results.

27.7. Each OBMAT program shall provide opportunities for family involvement where appropriate in the therapy provided to each patient and document such involvement in the individualized plans of care or treatment strategies.

27.8. The appropriate medical staff shall conduct careful discussions with the patient regarding the patient's continued desire to remain in the OBMAT program on a maintenance schedule of medication and document such discussions in the patient's chart and individualized plans of care.

27.8.a. OBMAT programs shall make every effort to retain patients in treatment as long as clinically appropriate and medically necessary in accordance with approved national guidelines, and acceptable to the patient and compliant with the treatment agreement.

27.8.b. A patient in good standing with the program, as defined by policy, has the right to continue to stay in the program. At no time should such a patient feel pressured to enter a program of withdrawal over his or her objections.

27.8.c. If a patient wishes to enter medically-supervised withdrawal, the individualized plan of care or treatment strategy shall reflect that choice.

27.9. With the patient's permission, the OBMAT program shall obtain complete medical records from other providers and maintain the records in the patient's chart and the individualized plan of care or treatment strategy.

27.10. Coordination of Care Agreement.

27.10.a. 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.

27.10.b. 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.

27.10.c. The coordination of care agreement shall include the following:

27.10.c.1. An authorization allowing communication between the program physician and primary counselor so that the patient may receive comprehensive and quality medication-assisted treatment;

27.10.c.2. The name and contact information for the program physician and primary counselor;

27.10.c.3. The categories of records which may be shared;

27.10.c.4. A summary of treatment and goals, diagnoses and services to be received onsite or by referral;

27.10.c.5. Current medications being prescribed, including dosage, frequency and delivery;

27.10.c.6. Date and prescription history for medication-assisted treatment medications; and

27.10.c.7. Estimated length of treatment.

27.10.d. The coordination of care agreement will be provided in a form prescribed and made available by the secretary.

§69-12-28. Detoxification Program.

28.1. In addition to recovery-oriented medication-assisted treatment services, each OBMAT program shall provide both long-term and short-term detoxification recovery treatment services, either-onsite or by referral. If detoxification treatment is provided by referral, the program physician shall maintain documentation and communication with the referred detoxification program and keep such documentation in the patient's record.

28.2. All patients shall be offered the opportunity to participate in either a recovery-oriented long-term detoxification treatment services plan or a short-term detoxification services plan of varying durations. A detoxification treatment services plan shall be implemented only if agreed upon by the patient and deemed appropriate by the physician or physician extender through utilizing and applying established diagnostic criteria.

28.3. Exceptions to treatment guidelines or a patient's refusal to participate in the program shall be documented and tracked by the program.

§69-12-29. Administrative Withdrawal.

29.1. Administrative withdrawal is an involuntary withdrawal or administrative discharge from pharmacotherapy. The schedule of withdrawal may be brief; less than 30 days, if necessary.

29.2. 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.

29.3. On admission, the patient shall be given a copy of the administrative withdrawal policies and procedures and shall sign a statement acknowledging receipt of the same. The signed acknowledgement shall be maintained in the patient's record.

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

29.4.a. 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.

29.4.b. 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.

29.4.c. Incarceration or other confinement. The OBMAT program is responsible for working with law enforcement and corrections personnel in order to avoid mandatory withdrawal whenever possible.

29.5. 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.

29.6. Female patients shall have a negative pregnancy screen prior to the onset of administrative withdrawal.

29.7. The program shall have in place a detailed relapse prevention plan developed by the counselor in accordance with 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.

§69-12-30. Medical Withdrawal.

30.1. 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.

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

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

30.4. If the patient leaves the OBMAT program abruptly against medical advice, the program may re-admit the patient within 30 days without a formal reassessment procedure. However, the program must perform a physical assessment and a biopsychosocial assessment upon re-admission after 30 days of departure. The program shall document attempting to assist the patient with any issues which may have triggered his or her abrupt departure.

30.5. 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.

30.6. Female patients shall have a negative pregnancy screen prior to the onset of medically-supervised withdrawal.

30.7. The program shall have in place a detailed relapse prevention plan developed by the primary counselor in accordance with 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.

§69-12-31. Laboratory Services; Drug Screens.

31.1. 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.

31.2. Collection and Testing.

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

31.2.b. 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.

31.2.c. 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.

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

31.2.d.1. A patient receiving medication-assisted treatment medication maintenance services must have at least one random drug screen per month during the first year of treatment and random drug screens quarterly thereafter.

31.2.d.2. A patient undergoing medically-supervised or other types of withdrawal may be required to have more frequent collection and analysis of samples.

31.2.d.3. 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.

31.2.d.4. 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.

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

31.2.e.1. Buprenorphine, including in ratio to Norbuprenorphine, if clinically indicated;

31.2.e.2. Opiates including oxycodone at common levels of dosing;

31.2.e.3. Methadone, medication-assisted treatment medications or any other medication used by the program as an intervention for that patient;

31.2.e.4. Benzodiazepines;

31.2.e.5. Cocaine, including its metabolites, if clinically indicated;

31.2.e.6. Meth-amphetamine/amphetamines;

31.2.e.7. Tetrahydrocannabinol, delta-9-tetrahydrocannabinol, dronabinol, including its metabolites, if clinically indicated, or other similar substances; or

31.2.e.8. Other drugs or substances as determined by community standards, regional variation or clinical indication, such as carisoprodol or barbiturates.

31.2.f. 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.

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

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

31.2.i. 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 opiates.

31.2.j. The program physician shall thoroughly evaluate a positive toxicological screen for any potentially licit substance such as benzodiazepines, carisoprodol, barbiturates and amphetamines. The program shall verify with appropriate releases of information that:

31.2.j.1. The patient has been prescribed these medications by a licensed physician for a legitimate medical purpose; and

31.2.j.2. The prescribing physician is aware that the patient is enrolled in an OBMAT program.

31.2.k. If a patient refuses the release of information to contact his or her physician but 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.

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

31.3. Test Results.

31.3.a. Each positive drug test result after the first six months in an OBMAT program shall result in a re-evaluation of the patient's individual plan of care or treatment strategy and additional counseling as clinically indicated.

31.3.b. Positive screens for tetrahydrocannabinol, delta-9-tetrahydrocannabinol, dronabinol or similar substances shall be carefully clinically evaluated. Testing positive solely for any illicit drug shall not serve as a basis for discharge from the program. Each OBMAT shall develop policies and practices based on sound clinical judgment and individualized for each particular patient.

31.3.c. 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.

31.3.d. 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.

§69-12-32. Special Populations.

32.1. Concurrent Alcohol and Polysubstance Abuse.

32.1.a. Each OBMAT program shall address abuse of alcohol and other non-opioid substances within the context of the medication-assisted therapy effort.

32.1.b. 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 abuse.

32.1.c. 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.

32.1.d. 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. The program shall develop interagency agreements whenever possible to ensure smooth referral processes and interchange of information.

32.2. Behavioral Health Needs.

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

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

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

32.2.d. 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.

32.3. HIV Patients.

32.3.a. 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.

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

32.4. Chronic Pain Patients.

32.4.a. 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.

32.4.b. 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 take-home medication privileges and continuation in treatment.

32.5. Pregnant Patients.

32.5.a. 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.

32.5.b. The OBMAT program shall ensure referrals for every pregnant patient who does not have an obstetrical provider. Care for the pregnant patient with an opioid 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.

32.5.c. If not available elsewhere, the program shall offer basic instruction on maternal, physical and dietary care as part of its counseling services and document the provision of the services in the clinical record.

32.5.d. With respect to pharmacotherapy for opioid-addicted pregnant women in medication-assisted therapy, the program shall ensure that:

32.5.d.1. Maintenance medication levels shall be maintained at the lowest possible dosage level that is a medically appropriate therapeutic dose as determined by the medical director or program physician taking the pregnancy into account.

32.5.d.2. 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;

32.5.d.3. The dose is monitored carefully to supply increased or split dose if it becomes necessary; and

32.5.d.4. If a pregnant patient elects to withdraw from medication-assisted treatment against medical advice, withdrawal is not initiated by the program before 14 weeks and after 32 weeks gestation and require that withdrawal is supervised by a physician experienced in substance use disorder medicine.

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

32.5.e. If a pregnant patient is discharged, the OBMAT program shall identify the physician to whom the patient is being discharged and this information shall be retained in the clinical record.

32.5.f. The program shall offer onsite parenting education and training to all male and female patients who are parents or shall refer interested patients to alternative services for training. Any referral shall be documented in the patient's record.

§69-12-33. Advertisement Disclosure.

33.1. Any advertisement made by or on behalf of an OBMAT program through public media, such as a telephone directory, medical directory, newspaper or other periodical, outdoor advertising, radio or television, or through written or recorded communication, concerning the treatment of substance use disorder shall include the name of, at a minimum, one program physician responsible for the content of the advertisement.

§69-12-34. Registration Denials, Revocations and Suspensions.

34.1. Grounds for Denial, Revocation or Suspension.

34.1.a. 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.

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

34.1.b.1. The secretary makes a determination that fraud or other illegal action has been committed by any owner of the OBMAT program.

34.1.b.2. The OBMAT program has violated federal, state or local law relating to registration, building, health, fire protection, safety, sanitation or zoning;

34.1.b.3. The OBMAT program engages in practices that jeopardize the health, safety, welfare or clinical treatment of a patient;

34.1.b.4. The OBMAT program has failed or refused to submit reports or make records available as requested by the secretary;

34.1.b.5. AN OBMAT program has refused to provide access to its location or records as requested by the secretary;

34.1.b.6. AN OBMAT program's medical director has knowingly and intentionally misrepresented actions taken to correct a violation;

34.1.b.7. An owner or medical director of an OBMAT program concurrently operates an unregistered OBMAT program;

34.1.b.8. A program physician or any owner knowingly operates, owns or manages an unregistered OBMAT program that is required to be registered;

34.1.b.9. 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;

34.1.b.10. 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

34.1.b.11. The OBMAT program fails to have a medical director practicing at the program location as required by this rule.

34.2. Effect of Denial, Revocation or Suspension.

34.2.a. 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.

34.2.b. 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 from the date of the denial, revocation or suspension.

34.2.c. 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:

34.2.c.1. A closure notice to be mailed to all active patients meeting the guidelines set forth by its respective medical board;

34.2.c.2. The date the closure letter will be mailed to all active patients;

34.2.c.3. The number of active patients to receive the closure notice;

34.2.c.4. 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

34.2.c.5. Contact information the program has supplied to patients who may need help locating a new treating physician or program.

34.2.d. 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.

34.2.e. If the registration of an OBMAT program is revoked or suspended, no person named in the registering 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.

34.2.f. 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.

§69-12-35. Penalties and Equitable Relief.

35.1. Grounds for Penalties and Injunctions.

35.1.a. 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 law or rule shall be assessed a civil money penalty by the secretary in accordance with this rule.

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

35.1.c. 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.

35.1.d. 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.

35.1.e. 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.

35.1.f. 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.

35.1.g. 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.

35.2. The secretary may deny an OBMAT program's application for licensure or 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:

35.2.a. The secretary makes a determination that fraud or other illegal action has been committed;

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

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

352.d. 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

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

35.3. 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.

35.3.a. 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.

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

35.3.b.1. The gravity of the violation, including the probability that death or serious physical or emotional harm to a patient has resulted, or could have resulted, from the 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.

35.3.b.2. What actions, if any, the medical director or treating physician took to correct the violations;

35.3.b.3. Whether there were any previous violations at the OBMAT program; and

35.3.b.4. The financial benefits that the OBMAT program derived from committing or continuing to commit the violation.

35.4. 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.

§69-12-36. Administrative Due Process.

36.1. 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.

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

36.1.b. 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.

36.1.c. 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.

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

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

36.1.f. 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.

§69-12-37. Administrative Appeals and Judicial Review.

37.1. 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 to the Circuit Court of Kanawha County or in the county where the petitioner resides or does business.

37.1.a. 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.

37.1.b. 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.