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 **69-11**
RULE NAME **Medication- Assisted Treatment - Opioid Treatment Programs**

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: 69-11 Rule Id: 10219 Document: 28901

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FORM 10 -- LEGISLATIVE QUESTIONNAIRE (Page 1)

AGENCY **Health And Human Resources**
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RULE NAME **Medication- Assisted Treatment - Opioid Treatment Programs**

CITE AUTHORITY **§16-5Y-1 et seq**

PRIMARY CONTACT
M. Kathy Lawson
Building 6, Room S17-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?
An internal and external stakeholders meetings were held, the rule was listed on the OFLAC's website, emailed to stakeholders once published for public comments.

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.

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FORM 10 -- LEGISLATIVE QUESTIONNAIRE (Page 2)

AGENCY **Health And Human Resources**
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RULE NAME **Medication- Assisted Treatment - Opioid Treatment Programs**

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: 69-11 Rule Id: 10219 Document: 28901

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FORM 10 -- LEGISLATIVE QUESTIONNAIRE (Page 3)

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RULE TYPE **Legislative** AMENDMENT TO EXISTING RULE **No** TITLE-SERIES **69-11**
RULE NAME **Medication- Assisted Treatment - Opioid Treatment Programs**

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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RULE NAME **Medication- Assisted Treatment - Opioid Treatment Programs**

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

AGENCY **Health And Human Resources**
RULE TYPE **Legislative** AMENDMENT TO EXISTING RULE **No** TITLE-SERIES **69-11**
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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.

a separate fiscal note was created for the MAT-Office Based Medication. The estimated cost for this rule and the Office Based MAT is all included in the Office Based Medication fiscal note.

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)

AGENCY **Health And Human Resources**
RULE TYPE **Legislative** AMENDMENT TO EXISTING RULE **No** TITLE-SERIES **69-11**
RULE NAME **Medication- Assisted Treatment - Opioid Treatment Programs**

CITE AUTHORITY **§16-5Y-1 et seq**

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
PERSONAL SERVICES			
CURRENT EXPENSES			
REPAIRS AND ALTERATIONS			
ASSETS			
OTHER			
ESTIMATED TOTAL REVENUES	0.00		0.00

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 3)

AGENCY **Health And Human Resources**
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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.

a separate fiscal note was created for the MAT-Office Based Medication. The estimated cost for this rule and the Office Based MAT is all included in the Office Based Medication fiscal note.

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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CITE AUTHORITY **§16-5Y-1 et seq**

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. For rulemaking purposes it was determined that two rules were necessary to implement the program.

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

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

AGENCY **Health And Human Resources**
RULE TYPE **Legislative** AMENDMENT TO EXISTING RULE **No** TITLE-SERIES **69-11**
RULE NAME **Medication- Assisted Treatment - Opioid Treatment Programs**

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 opioid treatment program in clinics or facilities 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 opioid treatment programs. Facilities previously licensed and regulated under the opioid treatment program rule, 69 CSR 7, will be absorbed and thereafter licensed and regulated under W. Va. Code §§ 16-5Y-1, et seq. (2016) and this rule. The other type of medication-assisted treatment program authorized by SB 454 will be addressed in a separate rule, 69 CSR 12.

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 69
LEGISLATIVE RULE
DEPARTMENT OF HEALTH AND HUMAN RESOURCES

SERIES 11
MEDICATION-ASSISTED TREATMENT - OPIOID TREATMENT PROGRAMS

§69-11-1. General.

1.1. Scope. -- This legislative rule establishes standards and procedures for the licensure of opioid treatment programs (OTP) - medication-assisted treatment programs (MAT 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 sunset five years from the effective date.

1.6. Purpose. -- The purpose of this rule is to ensure that all West Virginia OTP/MAT 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~~6. Enforcement. -- This rule is enforced by the Secretary of the Department of Health and Human Resources or his or her designee.

1.~~8~~7. Adoption of Other Standards. -- In addition to the standards set forth in this rule, the provisions of the federal regulation entitled "Certification of Opioid Treatment Programs," 42 C.F.R § 8, Subpart B are hereby adopted in their entirety by reference.

§69-11-2. 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. Accreditation Body -- A body approved by the Substance Abuse and Mental Health Services Administration (SAMHSA) under 42 C.F.R § 8.3 to accredit opioid treatment programs that use medication-assisted treatment medications.

2.3. 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 MAT program.

2.4. Admissions Committee -- A designated group of individuals within the opioid treatment program consisting of the program administrator, or his or her designee; the medical director, or his or her designee; and a senior counselor, who is responsible for developing, implementing, administering and reviewing program admissions policies and procedures, granting any exceptions to program admissions policies and procedures, and tracking the outcomes of patient admissions and exceptions.

2.5. 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.

2.6. 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 MAT program facility; or the potential to undermine public confidence in the MAT program.

2.7. Advisory Council -- A designated group of individuals representing staff, patients and the community who are appointed to serve in a non-managerial advisory capacity to the governing body of an opioid treatment program.

2.8. Approved Authorities -- Programs or authorities that publish practice or treatment guidelines, standards or protocols that the secretary has approved for use by MAT programs. Approved authorities include the American Society of Addiction Medicine (ASAM); the Center for Substance Abuse Treatment (CSAT); the National Institute on Drug Abuse (NIDA); the American Association for the Treatment of Opioid Dependence (AATOD); the Federation of State Medical Boards; and any other program or authority approved by the secretary.

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

2.10. Certification -- The process by which SAMHSA determines that an opioid treatment program is qualified to provide medication-assisted treatment under federal opioid treatment standards.

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

2.13. 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.

2.14. 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 treatment plan of care.

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

2.16. 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.

2.17. 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.

2.18. 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.

2.19. 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.

2.20. Dispense -- The preparation and delivery of a medication-assisted treatment medication in an appropriately labeled and suitable container to a patient by a MAT 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.*

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

2.22. Diversion Control Plan -- A required plan developed and implemented by the MAT 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.

2.23. Federal Opioid Treatment Standards -- The standards established by the United States Department of Health and Human Services, 42 C.F.R. § 8.12, that are used to determine whether an opioid treatment program is qualified to engage in medication-assisted treatment and to determine the quantities of medication-assisted treatment medications which may be provided for unsupervised use.

2.24. For-Cause Inspection -- An inspection by any federal or state agency or accreditation body of a MAT 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.

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

2.26. Individualized Treatment Plan of Care or Treatment Plan -- 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 MAT program and which specifies the services to be provided and the frequency and schedule for their provision.

2.27. 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.

2.29. 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 treatment plan of care.

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

2.31. Interdisciplinary Team -- A representative of the clinical staff of the opioid treatment program, and the patient's primary substance abuse counselor, working in conjunction with the patient and family members, if desired by the patient, to develop, approve and coordinate the individualized treatment plan of care for the patient.

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

2.33. 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.

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

2.35. 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.

2.36. 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.

2.37. Medication Administration -- The direct application of medications by injection, inhalation, ingestion or any other means to a patient receiving services by persons legally permitted to administer medication-assisted treatment medications or the individual at the direction and in the presence of persons legally permitted to administer medication-assisted treatment medications.

2.38. 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.

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

2.40. Misuse or Non-Medical Use -- All uses of a prescription medication or substance other than those that are directed by a physician and used by an intended patient within the law and the requirements of good medical practice.

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

2.42. Opioid Treatment Services -- Treatment and services provided by a MAT 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.

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

2.44. Peer Review Committee -- A group of individuals designated by each opioid treatment program that is responsible for ensuring that the program follow approved national guidelines for opioid treatment facilities and programs; and shall include at least one physician licensed in the state of West Virginia.

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

2.46. 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.

2.47. Physician Assistant – A person who meets the qualifications set forth in W.Va. Code §30-3E-1, et seq. and is licensed pursuant to this article to practice medicine under supervision.

2.48. 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 MAT programs. Physician extenders approved for employment at a MAT program include advanced practice registered nurses and physician assistants. Registered nurses and licensed practical nurses are not authorized to act as physician extenders in a MAT program, although they may work within the program in other capacities.

2.49. Plan of Correction -- A written description of the actions the MAT 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.

2.50. 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.

2.51. Positive Drug Screen -- A test that results in the presence of any drug or substance listed in section 37.2.c. of this rule or any other drug or substance prohibited by the MAT program. The presence of medication which is part of the patient's individualized treatment plan of care shall not be considered a positive test. Any refusal to participate in a random drug test shall be considered a positive drug test.

2.52. Primary Counselor -- The individual designated by the MAT 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.

2.53. Program Physician --– Any physician designated and approved by the medical director to prescribe and monitor medication-assisted treatment for patients admitted to a MAT program. The medical director may serve as a program physician.

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

2.55. 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.

2.56. 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.

2.57. Take-Home Medication -- Any medication that is approved under federal standards to be dispensed to a patient for unsupervised use based upon the patient's demonstrated compliance with the individualized treatment plan of care. Each dose of take-home medication must be recommended by the primary counselor and be approved by the medical director or program physician. Take-home medication may not exceed the dosages permitted under federal law or recommended by approved national guidelines.

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

§69-11-3. State Opioid Treatment Authority.

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

§69-11-4. 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, licensing and inspection of MAT 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, regulations and standards regarding the licensure and oversight of MAT programs;

4.2.b. Accept applications and fees for licensure of MAT programs and conduct all necessary reviews, inspections or investigations in order to determine whether a license should be issued;

4.2.c. Issue initial, amended and renewed licenses to a MAT program upon a determination that the program is qualified;

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

4.2.e. Monitor the activities of all MAT 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 a MAT program;

4.2.h. Assist a MAT program in developing a plan of correction in order to correct any noted violations or deficiencies;

4.2.i. Deny, revoke or suspend the license of a MAT program in accordance with the applicable administrative proceedings; and

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

§69-11-5. 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 licensing requirements as specified by the secretary.

5.2. A MAT 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 license.

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

5.3.a. Treatment at the CSU is for no more than ~~7~~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.

§69-11-6. Licensure; Fees and Costs.

6.1. General Licensure Provisions.

6.1.a. No person, partnership, association or corporation may operate an opioid treatment program in the state of West Virginia without first obtaining a license pursuant to W. Va. Code § 16-5Y-3.

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

6.1.c. Each opioid treatment program location shall be licensed 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 opioid treatment program within the state of West Virginia, a program shall:

6.1.d.1. Hold current, valid certification from the SAMHSA;

6.1.d.2. 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;

6.1.d.3. Be approved by the state opioid treatment authority for operation of an opioid treatment program in this state;

6.1.d.4. Have been approved for a certificate of need pursuant to W. Va. Code § 16-5Y-12 and §§ 16-2D-1, *et seq.*; and

6.1.d.5. Obtain from the secretary a license authorizing the operation of the opioid treatment program and facility.

6.1.e. Each licensed opioid treatment program shall designate a medical. The medical director shall practice at the program and be responsible for the operation of the program in accordance with the requirements of this rule. An opioid treatment program may have two co-medical directors.

6.1.f. A license is not transferable or assignable.

6.1.g. If the ownership of an opioid treatment program changes, the new owner shall notify the secretary within 10 days and immediately apply for a new license. The new owner's application for a license is valid for three months from the date the application is received by the director.

6.1.h. The opioid treatment 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 license amendment.

6.1.i. If there is a change in the medical director, the opioid treatment program must comply with the provisions of section 6.1.e. and 8.4.f. of this rule.

6.1.j. If the opioid treatment 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 license expiring in less than one year may be issued.

6.1.k. A licensure survey may be conducted periodically during the course of the annual licensing term.

6.1.l. 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 a opioid treatment program without a license.

6.1.m. If the owner, medical director or other person in charge of a licensed opioid treatment program or of any other unlicensed practice, office or facility which the secretary has reasonable belief is being operated as a opioid treatment 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.n. If the secretary finds on the basis of an inspection that any person, partnership, association or corporation is operating as an opioid treatment program without a license, the opioid treatment program shall apply for a license within 10 days.

6.1.o. A opioid treatment program that fails to apply for a license is subject to the penalties established by section 38 of this rule.

6.1.p. An opioid treatment program shall surrender an expired, revoked or otherwise invalid license to the secretary upon written demand.

6.2. Licensure Application.

6.2.a. The program sponsor an opioid treatment program shall submit an application for an opioid treatment program license 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 license shall include and provide the documentation specified in W. Va. Code § 16-5Y-3 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 opioid treatment program, including identification of the governing body, advisory council and peer review committee.

6.3. License Fees and Inspection Costs.

6.3.a. All applicants for an initial, provisional or renewed license shall be accompanied by a non-refundable fee in the amount required by this rule. The annual renewal fee is based upon the average daily total census of the program. 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 license fee – $250;

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

6.3.a.3. Renewal license fee – fewer than 500 patients – $500 plus adjustment;

6.3.a.4. Renewal license fee – 500 to 1,000 patients – $1,000 plus adjustment; and

6.3.a.5. Renewal license fee – more than 1,000 patients – $1,500 plus adjustment.

6.3.b. An opioid treatment program shall pay for the cost of the initial inspection made by the secretary prior to issuance of a license. The cost of the initial inspection of an opioid treatment program is $400, plus the actual costs of the initial inspections and shall be billed by the secretary.

6.4. Initial Inspection and Issuance of License.

6.4.a. Upon receipt of an application for an initial license to operate as an opioid treatment program, the secretary or his or her designee 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 licensure.

6.4.b. If the inspection reveals violations, deficiencies or shortcomings on the part of the opioid treatment program or facility, 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 section 6.3.b., the secretary shall issue a license in one of three categories:

6.4.c.1. An initial license, 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 license shall be issued when an opioid treatment program seeks a renewal, or is an existing program as of the effective date of this rule and is seeking an initial license, and the opioid treatment 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 license shall be issued when an opioid treatment program is in substantial compliance with this rule. A renewal license shall expire not more than 12 months from the date of issuance.

6.4.d. A license is valid for the opioid treatment program named in the application and is not transferrable or assignable.

6.5. Denial of License.

6.5.a. The secretary may deny an application for an initial, provisional or renewal license if:

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

6.5.a.2. The opioid treatment 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 opioid treatment program will not permit an inspection or survey to proceed or will not permit in a timely manner access to records or information deemed relevant by the secretary;

6.5.a.4. The opioid treatment program has made misrepresentations in obtaining accreditation, certification or licensure;

6.5.a.5. The opioid treatment program has an owner, employee or associate who has received an ineligible employment fitness determination from the West Virginia Clearance for Access: Registry and Employment Screening unit of the West Virginia Department of Health and Human Resources and has not received a variance;

6.5.a.6. The opioid treatment program fails to have a medical director practicing at the program location; or

6.5.a.7. The opioid treatment 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 license, 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 section 37.2.c. of this rule, including notification to existing patients.

6.5.c. An opioid treatment program shall surrender an expired, revoked or otherwise invalid license to the secretary upon written demand.

6.5.d. An opioid treatment program may protest the denial of an initial, provisional or renewal license pursuant to the administrative procedures in section 39 of this rule.

6.6. Renewed or Amended Licenses.

26.6.a. The opioid treatment program shall submit an application for a license to the secretary not less than 60 days prior to the expiration of the current license. After the secretary receives a complete renewal application with the required fee, the existing license shall not expire until the new license 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 opioid treatment program and simultaneously shall apply for a license amendment.

§69-11-7. Annual Inspections.

7.1. All opioid treatment programs shall permit inspections and surveys by duly authorized employees of the secretary and any other state or federal governmental authority or accreditation or certification body. All inspections shall be conducted in accordance with applicable federal and state licensing, controlled substance and confidentiality laws.

7.2. Each opioid treatment program shall be accredited and registered as required by the federal agency responsible for oversight of opioid treatment programs. The opioid treatment program shall permit inspections and surveys by all accreditation agencies and shall submit a copy of the results of the accreditation survey to the secretary and to the state opioid treatment authority when they become available.

7.3. Each licensed opioid treatment program shall be inspected annually by employees or agents designated by the secretary. Inspections shall include, but are not limited to:

7.3.a. Observation of service delivery;

7.3.b. Review of life safety and environmental conditions;

7.3.c. Review of clinical and administrative records;

7.3.d. Interviews with staff, administrators and consenting patients; and

7.3.e. Review of staff education and training requirements.

7.4. The opioid treatment program shall comply with any reasonable requests from the secretary to have access to the service, staff, patients, records of the operation of the opioid treatment program, and records of services provided to patients. Patient records shall remain confidential unless otherwise permitted by law.

7.5. Within 30 working days of completion of an inspection, the secretary shall issue a report reflecting the findings of the investigation and conclusions as to whether the opioid treatment program passed the inspection. Deficiencies and shortcomings shall be noted in the report. The secretary may permit the opioid treatment program to develop a plan of correction.

7.6. Based upon an opioid treatment program's previous substantial compliance with this rule, the secretary may waive the requirement for an onsite inspection for issuance of an amended license.

§69-11-8. Administrative Organization and Management.

8.1. All employees and volunteers of an opioid treatment program shall be subject to the provisions of the West Virginia Clearance for Access: Registry and Employment Screening Act, W. Va. Code §§16-49-1 *et seq.*, and 69 CSR 10.

8.2. Each opioid treatment program shall identify a program administrator, medical director(s), program physician(s), counseling staff, a program sponsor, a governing body, an advisory council, and a peer review committee.

8.3. Program Administrator.

8.3.a. The administrator of the opioid treatment program shall have at a minimum a bachelor's degree in an appropriate area of study and a minimum of four 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 and a minimum of two years of experience in the fields of substance use disorders, behavioral health or health care administration; or eight years of experience in the fields of substance use disorders, behavioral health or health care administration.

8.3.b. The administrator is responsible for the day-to-day operation of the opioid treatment 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.

8.3.c. Duties of the administrator include:

8.3.c.1. Contributing to development of policies and procedures for operation of the program;

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

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

8.3c.4. Protection of patient rights;

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

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

8.3.c.7. Management of the facility budget;

8.3.c.8. Implementation of program policies and procedures and governing body policy; and

8.3.c.9. Communication with the medical director and governing body.

8.4. Medical Director.

8.4.a. Each opioid treatment program shall have a designated medical director. The medical director shall 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.

8.4.b. The medical director shall also meet the following requirements:

8.4.b.1. If the medical director prescribes a partial opioid agonist, he or she shall complete the requirements for the Drug Addiction Treatment Act of 2000; and

8.4.b.2. Demonstrate experience in substance use disorder treatment and medication-assisted treatment; or

8.4.b.3. Have a written plan to attain competence in substance use disorder treatment and medication-assisted treatment within a probationary time period as provided in section 8.4.c. herein.

8.4.c. The medical director may submit a written plan to attain competence in substance use disorder treatment and medication-assisted treatment to the state opioid treatment authority and state oversight authority for approval at least two weeks prior to employment at an opioid treatment program.

8.4.c.1. The time frame for completion of the plan may not exceed 12 months from the date of the appointment as medical director. The physician may work as a medical director during this probationary time period, subject to the supervision and reporting requirements of this rule.

8.4.c.2. During the probationary time period, the medical director shall be supervised on a regular basis by a physician licensed in this state with demonstrated competence in the field of substance use disorder and medication-assisted treatment.

8.4.c.3. Consultation with and supervision of a medical director during the probationary time period may be provided by telephone or video conferencing and shall be documented, initialed or verified, either in ink or electronically, and dated by both the supervising and supervised physicians.

8.4.c.4. The administrator of the opioid treatment program is responsible for maintaining documentation regarding the medical director's training and experience in a file which is current and readily available at all times. The administrator also is responsible for ensuring that the plan of development is completed within the approved time lines.

8.4.c.5. The state opioid treatment authority may request periodic documentation of continuing education during the initial probationary period and afterward if the documentation provided at the end of that period is not satisfactory.

8.4.d. The medical director shall maintain authority over the medical aspects of treatment offered by the opioid treatment program. The medical director is responsible for:

8.4.d.1. All medication-assisted treatment decisions;

8.4.d.2. Operation of all medical aspects of the treatment program;

8.4.d.3. Administration and supervision of all medical services;

8.4.d.4. Ensuring that the opioid treatment program is in compliance with all applicable federal, state and local laws, rules and regulations;

8.4.d.5. Obtaining and maintaining his or her continuing medical education in the field of substance use disorder treatment and medication-assisted treatment on a documented and ongoing basis;

8.4.d.6. Approving the basic and continuing educational programs of all staff employed by or volunteering at the opioid treatment program; and

8.4.d.7. Determining the ability of the program physicians and physician extenders to work independently within the applicable scope of practice.

8.4.e. A medical director, or his or her designee, shall practice 90 percent of the hours in which the opioid treatment program is dispensing or administering medications each week in order to ensure regulatory compliance and carry out those duties specifically assigned to the medical director. A medical director may delegate the day to day operation of the program to a program physician or physician extender as defined by this rule. An opioid treatment program may designate two co-medical directors.

8.4.f. 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. During the interim, not to exceed 60 days, another licensed physician shall be present during the dispensing or administering of medications and shall assume the duties of the medical director on a temporary basis until such time as 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.

8.5. Professional Medical Staff.

8.5.a. The opioid treatment 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. The opioid treatment program may only employ advance practice registered nurses and physician's assistants as physician extenders.

8.5.b. All physicians and physician extenders employed by the opioid treatment program shall be actively licensed in West Virginia and shall have:

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

8.5.b.2. Meet the following requirements:

8.5.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

8.5.b.2.B. Complete the certification, training programs or continuing education programs recommended and approved by the medical director of the opioid treatment program.

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

8.5.d. During all hours of operation every opioid treatment program shall have present and on duty at the program at least one of the following actively-licensed health care professionals:

8.5.d.1. Program physician;

8.5.d.2. Physician extender;

8.5.d.3. Registered nurse.

8.5.e. Plans of Education.

8.5.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.

8.5.e.2. The program administrator of the opioid treatment program 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.

8.5.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 sign an affidavit that verifies and documents an employee's successful completion of a plan of education and the medical director's approval for that person to provide services on an independent basis within his or her scope of practice.

8.6. Counseling Staff.

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

8.6.b. The opioid treatment program shall assign a primary counselor to each patient to contribute to the appropriate treatment plan for the patient and to monitor patient progress.

8.6.c. Each opioid treatment program's policies and procedures shall establish ratios of primary counselors to persons served that are adequate to allow sessions to occur as mandated and that will allow persons served access to a primary counselor, either on site or by referral, but there shall be at least one counselor for every 50 patients in the program.

8.6.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.

8.6.e. The administrator of the opioid treatment program is responsible for documentation of supervision, which shall be available for review at all times.

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

8.6.f.1. Substance use disorder overview;

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

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

8.6.f.4. Drug screening and observation of sample collection;

8.6.f.5. Program policy and procedure;

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

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

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

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

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

8.6.g. An experienced counselor newly employed from another MAT program may be exempt from the mandatory initial training required by this rule, if the program is able to verify and document that mandatory initial training has been received within the previous two years. The administrator of the opioid treatment program shall document in the personnel file any exemption granted and the basis for the exemption.

8.6.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.

8.7. Unlicensed Clinical Staff and Volunteers.

8.7.a. An opioid treatment 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.

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

8.8. Program Sponsor.

8.8.a. The program sponsor is the person named in the application for certification and licensure of an opioid treatment program. The program sponsor shall agree on behalf of the opioid treatment program to adhere to all requirements set forth in federal or state laws, rules or regulations regarding the use of medication-assisted treatment medications in the treatment of substance use disorder.

8.8.b. The program sponsor is responsible for the general establishment, certification, licensure and operation of the opioid treatment program.

8.8.c. The program sponsor need not be a licensed physician. If the program sponsor is not a licensed physician, the opioid treatment program shall employ a licensed physician for the position of medical director.

8.9. Governing Body.

8.9.a. The governing body is one or more persons identified by the program sponsor as being legally responsible for the operation of the opioid treatment program. A governing body may be a board, a single entity or owner or a partnership.

8.9.b. The governing body is responsible for designation of an administrator of the opioid treatment program.

8.10. Advisory Council.

8.10.a. Each opioid treatment program shall have an advisory council comprised of a designated group of no fewer than three individuals to serve in a non-managerial advisory capacity to the administrator and governing body. The advisory council shall consist of individuals served by the program, at least one staff representative and interested community representatives or advocates.

8.10.b. The advisory council shall not have access to any patient identifying information. The staff liaison to the administrator is responsible for ensuring that no identifying information is provided to the advisory council.

8.10.c. The advisory council shall meet at least quarterly during hours other than when patients are present in the building and shall:

8.10.c.1. Review program policies and procedures annually or as proposed for revision;

8.10.c.2. Review incidents and grievances quarterly;

8.10.c.3. Review administrative discharges quarterly;

8.10.c.4. Make recommendations for operational changes or improvements;

8.10.c.5. Be trained in patient confidentiality regulations;

8.10.c.6. Keep records of meetings and describe business conducted, members present and members absent; and

8.10.c.7. Work to assist the opioid treatment program in identifying, addressing and resolving community problems such as traffic, patient loitering and medication diversion so as to ensure the program operations do not adversely affect community life.

8.11. Peer Review Committee.

8.11.a. Each opioid treatment program shall establish a peer review committee to review whether the program is following protocols and guidelines from approved authorities. At least one member of the peer review committee shall be a physician with documented training and experience in the field of substance use disorders and medication-assisted treatment.

8.11.b. The peer review committee shall evaluate the opioid treatment program at least once every four months to ensure that it follows treatment guidelines from approved authorities. The review shall consist of a survey of no less than 20 randomly chosen active clinical files. The survey shall be documented on a form approved by the secretary.

8.11.c. The peer review committee shall review the selected case files in order to determine whether the opioid treatment program is in compliance with all applicable policies and procedures regarding patient intake, assessment, treatment, detoxification, maintenance and recovery.

8.11.d. The peer review committee shall make a determination of the effectiveness of existing policies and procedures and make recommendations to the governing body for any changes that should be made. The peer review committee may also make recommendations to the governing body for updates to policies and procedures in accordance with updated and approved national standards and other factors deemed relevant by the peer review committee.

8.11.e. The results of each peer review committee evaluation shall be included in a report that is submitted to the secretary on a quarterly basis.

8.12. Admissions Committee.

8.12.a. Each opioid treatment program shall have an admissions committee, consisting of the program administrator or his or her designee, the medical director or his or her designee, and a senior counselor.

8.12.b. Exceptions to the general admissions criteria shall be documented and approved by the admissions committee.

8.12.c. Exceptions to the admissions criteria include, but are not limited to:

8.12.c.1. Circumstances where a physician did not observe or interview the patient within three days of admission; and

8.12.c.2. Circumstances where a physician did not observe or interview the patient at all.

8.12.d. Patients admitted to an opioid treatment program as an exception to the general admissions criteria shall be monitored and tracked annually for relevant clinical patterns. The results of the tracking shall be submitted to the state opioid treatment authority or other monitoring body upon request.

§69-11-9 Environment and Operations.

9.1. Service Operation Schedule.

9.1.a. Except as otherwise provided herein, all opioid treatment programs shall be open for business seven days-per-week. The program may be closed for eight holidays and two training days per year.

9.1.b. Opioid treatment programs may close on Sundays if the following criteria are met:

9.1.b.1. The program develops and implements policies and procedures that address recently inducted patients receiving services, patients not currently on a stable dose of medication, patients that present as non-compliant with program policies and procedures and their individualized treatment plan of care, and individuals who previously picked up take-home medications on Sundays, security of take-home medication doses, and health and safety of individuals receiving services;

9.1.b.2. The program receives prior approval from the state opioid treatment authority for Sunday closings;

9.1.b.3. Once approved, the program shall notify individuals receiving services in writing at least 30 days in advance of their intent to close on Sunday. The notice shall address the risks to the patients the security of take-home medications. All individuals shall receive an orientation addressing take-home policies and procedures, and this orientation shall be documented in the individual's record prior to receiving take-home medications; and

9.1.b.4. The program shall establish procedures for emergency access to dosing information 24 hours a day, seven days-per-week. This information may be provided via an

answering service or other electronic measures. Information needed includes the patient's last dosing time and date, and dose.

9.1.c. Medication dispensing hours shall include at least two hours each day of operation outside normal working hours, i.e., before 9:00 a.m. and after 5:00 p.m. The state opioid treatment authority may approve an alternate schedule if that schedule meets the needs of the population served by the program.

9.2. Payments for services rendered may be made either by West Virginia Medicaid, private insurance, or by cash as described in 9.2.d.

9.2.a. The opioid treatment program shall be eligible for, and not prohibited from, enrollment with West Virginia Medicaid and other private insurance.

9.2.b. Prior to directly billing a patient for any opioid treatment, an opioid treatment program must receive either a rejection of prior authorization, or rejection of a submitted claim or a written denial from a patient's insurer or West Virginia Medicaid denying coverage for such treatment.

9.2.c. The opioid treatment program shall document in the patient's record any rejection of prior authorization, rejection of a submitted claim for written denial from a patient's insurer or West Virginia Medicaid denying coverage for opioid treatment. The opioid treatment 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 or West Virginia Medicaid. When any instance described in this section regarding direct billing and acceptance of cash payments from a patient occurs, the opioid treatment program shall clearly document in the patient's record the rationale and medical necessity for acceptance into the program.

9.2.d. The opioid treatment program may directly bill and accept cash payments from a patient only after the requirements of sections 9.2.a., 9.2.b. and 9.2.c. herein, have been fulfilled and documented.

9.2.e. At the option of the opioid treatment program, treatment may commence prior to billing.

9.3. Each opioid treatment program facility shall have:

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

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

9.3.c. A secure room and lockable equipment for patient records;

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

9.3.e. Sanitary, secure and private dosing areas;

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

9.3.g. Adequate parking areas for the expected flow of traffic.

9.4. The opioid treatment 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.

9.5. Infection Control.

9.5.a. The opioid treatment 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.

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

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

9.5.d. The opioid treatment 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.

9.6. Community Relations.

9.6.a. The program shall develop and implement policies and procedures for community relations to include the following:

9.6.a.1. A program shall be responsible for ensuring that its patients do not cause unnecessary disruption to the community or act in a manner that would constitute disorderly conduct or harassment by loitering on the program's property;

9.6.a.2. Each program shall provide the state opioid treatment authority and state oversight authority, when requested, with a specific plan describing the efforts it will make to avoid disruption of the community by its patients and the actions it will take to assure responsiveness to community needs. This plan shall, at a minimum:

9.6.a.2.A. Identify program personnel who will function as community relations coordinators and define the goals and procedures of the community relations plan;

9.6.a.2.B. Include policies and procedures to resolve community problems, including, but not limited to, patient loitering and medication diversion, to ensure that program operations do not affect community life adversely; and

9.6.a.2.C. Include policies and procedures for soliciting patient and community ideas about medication-assisted treatment, addressing community concerns and the program's presence in the community.

9.6.a.3. Each program shall document community relations efforts and community contacts, including the resolution of issues identified by community members or patients.

9.7. Emergency Preparedness. -- The program's emergency preparedness plan shall include, but not be limited to, the provision of the continuation of medication-assisted treatment in the event of an emergency or natural disaster.

§69-11-10. Facility Construction and Renovations; Life Safety Policies and Procedures

10.1. Before extensive construction or renovation of a MAT program facility begins, the program shall submit to the secretary for approval a complete set of the plans for the project, which includes the drawings and specifications for the architectural, structural and mechanical design and work.

10.2. The secretary shall advise the program whether approval has been granted. In the event the plans for the project are not approved, the secretary shall set forth in writing the reasons for the disapproval and provide the program the opportunity to correct any deficiencies. Extensive construction or renovation of a facility may not begin until the secretary has issued final approval of the plans.

10.3. All MAT program facilities shall comply with the current standards of the Americans with Disabilities Act of 1990, as amended.

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

10.5. Life Safety Policies and Procedures.

10.5.a. Each MAT program shall develop, implement and maintain policies and procedures regarding the appropriate and safe administration of medications and other medical treatment. The policies and procedures shall:

10.5.a.1. Ensure that the correct dose of medication is administered and that appropriate actions are taken if a mistake is made, including a mechanism for reporting unusual incidents to appropriate program staff;

10.5.a.2. Establish a current plan of emergency administration of medications in case the program must be closed temporarily, including how patients will be informed of these emergency arrangements;

10.5.a.3. Ensure that there is appropriately trained staff on duty at all times who are proficient in cardiopulmonary resuscitation and reversal of opiate overdose; and

10.5.a.4. Ensure that each medication-assisted treatment medication used by the MAT program is administered and dispensed, if applicable, in accordance with its approved product labeling. Dosing, dispensing and administration decisions shall be made by a program physician familiar with the most up-to-date product labeling. These procedures must ensure that any significant deviations from the approved labeling, including deviations with regard to dose frequency, or the conditions of use described in the approved labeling, are specifically documented in the patient's record.

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

10.6.a. Provide 24 hour, seven day-per-week access to designated program staff, as described in section 9.1.b.4., so that patient emergencies may be immediately addressed and dosage levels verified;

10.6.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;

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

10.6.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.

§69-11-11. For-Cause Inspections; Complaints.

11.1. The secretary may at any time conduct unannounced inspections of a MAT 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.

11.2. Any person may file a complaint with the secretary alleging violation of applicable laws, rules or policies by a MAT program. A complaint shall identify the MAT program by name and state the nature of the complaint.

11.3. At the time of any on-site investigation activities, the investigator shall notify the program sponsor or administrator at opioid treatment programs and medical director of the general reason for the investigation.

11.4. Within 15 working days of the investigation, the secretary shall provide to the program sponsor or administrator 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.

11.5. The secretary may permit the MAT program to develop a plan of correction to address any noted violations or deficiencies. The secretary may advise and consult with the program sponsor, administrator or other personnel with the opioid treatment programs in order to assist with a plan of correction.

11.6. The secretary may impose a civil money penalty, suspend or revoke a license 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 MAT 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.

11.7. 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.

11.8. 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.

11.9. 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.

11.10. The secretary may suspend or revoke a license of a MAT program for violating the prohibitions of this section.

§69-11-12. Plans of Correction.

12.1. Within 10 working days after receipt of the inspection report, the program sponsor or administrator shall submit to the secretary for approval a written plan to correct all deficiencies that are in violation of this rule, unless a waiver or variance is requested by the MAT program and granted by the secretary. The plan of correction shall specify:

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

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

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

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

12.3. The secretary shall state the reasons for rejection or modification of any plan of correction.

12.4. The program sponsor or administrator shall submit a revised plan of correction to the secretary within 10 working days of receipt of a rejection by the secretary.

12.5. The MAT program shall immediately correct a violation that severely risks the health or safety of a patient or other persons.

12.6. The secretary shall determine if satisfactory corrections have been made and advise the program sponsor of any compliance or continued deficiencies in writing.

12.7. The secretary may provide consultation to the applicant or licensee in obtaining compliance with this rule.

§69-11-13. Waivers and Variances.

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

13.1.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

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

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

13.2. Any waiver or variance approved by the secretary shall be in writing.

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

§69-11-14. Reports and Records.

14.1. Inspection Reports and Records.

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

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

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

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

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

14.1.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.

14.2. Statistical Reports and Records.

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

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

14.2.a.2. The number of patients who have been continually receiving medication-assisted treatment in excess of two years, including the total number of months of treatment for each of these patients;

14.2.a.3. The state of residency of each patient;

14.2.a.4. The number of patients discharged from the program;

14.2.a.5. The total months the patients were in the treatment program prior to discharge;

14.2.a.6. Whether the discharge was for:

14.2.a.6.A. Termination or disqualification;

14.2.a.6.B. Voluntary withdrawal prior to completion of all requirements of detoxification as determined by the MAT program;

14.2.a.6.C. Successful completion of the individualized treatment plan of care; or

14.2.a.6.D. An unexplained reason;

14.2.a.7. Statistics demonstrating program compliance with the random drug testing requirements of section 34.2.d.1. of this rule;

14.2.a.8. Confirmation that the random drug tests were truly random in regard to both the patients tested and to the times random drug tests were administered by lottery or some other objective standard so as not to prejudice or protect any particular patient;

14.2.a.9. Confirmation that the random drug tests were performed in accordance with the requirements in section 34.2.d.1.;

14.2.a.10. The total number tested and the number of positive results; and

14.2.a.11. The number of expulsions from the MAT program.

14.3. Incident Reporting and Adverse Events.

14.3.a. Each MAT program shall develop and implement policies and procedures for comprehensively documenting, investigating, taking corrective action and tracking instances of adverse events or incidents.

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

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

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

14.3.b.3. The potential to undermine public confidence in the MAT program.

14.3.c. Incidents or adverse events may include:

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

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

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

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

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

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

14.3.c.7. Medication diversion;

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

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

14.3.c.10. Violence;

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

14.3.c.12. Incident with potential for negative community reaction or which the program director or medical director believes may lead to community concern.

14.3.d. Incidents or adverse events shall be reviewed on a quarterly basis by the advisory council which may choose to make recommendations to the administration, governing body or owner or owners regarding the improvements in the process to prevent further incidents.

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

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

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

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

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

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

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

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

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

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

14.3.g. The MAT program shall report any 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.

14.3.h. A root-cause analysis shall be done for each incident or adverse effect.

§69-11-15. Staff Training and Credentialing

15.1. Each MAT program shall ensure that all doctors, physician assistants, advance practice 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.

15.2. Clinical staff of a MAT program may include employees, independent contractors or both. The MAT 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.

15.3. Each MAT 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.

15.4. Within 10 days of the date any new clinical staff member or volunteer begins working at a MAT 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 beginning work at the program.

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

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

15.5.b. Documentation of the date of employment;

15.5.c. Identifying information and emergency contacts;

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

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

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

15.5.g. Detailed job descriptions; and

15.5.h. Evidence that each opioid treatment program employee, independent contractor or volunteer has received an eligibility fitness determination or variance from the West Virginia Clearance for Access: Registry and Employment Screening Unit of the Department of Health and Human Resources.

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

§69-11-16. Risk Management.

16.1. Each MAT program shall:

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

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

16.1.c. Obtain voluntary, written, informed consent to the prescribed therapy from each patient before dosing begins;

16.1.d. Inform each patient that:

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

16.1.d.2. Detoxification from opioids or other substances is a treatment alternative to an ongoing, recovery-oriented plan of care, and that under the detoxification protocol:

16.1.d.2.A. The strength of maintenance doses of medication-assisted treatment medications should decrease over time, as clinically appropriate; and

16.1.d.2.B. The participant is required to work toward a recovery-oriented lifestyle.

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

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

16.2. Each MAT 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.

16.3. Each MAT 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.

16.4. Each MAT program shall:

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

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

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

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

§69-11-17. Medication Security, Storage, Administration and Documentation.

17.1. Medication Security.

17.1.a. Each MAT program shall develop and implement policies and procedures that comply with all relevant federal and state laws, rules and regulations regarding the storage and management of medications kept at the facility, if applicable, including measures that:

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

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

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

17.1.b. Each MAT program shall develop and implement policies and procedures that comply with all relevant federal and state laws, rules and regulations regarding the storage, management and disbursement of take-home medications. The policies and procedures shall include measures that:

17.1.b.1. Ensure responsible handling and secure storage of take-home medications in child-proof and tamper-resistant containers;

17.1.b.2. Require each patient to demonstrate the ability to provide secure storage for take-home medications; and

17.1.b.3. Inform patients of their rights and responsibilities in writing to ensure the security of medication-assisted treatment medications.

17.1.c. The MAT program shall establish and implement policies and procedures for monitoring medications to prevent diversion. The policies and procedures shall include random call backs of individuals with more than one week of take-home dosage, required program attendance, random drug screens and random medication counts.

17.1.c.1. All patients shall undergo random drug screens, as required in section 34.2.d.1.

17.1.c.2. Frequency of call backs, random drug screens and medication counts shall be individually determined for each patient by the interdisciplinary team.

17.2. Each MAT program shall have policies and procedures consistent with the DEA's statutes and regulations regarding the storage, administration and documentation of medications, if applicable.

17.3. Administration of Medications.

17.3.a. The policies and procedures of a MAT program shall require all personnel dispensing medication-assisted treatment medications to adhere to federal and state laws, rules and regulations and to protocols and guidelines from approved authorities.

17.3.b. Each MAT program shall calibrate medication dispensing instruments consistent with the manufacturer's recommendations to ensure accurate patient dosing, if applicable, and substance tracking.

17.3.c. Each MAT program shall ensure that medication-assisted treatment medications are administered or dispensed only by a practitioner who is qualified to do so by his or her scope of practice; is licensed under the appropriate state law; and is registered under the appropriate state and federal laws to administer or dispense medication-assisted treatment medications.

17.3.d. Only the program physician may order medication and dosages; only the program physician may approve changes in dosage or take-home privileges.

17.3.e. The patient shall be advised of any change in medication dosage or administration.

17.4. Each MAT program shall maintain current procedures adequate to ensure that all medication-assisted treatment medication is administered or dispensed in accordance with its approved product labeling. Dosing and administration decisions shall be made by a program physician familiar with the most up-to-date product labeling. The procedures must ensure that any significant deviations from the approved labeling, including deviations with regard to dose frequency or the conditions of use described in the approved labeling, are specifically documented in the patient's record.

17.5. Documentation.

17.5.a. Each MAT program is responsible for proper documentation of medications stored, administered or dispensed.

17.5.b. Documentation of medication administered or dispensed requires, at a minimum, the following:

17.5.b.1. The signature or initials of the qualified person administering or dispensing medication;

17.5.b.2. The exact number of milligrams of the substance administered or dispensed; and

17.5.b.3. The daily totals of the substance administered or dispensed.

17.5.c. Each dosage administered or dispensed, prepared or received shall be recorded and accounted for by written signed notation in a manner that creates a perpetual and accurate inventory of all medication-assisted treatment medications in stock at all times.

17.5.d. The medication shall be totaled in milligrams daily.

17.5.e. Each medication order and dosage change shall be written on an acceptable order sheet and signed and dated by only the program physician. If initials are used, the full signature of the qualified person administering or dispensing shall appear at the end of each page of the medication sheet.

17.5.f. At the time any medication is administered or dispensed, each dose shall be recorded on an administration sheet; in the patient's individual medication dose history included in the patient's individualized treatment plan of care and patient chart; and in the inventory control program used by the facility to monitor and ensure an accurate inventory of all medication on the premises.

17.6. Patient Meetings and Screenings.

17.6.a. Each MAT program shall have the capability of obtaining medication levels clinically indicated, through random drug screening of all patients and at least on a required monthly basis.

17.6.b. The program physician or physician extender shall meet with each patient prior to prescribing the initial dose of medication and perform an initial medical and drug screening. All patients must undergo comprehensive monthly drug screenings, which shall include testing for controlled substances, including the substance prescribed by the program.

17.6.c. During the first month of treatment, the program physician or physician extender shall meet individually with the patient at least once per week to discuss dosage and symptoms. The weekly meetings shall occur until the dosage is considered stable by the patient and the physician. Thereafter, the program physician or approved physician extender shall meet with the patient at least annually to discuss the possibility of consideration of titration of medications.

17.6.e. All meetings, test results and discussions shall be documented in the patient's chart and individualized treatment plan of care, along with the individual's decision whether to continue medications at current levels or to begin a slow titration process.

17.7. Approved Medications.

17.7.a. A MAT 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.

17.7.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 MAT program is responsible for remaining in conformity with practice guidelines as issued or approved by the state opioid treatment authority.

17.8. Dosage.

17.8.a. Each MAT program shall have a procedure through which the patient can discuss dosages of medication he or she receives with appropriate staff members regularly and upon request. This procedure shall be clearly described to the patient during orientation, upon admission and at least annually thereafter. A written explanation of the dosing procedures shall be initialed and dated by the patient and maintained in the patient chart and individualized treatment plan of care.

17.8.b. The maintenance dose of medication prescribed for a patient shall be individually determined in accordance with federal law and with guidelines and protocols from approved authorities. 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, in accordance with the approved guidelines and protocols.

17.8.c. The initial full-day dose of medication shall be based on the physician's evaluation of the history and condition of the patient and made in accordance with established guidelines. Doses shall be sufficient to produce the desired response in the patient for the desired duration of time, with allowance for a margin of effectiveness and safety.

17.8.d. Dosage administration and adjustment shall be guided by outcomes criteria, which shall be documented and include:

17.8.d.1. Cessation of withdrawal symptoms;

17.8.d.2. Cessation of illicit opioid use as documented by negative drug tests and reduction of drug-seeking behavior;

17.8.d.3. Establishment of a blockade dose of an agonist;

17.8.d.4. Absence of problematic craving as documented by a subjective report and clinical observations; and

17.8.d.5. Absence of signs and symptoms of too large a dose of a medication-assisted treatment medication after an interval adequate for the patient to develop complete tolerance to the blocking dose.

17.8.e. Dosages of medication should be adjusted so that they shall ultimately:

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

17.8.e.2. Reduce or eliminate drug cravings; and

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

17.8.f. The ordering physician shall ensure that the justification for daily doses above 100 milligrams is documented in the patient's record.

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

17.10. 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 MAT program's license number; and the prescribing program physician's regular DEA number and DATA 2000 identification number, if applicable.

17.11. The program shall check the Controlled Substances Monitoring Program database upon admission of the patient, at least every 90 days to determine if controlled substances other than those prescribed medication-assisted treatment medications are being prescribed for the patient, and at each patient's physical assessment. The patient's record shall include documentation of the check of the Controlled Substances Monitoring Program database and the date upon which it occurred.

17.12. Methadone.

17.12.a. Methadone shall be administered only in oral form and shall be formulated in such a way as to reduce its potential for parenteral abuse and diversion.

17.12.b. For each new patient enrolled in an opioid treatment program, the initial dose of methadone shall not exceed 30 milligrams. The total dose for the first day shall not exceed 40 milligrams, unless the program physician documents in the patient's record that 40 milligrams did not suppress opiate abstinence symptoms after a three-hour period of observation.

17.12.c. The total dose of methadone and the interval between doses may be adjusted for patients documented to have atypical metabolic patterns or those prescribed other concurrent medications which alter rates of methadone metabolism.

§69-11-18. Continuous Quality Improvement Policies, Diversion Control Plan.

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

18.1.a. Regular and continuous staff education;

18.1.b. An annual review, in consultation with the advisory council and the peer review committee of program policies and procedures;

18.1.c. 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;

18.1.d. Consideration of ongoing input into program policies and procedures by patients regarding community concerns;

18.1.e. Development and implementation of annual patient satisfaction surveys that include a review of patient satisfaction;

18.1.f. ~~Adherence to universal infection control precautions promulgated by the Center for Disease Control;~~

18.1.~~g~~f. An ongoing assessment, measurement and monitoring of patient outcomes, treatment outcomes and the various processes including, but not limited to:

18.1.~~g~~f.1. Reduction or elimination of the patient's use of illicit opioids, illicit drugs and the problematic use of licit drugs;

18.1.~~g~~f.2. Reduction or elimination of associated criminal activities;

18.1.~~g~~f.3. Reduction of the patient's behaviors contributing to the spread of infectious diseases;

18.1.~~g~~f.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

18.1.~~g~~f.5. Assessment of medication-related issues, including, but not limited to, take-home procedures, security, inventory and dosage issues.

18.2. The MAT program shall annually collect outcome measurements and results of patient satisfaction surveys. The governing body and the advisory council shall review the results and submit the reports to the state authority.

18.3. Each MAT program shall participate in additional quality improvement outcome studies as directed by the designated state oversight authority.

18.4. A MAT program shall maintain a current "Diversion Control Plan" (DCP) as part of its quality assurance programs that contains specific measures to reduce the possibility of diversion of controlled substances from legitimate treatment use. The DCP shall assign specific responsibility to the medical and administrative staff of the MAT program for carrying out the diversion control measures and functions described in the DCP.

18.4.a. The DCP shall be reviewed and approved by the governing body, advisory council and peer review council and the state opioid treatment authority.

18.4.b. The DCP shall minimize the diversion of methadone, in all forms, or other medication-assisted treatment medications to illicit use. The plan shall include:

18.4.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

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

18.4.c. The DCP 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.

18.4.c.1. Each patient receiving three or more consecutive doses of unsupervised or take-home medications shall be called back randomly within the 90-day period immediately following the previous call-back.

18.4.c.2. Upon call-back, a patient shall report to the program within 24 hours of notification, or sooner if directed by the physician, with all take-home medications. The quantity and integrity of packaging shall be verified for all doses. If a take-home dose shows evidence of tampering, the program shall impose uniform sanctions for violating take-home policies, including sanctions for a patient's tampering with a take-home dose, if applicable.

18.4.c.3. Patients shall be informed of consequences for violating the take-home policy.

18.4.c.4. The program shall maintain individual call-back results in the patient record and individualized treatment plan.

§69-11-19. Patient Rights.

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

19.1.a. To be informed, both verbally and in writing, of program rules and regulations and patient's 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 that changes in the rights and responsibilities occur;

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

19.1.c. To receive an individualized treatment plan of care developed according to guidelines established by a nationally recognized authority and approved by the secretary. The individualized treatment plan of care shall include a recovery model, shall be reviewed periodically by the interdisciplinary team, and shall be maintained in the patient's chart;

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

19.1.e. To be informed that random drug testing of all patients shall be conducted during the course of treatment as required by section 34.2.d.1., 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;

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

19.1.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;

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

19.1.i. To be given a copy of the initial assessment, written acceptance into the program; or, in the case of denial of admission, a full explanation as to the basis of the denial, and a referral to another MAT program based upon the results of the initial assessment;

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

19.1.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;

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

19.1.m. To 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

19.1.n. The patient, as well as the staff and the public, are entitled to protection from other patients who act out. 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.

19.2. The MAT 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:

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

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

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

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

19.3. 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.

§69-11-20. Patient Records.

20.1. Each MAT 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 opioid medications approved for use in treatment of substance use disorder.

20.2. 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.

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

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

20.5. 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.

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

20.7. Individual patient records shall contain:

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

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

20.7.c. An initial assessment report;

20.7.d. A narrative biopsychosocial history ~~completed within 30 days of the patient's admission~~;

20.7.e. All physical and biopsychosocial assessments ~~completed every 90 days~~;

20.7.f. Medical reports including results of the physical assessment; family medical history; review of systems; laboratory reports, including results of required drug screens; results

obtained from the Controlled Substances Monitoring Program database; and progress notes, including documentation of current dose and other dosage data;

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

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

20.7.i. The initial and post-admission individualized treatment plans of care, and any amendments, reviews or changes to the plans;

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

20.7.k. A written report of the treatment process; factors considered in decisions impacting patient treatment, e.g., take-home medication privileges, changes in counseling sessions, changes in frequency of drug screens; results from the Controlled Substances Monitoring Program database; documentation of whether the patient was offered or accepted a detoxification treatment plan option; and any other significant change in treatment, both positive and negative;

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

20.7.m. Documentation that the MAT program made a good faith effort to review whether the patient is enrolled in any other MAT program;

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

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

20.7.p. 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 treatment plan of care; a copy of the patient's goals; and documentation that each of these items was discussed with the patient;

20.7.q. Consent forms, releases of information, prescription documentation, travel, employment and "take-home" documentation; and

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

20.8. Documentation of Patient Contact.

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

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

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

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

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

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

20.8.b. Each entry shall be completed by the next business day following the contact and shall be clearly dated and initialed or signed by the staff person involved.

20.9. A MAT program that closes or discontinues MAT program services shall arrange for continued management of all patient records as follows:

20.9.a. The owner of the MAT program shall notify the secretary or his or her designee 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.

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

20.9.b.1. The owner of the MAT program shall continue to manage the records and give written assurance to the secretary or his or her designee that it will respond to authorized requests for copies of patient records within 10 working days.

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

20.9.b.3. The owner of the MAT program will enter into an agreement with another MAT program to store and manage the patient records.

§69-11-21. Pre-Admission Assessment; Admission Criteria and Admission Process.

21.1. Each MAT 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.

21.2. Any individual seeking admittance to the MAT program shall undergo a pre-admission initial assessment in order to determine whether the person meets the criteria for admission to a MAT program. The initial assessment, consisting of a physical assessment and an intake screening, shall be conducted by the medical director, an approved program physician or a supervised physician extender. The initial assessment shall focus on the individual'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.

21.3. The initial physical assessment shall include documentation of:

21.3.a. A brief physical examination;

21.3.b. The patient's immediately 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;

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

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

21.3.e. Determination of current substance use disorder;

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

21.3.g. An initial drug test and full drug screen to identify whether the patient is using other drugs, including opiates, methadone, buprenorphine, amphetamines, cocaine, barbiturates, benzodiazepines, marijuana or other drugs or substances as determined by community standards, regional variation or clinical indication, such as carispodol; to determine whether the individual has a substance use disorder from another MAT program;

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

21.3.i. An inquiry whether the patient is enrolled in any other MAT program;

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

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

21.3.l. Assess the individual's access to social supports, family, friends, employment, housing, finances and whether any legal problems exist; and

21.3.m. Determine the patient's readiness to participate in treatment.

21.4. The individual 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 by the treating physician with parental consent to the state opioid treatment authority.

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

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

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

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

21.5.c.1. Onset of opioid physical dependence prior to admission with continuous use the greater part of the year; and

21.5.c.2. Multiple or daily self-administration of an opioid, or both.

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

21.6.a. Unsuccessful efforts to control use;

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

21.6.c. Continual use despite harmful consequences;

21.6.d. Obtaining opiates illegally;

21.6.e. Inappropriate use of prescribed opiates;

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

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

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

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

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

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

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

21.8.c. There is objective evidence that the individual qualifies under the provisions of section 21.9. of this rule.

21.9. Admission to the MAT 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:

21.9.a. The individual is a pregnant woman with a history of substance use disorder;

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

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

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

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

21.10. A patient enrolled in a MAT program shall not be permitted to obtain treatment in any other MAT program except in exceptional circumstances and ~~only~~ as provided in section 30.14 of these rules.

21.11. The admission and initial dosing of the patient may take place only after the patient is seen by a program physician, or an experienced medical professional working within the scope of his or her license who:

21.11.a. Has consulted by telephone or in person with the program physician;

21.11.b. Is approved by the medical director; and

21.11.c. Has completed a plan of development.

21.12. Whenever possible, the patient shall be admitted only after observation by and an interview with the program physician. Under unusual circumstances, an experienced medical professional working within the scope of his or her license may conduct the interview and observation and obtain telephone or fax orders from the physician to initiate treatment. Any patient admitted under those circumstances must be seen by the program physician within three working days of admission for verification of appropriate admission and treatment. All unusual circumstances and their outcomes shall be reviewed by the admissions committee.

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

21.14. The program physician 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 physician shall ensure that each newly admitted patient provides informed written consent to treatment.

21.15. Every individual shall be given the opportunity to enter into a detoxification program and shall be fully informed of the protocol, goals and procedures for detoxification. The individual shall specifically consent to participation in the detoxification program in writing. The consent form shall be maintained in the patient chart and with the patient's individualized treatment plan of care.

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

21.17. 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.

21.18. Exceptions to admission policy shall be reviewed and tracked by the admissions committee and be made available to regulatory bodies.

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

21.20. 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 individuals were not admitted and what referrals were made for them by the program.

21.21. Patient Transfers.

21.21.a. MAT programs shall accept patients transferring from another MAT program within the state of West Virginia, if:

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

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

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

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

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

21.21.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.

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

§69-11-22. Multiple Program Enrollments.

22.1. A patient enrolled in a MAT program shall not be permitted to obtain treatment in any other MAT program except in exceptional circumstances.

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

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

22.2. When practicable, the MAT program shall obtain a written consent for release of information from the patient in order to check the records of every MAT 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 MAT program shall protect patient confidentiality at all times and with all procedures used in acquiring medical or health information.

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

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

§69-11-23. Controlled Substances Monitoring Program Database.

23.1. Each MAT 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 a MAT program access to the Controlled Substances Monitoring Program database maintained by the West Virginia Board of Pharmacy.

23.2. Program physicians shall access the database:

23.2.a. At the patient's intake;

23.2.b. Before the administration of medication-assisted treatment medications or other treatment in a MAT program;

23.2.c. After the initial 30 days of treatment;

23.2.d. Prior to any take home medication being granted, if applicable;

23.2.e. After any positive drug test; and

23.2.f. At each 90-day treatment review.

23.3. The program physician 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.

§69-11-24. Orientation.

24.1. Every person admitted to a MAT program shall receive program orientation. The orientation shall be made verbally at the earliest opportunity at which the patient is stable and capable of understanding and retaining the information presented. 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.

24.2. Orientation shall include the following:

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

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

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

24.2.c.1. Expectations and rules;

24.2.c.2. Hours of operation;

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

24.2.c.4. Confidentiality policy;

24.2.c.5. Drug screening and random drug-testing policies;

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

24.2.c.7. Interventions;

24.2.c.8. Incentives; and

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

24.2.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.

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

24.2.f. Familiarization with the MAT program facility and premises.

24.2.g. A description of the MAT program's policies regarding:

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

24.2.g.2. Smoking;

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

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

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

24.2.i. A copy of the MAT program rules identifying the following:

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

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

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

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

24.2.k. A description of how the individualized treatment plan of care and coordination of care agreement will be developed and the patient's expected participation in the plan of care; and

24.2.l. An explanation of alternative methods that are available for treatment of substance use disorder, whether offered by the program or not, and the potential benefits and risks.

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

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

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

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

24.3.d. Patient's rights;

24.3.e. Confidentiality policies;

24.3.f. The program's processes for dispensing medication; and

24.3.g. 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.

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

24.4.a. Medication administration, including methods of dispensing and dosage restrictions;

24.4.b. 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;

24.4.c. The anticipated benefits of treatment;

24.4.d. The nature of the recovery process;

24.4.e. HIV spectrum and other infectious diseases;

24.4.f. Potential drug interactions;

24.4.g. Self-help groups;

24.4.h. Medical issues related to detoxification from medication-assisted treatment medications;

24.4.i. 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;

24.4.j. Characteristics of the medications administered or prescribed by the program;

24.4.k. Drug safety issues;

24.4.l. Dispensing procedures; and

24.4.m. Side effects of medications administered or prescribed by the program.

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

§69-11-25. Required Services.

25.1. Each MAT program shall provide adequate medical, counseling, vocational, educational, recovery and other assessment and treatment services. These services must be available onsite at the facility or on a referral basis to outside providers and the program sponsor or administrator must be able to document that these services are fully and reasonably available to patients and comply with all federal and state laws, rules and regulations.

25.2. Each MAT program shall require every patient to undergo a documented physical assessment by a program physician or a physician extender under the supervision of a program physician, before admission to the MAT program. The medical assessment shall be completed at the time of admission and prior to the first dose of medication-assisted treatment medication. The results of serology, drug screens and other tests must be completed within 14 days following admission.

25.3. Each MAT program shall require every patient to undergo a documented biopsychosocial assessment by a program counselor before admission to the MAT program. The biopsychosocial assessment shall be completed at the time of admission and prior to the first dose of medication-assisted treatment medication.

25.4. Each patient accepted for treatment at a MAT program shall be assessed ~~including physical and biopsychosocial assessments~~ initially and at least every 90 days following the initial assessment by qualified personnel who shall determine the most appropriate combination of recovery-oriented services and treatment for the patient.

25.5. Within seven days of the admission of a patient, the MAT program shall complete a post-admission initial assessment, an initial individualized treatment plan of care and a coordination of care agreement.

25.6. Random drug testing of all patients shall be conducted during the course of treatment as required in section 34.2.d.1. Each MAT program must provide adequate testing or analysis for drugs of abuse in accordance with generally accepted clinical practice.

25.7. Each MAT program must provide adequate substance use disorder counseling to each patient as clinically necessary and at the minimum levels as required by section 26.8 of this rule. Counseling shall be provided by a program counselor, qualified by education, training or experience to assess the psychological and sociological background of patients, to contribute to the appropriate individualized treatment plan of care for the patient and to monitor patient progress.

25.8. Each MAT 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 MAT program or by referral to appropriate health care providers. Services rendered to pregnant patients shall comply with the requirements of section 35.5 of this rule.

25.9. Each MAT program shall provide 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 section 35.3 of this rule.

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

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

25.10.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 MAT program;

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

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

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

25.11. Services provided by a MAT 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; ensuring that the patient lives in a stable and safe place; engaging the patient 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.

§69-11-26. Counseling.

26.1. Each MAT 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.

26.2. The counseling shall be provided by a counselor or other 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 treatment plan of care, in coordination with the medical staff and program physician. The individualized treatment plan of care shall address the social, environmental, psychological, social and familial issues relative to recognizing, correcting and eliminating the individual's maladaptive patterns of drug consumption and other high risk or destructive behaviors.

26.3. The primary counselor is responsible for assisting the patient in altering lifestyles and patterns of behavior in order to improve the individual's ability to function adaptively in his or her family and community. Counseling shall address the social, environmental, psychological and familial issues that contribute to the individual's maladaptive patterns of drug consumption and other high risk or destructive behaviors.

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

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

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

26.5. Each MAT 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 needed and clinically indicated.

26.6. Each MAT program must provide directly, or through referral to adequate and reasonably accessible community resources, vocational rehabilitation, education and employment services for patients who either request such services or who have been determined by the program staff to be in need of such services.

26.7. The clinical staff caseload ratio, as prescribed in section 8.6.c., shall:

26.7.a. Reflect an appropriate clinical mix of gender, race and ethnicity representative of the population served;

26.7.b. Allow the program to provide adequate psychosocial assessments, treatment planning and individualized counseling;

26.7.c. Allow for regularly scheduled, documented individual counseling sessions, as clinically indicated; and

26.7.d. Allow patients access to their primary counselor if more frequent contact is merited by need or is requested by the patient.

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

26.8.a. At least twice weekly during the first 30 days of treatment;

26.8.b. At least weekly during the next 90 days of treatment;

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

26.8.d. Thereafter, for subsequent 90-day periods of treatment, counseling sessions shall take place as needed or indicated in the patient's individualized treatment plan of care, but not less frequently than monthly as long as the patient is compliant.

26.9. The counseling program shall provide for mandatory and documented weekly counseling of any patient who has a positive drug test and is required by this rule to undergo additional counseling. The counseling sessions shall be no less than 30 minutes to a patient with a counselor or other professional as described in section 8.6.a., whichever is applicable, of this rule who is licensed, certified or enrolled in the process of obtaining licensure, registration or certification. The mandatory counseling sessions may consist of group counseling sessions. However, the patient must attend at least one individual, private session per month.

26.10. Exceptions to frequency of counselor-to-patient contact shall be clearly justified by program documentation. The program physician evaluating the patient's eligibility for take-home doses shall carefully consider the patient's participation in the counseling sessions and the patient's current phase in treatment as factors in the decision. A justified lack of participation, such as for reasons of employment, shall not be held against the patient in the take-home decision.

26.11. All counseling sessions shall be contained in the MAT program's patient record and shall include documentation of the following:

26.11.a. The reason for or nature of the contact;

26.11.b. The patient's current condition;

26.11.c. Significant events occurring since the prior contact;

26.11.d. The assessment of the patient's status; and

26.11.e. A plan for action or further treatment that addresses the goals of the individualized treatment plan of care.

26.12. Each counseling session shall be documented and completed within 72 hours of the contact and shall be clearly dated and initialed or signed the counselor providing the counseling session.

26.13. Counseling session opportunities for family or significant other involvement in counseling shall be provided and documented.

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

§69-11-27. Provision of Coordination of Patient Care; Post-Admission Assessment and Initial Plan of Care.

27.1. Each MAT 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.

27.2. Initial Post-Admission Assessments.

27.2.a. All patients shall undergo an initial post-admission assessment in order to determine the patient's condition, diagnosis and treatment. The assessment shall be conducted by one or more program physicians.

27.2.b. Upon admission to a MAT program, each patient shall undergo an initial post-admission assessment and the MAT program shall develop an initial plan of care. The initial assessment and plan of care shall be completed within seven days of the patient's admission.

27.2.c. The initial post-admission assessment shall consist of a medical assessment and include documentation of:

27.2.c.1. A physical assessment by a qualified medical professional within their scope of practice;

27.2.c.2. A psychiatric assessment, including mental status examination and psychiatric history;

27.2.c.3. A personal and family medical and health history;

27.2.c.4. All current medications, prescription or otherwise;

27.2.c.5. A comprehensive history of substance abuse, both personal and family;

27.2.c.6. Determination of current dependence on controlled substances;

27.2.c.7. A tuberculosis screening;

27.2.c.8. A screening test for syphilis;

27.2.c.9. A hepatitis C test;

27.2.c.10. An HIV test to the extent voluntarily elected by the patient;

27.2.c.11. An inquiry to and report from the Controlled Substances Monitoring Program database;

27.2.c.12. Laboratory tests;

27.2.c.13. A full drug screen;

27.2.c.14. An inquiry whether the patient is being treated at any other MAT program;

27.2.c.15. The diagnosis of all conditions, including a diagnosis of substance use disorder, including signs and symptoms;

27.2.c.16. A copy of the report by the referring physician and any medical records from other providers, if applicable;

27.2.c.17. The dates, amounts and dosage forms for any drugs prescribed, dispensed and administered; and

27.2.c.18. Other tests as necessary or appropriate, including, but not limited to, CBC, EKG, X-ray, pap smear, hepatitis B surface antigen and hepatitis B antibody testing.

27.2.d. A program physician or supervised physician extender shall perform a physical assessment of a patient on the same day that the program physician initially prescribes, dispenses or administers a medication-assisted treatment medication to a patient. If the patient continues to be treated for substance use disorder at the program, a ~~physical~~ assessment shall be performed at least every 90 days thereafter. All assessments shall be performed according to accepted and prevailing standards for medical care.

27.2.e. A repeat, full drug screen may be completed at 14 days after admission to identify whether the patient is using other drugs or substances, including, but not limited to, opiates, methadone, buprenorphine, amphetamines, cocaine, barbiturates, benzodiazepines and marijuana.

27.2.f. The initial post-admission assessment may include laboratory tests conducted by the MAT program or by other reliable sources.

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

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

27.2.f.3. Tests not directly conducted by the MAT 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.

27.3. Continued Post-Admission Assessments.

27.3.a. Subsequent patient assessments shall include documentation of:

27.3.a.1. Follow-up physical assessments, by a program physician or a supervised physician extender;

27.3.a.2. The patient's response to treatment;

27.3.a.3. Any modification to the plan of treatment;

27.3.a.4. The dates on which any medications were prescribed, dispensed or administered;

27.3.a.5. The amounts and dosage forms for any drugs prescribed, dispensed or administered;

27.3.a.6. Laboratory tests; and

27.3.a.7. Full drug screens.

27.4. Initial Plan of Care.

27.4.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 for every patient.

27.4.b. The initial plan of care shall include, at a minimum:

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

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

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

27.4.b.4. Laboratory test results;

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

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

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

27.4.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

27.4.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.

§69-11-28. Physical and Biopsychosocial Assessments.

28.1. ~~Within 30 days after admission, or when the patient is stable and able to fully participate, t~~The program shall complete a physical and biopsychosocial evaluation, which shall be used to develop the long-term individualized treatment plan of care. The physical and biopsychosocial evaluations shall integrate information obtained in all treatment of the patient at the MAT program.

28.2. The physical and biopsychosocial evaluations shall include information obtained from:

28.2.a. The patient;

28.2.b. Family members, when applicable and permitted;

28.2.c. Friends and peers, when appropriate and permitted; and

28.2.d. Other appropriate and permitted collateral sources.

28.3. The physical assessment shall include information regarding the following:

28.3.a. A physical assessment;

28.3.b. An update to any immediate relevant history, including, but not limited to, the determination of chronic or acute medical conditions such as diabetes, renal disease, hepatitis, sickle cell anemia, tuberculosis, HIV exposure, sexually transmitted disease, chronic cardiopulmonary disease and pregnancy;

28.3.c. A determination of currently prescribed medications or utilized over-the-counter substances;

28.3.d. A determination and evaluation of the patient's use of other substances of abuse and alcohol;

28.3.e. A drug screen;

28.3.f. An inquiry to and report from the Controlled Substances Monitoring Program database;

28.3.g. An inquiry whether the patient is enrolled in any other MAT program;

28.3.h. Screen for communicable disease and address them as needed and evaluate patient's level of physical, psychological and social functioning or impairment; and

28.3.i. Assess the individual's access to social supports, family, friends, employment, housing, finances and whether any legal problems exist.

28.4. The biopsychosocial assessment shall include information about the patient's:

28.4.a. Personal strengths;

28.4.b. Individualized needs;

28.4.c. Abilities or interests;

28.4.d. Presenting problems, including a thorough analysis of the individual's substance use disorders such as, licit and illicit drugs used, including alcohol; amounts of drugs or alcohol used; frequency of use; duration of use; symptoms of physical addiction; history of treatment for substance use disorder; adverse consequences of use; inappropriate use of prescribed substances; and urgent needs, including suicide risk;

28.4.e. Previous behavioral health services, including diagnostic information; treatment information; efficacy of current or previously used medication; physical health history and current status; diagnoses; mental status and current level of functioning;

28.4.f. Pertinent current and historical life situation information, including the patient's age; gender; employment history; involvement in legal proceedings; family history; history of abuse or neglect; and relationships, including natural supports;

28.4.g. Use of alcohol and tobacco;

28.4.h. Need for, and availability of, social supports;

28.4.i. Risk-taking behaviors;

28.4.j. Level of educational functioning;

28.4.k. Medications prescribed that are not a target of treatment or concern;

28.4.l. Medication allergies or adverse reactions to medications;

28.4.m. Adjustment to disabilities or disorders; and

28.4.n. Motivation for treatment.

28.5. The patient's primary counselor shall review the biopsychosocial assessment and prepare a concise, interpretive multidisciplinary summary that:

28.5.a. Is based on the assessment data;

28.5.b. Describes and evaluates the level and severity of the individual's substance use disorder behaviors;

28.5.c. Is used in the development of the individualized treatment plan of care; and

28.5.d. Identifies any co-occurring disabilities or disorders that should be addressed in the development of the individualized treatment plan of care.

§69-11-29. Individualized Treatment Plan of Care.

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

29.2. Within 30 days after admission of a patient, the MAT program shall develop a more comprehensive individualized treatment plan of care and attach it to the patient's chart no later than five days after the plan is developed. The individualized treatment plan of care 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 treatment plan of care shall include a recovery model based upon the approved guidelines and protocols.

29.3. The individualized treatment plan of care shall be reviewed by the program physician, primary counselor and patient at least every 90 days and documented in the patient record. Reviews shall address each of the objectives identified on the initial plan of care; document all treatment, counseling, medications and other services rendered to the patient; and document the patient's progress. A revised plan of care may be implemented with each review. If a new plan of care is not implemented, the reasons for such decision should be documented in the patient's record. Paper and electronic plans of care, including all reviews and updates, must be acknowledged by the patient.

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

health care providers. The individualized treatment plan of care shall be drafted to meet the specific needs of the patient. After the individualized treatment plan of care is developed and approved by the patient, the plan of care shall be placed in the patient's chart within five days of development. The patient shall receive a copy of all of his or her individualized treatment plans of care.

29.5. All individualized treatment plans of care shall include, at a minimum:

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

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

29.5.c. The identification of "triggers" for misuse of substances;

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

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

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

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

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

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

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

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

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

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

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

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

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

29.7. Each MAT program shall provide opportunities for family involvement in the therapy provided to each patient and document such involvement in the individualized treatment plans of care.

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

29.8.a. MAT 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.

29.8.b. At the time of the quarterly review, the patient shall again be presented with the option of participating in alternative treatment, such as medically-supervised withdrawal. The patient shall sign and date a statement indicating whether he or she wishes to participate in an alternative form of treatment or remain within the program in an ongoing recovery-oriented maintenance format. The statement shall be included with the patient's individualized treatment plan of care.

29.8.c. If the patient chooses the option of participating in alternative treatment, the individualized treatment plan of care shall include a consent form signed by the patient acknowledging that under the detoxification protocol the strength of maintenance doses of medication-assisted treatment medication should decrease over time and that the participant is required to work toward a recovery-oriented lifestyle.

29.8.d. 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.

29.8.e. If a patient wishes to enter medically-supervised withdrawal, the individualized treatment plan of care shall reflect that choice.

29.8.f. If at any time a patient in good standing wishes to re-enter a maintenance program, the patient may do so in consultation with the primary counselor and medical staff.

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

29.10. Coordination of Care Agreement.

29.10.a. The coordination of care agreement 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.

29.10.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.

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

29.10.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;

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

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

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

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

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

29.10.c.7. Estimated length of treatment.

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

§69-11-30. Unsupervised Take-Home Medications.

30.1. Each MAT program shall develop and implement policies and procedures regarding unsupervised take-home medication schedules that consider the best interests of each patient, as well as the interests of the public at large. The policies and procedures shall be developed and implemented in accordance with federal and state laws, rules and regulations and pursuant to guidelines and protocols from approved authorities. The policies and procedures should assist patients with treatment and recovery and simultaneously prevent diversion, ensure safe storage and security of medication and prevent overdoses. Policies and procedures shall address the granting and rescinding of take-home medication privileges.

30.2. Approved guidelines and protocols include those adopted by the American Society of Addiction Medicine (ASAM), the Center for Substance Abuse Treatment (CSAT), the National Institute on Drug Abuse (NIDA), the American Association for the Treatment of Opioid Dependence (AATOD) and other authorities approved by the secretary. A MAT program may submit a written request that the secretary approve another such program and shall provide all applicable documentation that supports such approval. The secretary has the sole discretion in determining whether to add another program to the list of approved authorities.

30.3. All MAT program facilities that provide unsupervised approved use of medications shall be open seven days per week, except for eight holidays and two training days per year, when the programs may be closed.

30.4. The interdisciplinary team shall make recommendations to the patient's program physician regarding take-home medications for each patient. The program physician shall make the final decision regarding approval of take-home medications in accordance with federal and state laws, rules and regulations and guidelines and protocols from approved authorities. The program physician shall document all approved changes in take-home privileges in the patient record and the individualized treatment plan of care.

30.5. In determining which patients may be permitted unsupervised use of medications, the program physician shall ensure the patient demonstrates a level of current lifestyle stability as evidenced by the following in determining whether a patient is responsible in handling medication-assisted treatment medications for unsupervised use:

30.5.a. Cessation of illicit drug use;

30.5.b. Absence of recent abuse of drugs, including opioid and non-narcotic drugs, and alcohol;

30.5.c. Regular program attendance, including dosing and participation in counseling and group sessions;

30.5.d. Absence of significant behavioral problems;

30.5.e. Absence of recent criminal activity, including, but not limited to, charges and convictions;

30.5.f. Stability of the patient's home environment and social relationships;

30.5.g. Demonstrated satisfactory adherence to MAT program rules, policies and procedures for at least three months;

30.5.h. Assurance that take-home medication can be safely stored within the patient's home, taking into account the patient's current living situation and other members of the household;

30.5.i. Whether the rehabilitative benefit the patient derives from decreasing the frequency of program attendance outweighs the potential risks of diversion;

30.5.j. The ability of the patient to responsibly self-medicate;

30.5.k. Other special needs of the patient, including, but not limited to, split dosing, physical health needs and pain treatment;

30.5.l. The patient's work, school or other daily-life activity schedule; and

30.5.m. Hardship experienced by the patient in traveling to and from the program.

30.6. The determination of whether to approve a patient for unsupervised take-home medications consistent with the criteria outlined in this section shall be documented in the patient's medical record.

30.7. The program physician and counselor shall educate the patient on the safe transportation and storage of take-home medications.

30.8. Each MAT program shall maintain current procedures adequate to identify the theft or diversion of take-home medications, including labeling containers with the MAT program's name, address and telephone number. Programs must also ensure that take-home supplies are packaged in a manner that is designed to reduce the risk of accidental ingestion, including child-proof containers.

30.9. The number of doses of take-home medication shall be determined by the program physician in accordance with guidelines and protocols of approved authorities and after consultation with the interdisciplinary team and shall not exceed the recommended doses. The take-home medication treatment plan shall be for 90-day periods. The patient's individualized treatment plan of care may include permission for the patient to take home doses of medication subject to the following restrictions:

30.9.a. During the first 90-day period of treatment, no take home doses shall be permitted during the first 30 days of treatment. Thereafter, the take home supply is limited to a single dose each week, except for holidays or days when the facility is closed. The patient shall ingest all other doses under appropriate supervision.

30.9.b. In the second 90-day period of treatment, the take home supply is limited to two doses per week.

30.9.c. In the third 90-day period of treatment, the take home supply is limited to three doses per week.

30.9.d. In the remaining months of the first year of treatment, a patient may be given a maximum six-day supply of take home medication.

30.9.e. After one year of continuous treatment, a patient may be given a maximum two-week supply of take home medication.

30.9.f. After two years of continuous treatment, a patient may be given a maximum one-month supply of take home medication, contingent upon the patient making monthly visits to the MAT program.

30.10. No medications shall be administered to patients in short-term detoxification treatment for unsupervised or take home use.

30.11. Any patient in comprehensive maintenance treatment may receive a single take home dose for a day that the MAT program facility is closed for business, including Sundays and state and federal holidays.

30.12. Patients participating in the unsupervised take-home medication plan are subject to the provisions of section 30 of this rule regarding positive drug test results. The failure to pass a drug test may result in a change to the individualized treatment plan of care, including a loss of unsupervised take home medication privileges or discharge from the program.

30.13. The program physician may approve temporary unsupervised take home medication for documented family or medical emergencies or other exceptional circumstances, pursuant to authorized guidelines and protocols approved by the state opioid treatment authority. Patterns of emergency take home provisions shall be tracked and monitored by the MAT program, included in the patient records and be made available for review by regulatory bodies and the designated state oversight authority.

30.14. Guest dosing at a nearby program is preferred whenever possible and shall be documented in the patient's chart and individualized treatment plan of care.

30.15. Each MAT program shall develop and implement policies and procedures that address the transfer of patients from one MAT program to another.

30.16~~5~~. The state opioid treatment authority may approve exceptions to the requirements of this section, including alternative medications, on a case-by-case basis upon application for an exemption by the program physician, relating to the length of time of satisfactory adherence to program rules, policies and procedures and the number of days of take home medication when a patient has provided documentation, which shall be included in the patient's record, of the following:

30.16~~5~~.a. The patient has a permanent physical disability;

30.16~~5~~.b. The patient has a temporary disability; or

30.16~~5~~.c. The patient has an exceptional circumstance such as illness, personal or family crisis, or travel which interferes with the patient's ability to conform to the applicable mandatory attendance schedules.

30.17~~6~~. An exemption granted under section 30.15.a. of this rule shall be reviewed at least annually to determine whether the need for the exception still exists.

30.18~~7~~. An exemption granted under section 30.15.b. of this rule shall continue only for so long as the temporary disability or exceptional circumstance exists.

30.19~~8~~. With an exemption granted under section 30.15.c. of this rule, the program may not permit a patient to receive more than a two-week take-home supply of medication.

§69-11-31. Detoxification Program.

31.1. In addition to recovery-oriented medication-assisted treatment services, each MAT program shall provide both long-term and short-term detoxification recovery treatment services, either onsite or by referral. The program physician or a physician extender shall provide onsite medical supervision and oversight of the detoxification treatment program. 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.

31.2. All potential 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.

31.3. Patients with two or more unsuccessful detoxification episodes within a 12-month period must be assessed by the MAT program physician for other forms of treatment. A program shall not admit a patient for more than two detoxification treatment episodes in one year. One year of physiologic dependence is not required for detoxification treatment although documentation of current dependency is required.

31.4. The patient's individualized treatment plan of care shall state whether the patient chose detoxification treatment services and, if so, whether the patient selected the short-term or long-term detoxification treatment program. If the patient selected the option for detoxification treatment services, the patient's chart shall include a consent form signed by the patient reflecting selection of such an option. The consent form shall include the patient's acknowledgement that under the detoxification protocol the strength of maintenance doses of medication-assisted treatment medications should decrease over time; that the treatment period should be in accordance with national guidelines; and that the patient is required to work toward a recovery-oriented lifestyle.

31.5. The estimated time of detoxification required to reach the point of elimination of the medication shall be specified by the physician and documented in the patient's individualized treatment plan of care. The titration schedule may be modified at any time. Any extension or modification of the titration schedule shall be documented in the patient's individualized treatment plan of care and chart.

31.6. The program physician shall determine on an individualized basis the appropriate dosage of medication-assisted treatment medication to ensure stabilization during detoxification. The determination shall be based upon individual clinical data in accordance with guidelines and protocols established by approved authorities.

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

31.8. Urine or other toxicological screening instruments shall be used by the MAT program staff during detoxification treatment in order to demonstrate the absence of use of alternative licit or illicit drugs.

31.9. The MAT program shall develop and implement a policy regarding recovery-oriented detoxification treatment from medication-assisted treatment medication that shall include:

31.9.a. Individualized determination of a schedule of detoxification that is well tolerated by the patient and consistent with approved national guidelines and sound medical practices;

31.9.b. Implementation of a higher stabilizing dose in the event of impending relapse as appropriate and possible;

31.9.c. Assurances that voluntary detoxification shall be discontinued in the event of relapse and that provisions for maintenance treatment shall be made;

31.9.d. Evaluation or testing for pregnancy prior to detoxification; and

31.9.e. Provision for continuing care after the last dose of methadone or other medication-assisted treatment medication.

31.10. The MAT program shall have procedures for providing detoxification treatment services to persons prior to their incarceration in criminal justice system facilities if possible and foreseeable. When appropriate, the MAT program shall have cooperative agreements with the criminal justice system to encourage detoxification treatment services to persons who are incarcerated or on probation or parole and are required to become abstinent.

31.11. Short-Term Detoxification Treatment Services.

31.11.a. Short-term detoxification treatment services are those services projected to last fewer than 30 days.

31.11.b. Unsupervised doses of medication may not be administered to patients admitted for short-term detoxification unless the patient qualifies under a federal or state-approved exemption and there is a verifiable emergency. If there is a verifiable exemption or emergency, the MAT program shall not allow the patient more than one unsupervised or take home medication dose per week. If the program operates on a seven day-per-week basis, no take home, unsupervised medications shall be allowed except on permitted holidays or closures or pursuant to an authorized exemption.

31.11.c. For a patient admitted for detoxification treatment services for 14 days or less, the program must offer a minimum of four counseling sessions per week.

31.12. Long-Term Detoxification Treatment Services.

31.12.a. Long-term detoxification treatment services are those services projected to last more than 30 and up to 180 or more days, depending on clinical need.

31.12.b. Frequency of access to unsupervised medications shall be determined by the program physician in accordance with federal law and guidelines and protocols from an approved authority.

31.12.c. In a detoxification program of more than 30 days' duration, the MAT program shall have a policy that grants the patient the opportunity to receive take home medications. No unsupervised take home medications may be administered or prescribed for a patient during the first 30 days of treatment unless the patient qualifies under an approved exemption or emergency. Thereafter, based upon federal law, approved national guidelines and the clinical judgment of the program physician, the quantity of unsupervised medication shall not exceed the following doses:

31.12.c.1. One unsupervised dose per week for the remaining 60 days of the first 90-day treatment plan. Provided, that in a week in which a holiday causes the MAT program to be closed, two doses may be allowed.

31.12.c.2. Two unsupervised doses per week during the second 90 days of treatment.

31.12.c.3. Three unsupervised doses per week during third 90 days of treatment.

31.12.c.4. A maximum six-day supply of take home medication in the remaining months of the first year of treatment.

31.13. Counseling Services.

31.13.a. Counseling services provided in conjunction with detoxification treatment services shall be designed to:

31.13.a.1. Explore other modalities of care, including drug and alcohol treatment following detoxification or discharge;

31.13.a.2. Motivate the patient to continue to receive services or to develop a plan for recovery following discharge; and

31.13.a.3. Identify triggers for relapse and a coping plan for dealing with each, detailed and in writing and given to the patient prior to discharge.

31.13.b. The counseling plan shall be developed in conjunction with the patient and included with the individualized treatment plan of care.

31.13.c. For a patient projected to be involved in detoxification treatment services for six months or less, the MAT program must offer the patient a minimum of three counseling sessions per week for the first month and a minimum of two counseling sessions each month thereafter.

31.14. Maintenance treatment shall be discontinued within two continuous years after the treatment is begun unless, based upon the clinical judgment of the medical director or program physician and staff which shall be recorded in the client's record, the client's status indicates that the treatment should be continued for a longer period of time because discontinuance from treatment would lead to a return to illicit opiate abuse or dependence, or increased psychiatric, behavioral or medical symptomology.

§69-11-32. Administrative Withdrawal.

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

32.2. MAT 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.

32.3. 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.

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

32.4.a. Non-payment of fees. The MAT 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.

32.4.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, repeated loitering, 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.

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

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

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

32.7. 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.

§69-11-33. Medical Withdrawal.

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

33.2. The MAT program shall supply a schedule of dose reduction well tolerated by the patient.

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

33.4. If the patient leaves the MAT program abruptly against medical advice, the program may readmit the patient within 30 days without a formal reassessment procedure. However, the program must perform a physical assessment and a biopsychosocial assessment upon readmission. The program shall document attempting to assist the patient with any issues which may have triggered his or her abrupt departure.

33.5. The MAT program shall make provisions for continuing care for each patient following the last dose of medication and for re-entry to maintenance treatment if relapse occurs or if the patient should reconsider withdrawal.

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

33.7. 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.

§69-11-34. Laboratory Services; Drug Screens.

34.1. All patients in the MAT program shall undergo monthly drug testing. Random drug testing of all patients shall be conducted during the course of treatment as required in section 34.2.d.1.

34.2. Collection and Testing.

34.2.a. MAT programs shall work carefully with toxicology laboratories to ensure valid, appropriate results of drug screens. Workplace testing standards are not appropriate for urine testing. Testing shall be done only by laboratories with appropriate federal certification.

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

34.2.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.

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

34.2.d.1. A patient receiving medication-assisted treatment medication maintenance services must have at least 12 random drug screens per year. The patient shall be tested upon admission; at approximately 14 days of treatment; and then monthly through the remainder of the time the patient remains in the MAT program.

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

34.2.d.3. When using urine as a screening mechanism, all patient drug testing shall be observed to minimize the chance of adulterating or substituting another individual's urine.

34.2.d.4. MAT 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.

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

34.2.e.1. Buprenorphine, especially in ratio to Norbuprenorphine;

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

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

34.2.e.4. Benzodiazepines, including testing procedures that detect diazepam, clonazepam, alprazolam and lorazepam;

34.2.e.5. Cocaine;

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

34.2.e.7. Tetrahydrocannabinol, delta-9-tetrahydrocannabinol, dronabinol or other similar substances; or

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

34.2.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.

34.2.g. When necessary and appropriate, breathalyzers or other testing equipment may be used to screen for possible alcohol abuse. No individual shall receive a daily dose who has a breathalyzer result which is equal to or greater than 0.02. The individual may return to the program for dosing during the same day if the breathalyzer results reach acceptable limits.

34.2.h. Each MAT program shall document both the results of drug tests and the follow-up therapeutic action taken in the patient record.

34.2.i. Each MAT program shall ensure that program physician 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.

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

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

34.2.j.2. The prescribing physician is aware that the patient is enrolled in a MAT program.

34.2.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 a MAT 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.

34.2.l. Nothing contained in this rule shall preclude any MAT program from administering any additional drug tests it determines are necessary.

34.3. Test Results.

34.3.a. A positive test is a test that results in the presence of any drug or substance listed in section 37.2.e. of this rule, or any other drug or substance prohibited by the MAT program. The presence of a drug or substance which is part of the patient's individualized treatment plan of care shall not be considered a positive test. Any refusal to participate in a random drug test shall be considered a positive drug test.

34.3.b. A positive drug test result after the first six months in a MAT program shall result in the following:

34.3.b.1. Upon the first positive drug test result, the MAT program shall:

34.3.b.1.A. Provide mandatory and documented weekly counseling to the patient of no less than 30 minutes, which shall include weekly meetings with a counselor or other professional as described in section 26.8 of this rule who is licensed, certified or enrolled in the process of obtaining licensure or certification in compliance with the rules on staff at the MAT program or by formal referral agreement; and

34.3.b.1.B. Immediately revoke the take-home medication privilege for a minimum of 30 days;

34.3.b.2. Upon a second positive drug test result within six months of a previous positive drug test result, the MAT program shall:

34.3.b.2.A. Provide mandatory and documented weekly counseling to the patient of no less than 30 minutes, which shall include weekly meetings with a counselor or other professional as described in section 26.8. of this rule who is licensed, certified or enrolled in the process of obtaining licensure or certification in compliance with the rules on staff at the MAT program;

34.3.b.2.B. Immediately revoke the take home medication privilege for a minimum of 60 days; and

34.3.b.2.C. Provide mandatory documented treatment to interdisciplinary team meetings with the patient.

34.3.b.3. Upon a third positive drug test result within a period of six months the MAT program shall:

34.3.b.3.a. Provide mandatory and documented weekly counseling to the patient of no less than 30 minutes, which shall include weekly meetings with a counselor or other professional as described in section 26.8. of this rule who is licensed, certified or enrolled in the process of obtaining licensure or certification in compliance with the rules on staff at the MAT program;

34.3.b.3.b. Immediately revoke the take home medication privilege for a minimum of 120 days, if applicable; and

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

34.3.b.4. Upon any subsequent positive drug test(s) within a six month period, the patient may be immediately discharged from the MAT program, or, at the option of the patient, may immediately be provided the opportunity to participate in a detoxification plan, followed by immediate discharge from the MAT program. If the patient remains in treatment with the OPT, the program physician and primary counselor must meet with the patient and revise the individual treatment plan of care and revise the coordination of care agreement.

34.3.c. Positive screens for tetrahydrocannabinol, delta-9-tetrahydrocannabinol, dronabinol or similar substances shall be carefully clinically evaluated and shall in most cases result in reduction in take-home medication privileges unless other action is considered appropriate by the medical director or program physician and primary counselor. Testing

positive solely for tetrahydrocannabinol, delta-9-tetrahydrocannabinol, dronabinol or similar substances shall not serve as a basis for discharge from the program.

34.3.d. 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 and interdisciplinary team and the individualized treatment plan of care shall be adjusted, if needed, accordingly.

§69-11-35. Special Populations.

35.1. Concurrent Alcohol and Polysubstance Abuse.

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

35.1.b. The MAT program shall ensure that its staff is fully trained and knowledgeable regarding current effective strategies for treating alcohol, cocaine and other drug abuse.

35.1.c. Ongoing polysubstance use is not a reason for discharge unless the patient refuses recommended, more intensive levels of care. 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.

35.1.d. Each MAT program shall have a policy regarding treatment of co-morbid 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.

35.2. Behavioral Health Needs.

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

35.2.b. At all phases of treatment, the MAT program shall monitor patients during detoxification withdrawal and recovery for indications of symptoms of behavioral illness.

35.2.c. Each MAT program shall establish linkages with licensed behavioral health providers in the community.

35.2.d. Each MAT 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 treatment plan of care shall document regular contact with the prescribing physician and/or physician extender for the distinct purpose of monitoring prescribed psychotropic medications.

35.3. HIV Patients.

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

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

35.4. Chronic Pain Patients.

35.4.a. Each MAT program shall ensure that physicians practicing at the facility are knowledgeable in the treatment and management of substance use disorder in a 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.

35.4.b. Each MAT program shall ensure continuity of care and communication between programs or physicians regarding patients receiving treatment in both a MAT 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.

35.5. Pregnant Patients.

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

35.5.b. The MAT program shall ensure that every pregnant patient has the opportunity for prenatal care, either onsite or by referral. If the arrangement is by referral, the program shall have agreements in place, including informed consent procedures, which ensure exchange of pertinent clinical information regarding compliance with the recommended plan of medical care.

35.5.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.

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

35.5.d.1. Maintenance treatment dosage 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.

35.5.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;

35.5.d.3. The dose is monitored carefully, moving rapidly to supply increased or split dose if it becomes necessary; and

35.5.d.4. If a pregnant patient elects to withdraw from medication-assisted treatment, that withdrawal is not initiated by the program before 14 weeks and after 32 weeks gestation; perform regular fetal assessments as appropriate for fetal age and require that withdrawal is supervised by a physician experienced in substance use disorder medicine.

35.5.e. The MAT program shall ensure appropriate referral for follow-up and primary care for the mother and infant.

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

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

35.5.h. The program shall offer reproductive health education to all patients and appropriate referrals for contraceptive services as necessary.

35.6. Criminal Justice.

35.6.a. Each MAT program shall establish agreements and develop and implement procedures to coordinate with agents of the criminal justice system on behalf of patients insofar as permitted by patient confidentiality requirements.

§69-11-36. Advertisement Disclosure.

36.1. Any advertisement made by or on behalf of a MAT 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.

§69-11-37. Licensure Denials, Revocations and Suspensions.

37.1. Grounds for Denial, Revocation or Suspension.

37.1.a. The secretary may deny, revoke or suspend a license issued pursuant to this rule if any provisions of federal or state law or this rule are violated. The secretary may revoke a license and prohibit all program physicians associated with that MAT 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 license of a MAT program shall be prescribed by the secretary, but may not exceed one year.

37.1.b. The secretary may deny, revoke or suspend a MAT program license for one or more of the following reasons:

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

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

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

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

37.1.b.5. A MAT program has refused to provide access to its location or records as requested by the secretary;

37.1.b.6. A MAT program's medical director has knowingly and intentionally misrepresented actions taken to correct a violation;

37.1.b.7. An owner or medical director of a MAT program concurrently operates an unlicensed MAT program;

37.1.b.8. A program physician or any owner knowingly operates, owns or manages an unlicensed MAT program that is required to be licensed;

37.1.b.9. The owners of a MAT program fail to apply for a new license for the program upon a change of ownership and operate the program under the new ownership;

37.1.b.10. A program physician or any owner acquires or attempts to acquire a license for a MAT program through misrepresentation or fraud or procures or attempts to procure a license for a MAT program for any other person by making or causing to be made any false representation; or

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

37.2. Effect of Denial, Revocation or Suspension.

37.2.a. If a license for a MAT 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.

37.2.b. If the license of a MAT program is denied, revoked or suspended, no person, firm, association or corporation may operate the program as a MAT program as of the effective date of the denial, revocation or suspension. The owners of the MAT program are responsible for removing all signs and symbols identifying the premises as a MAT program within thirty days from the date of the denial, revocation or suspension.

37.2.c. If a license for a MAT program has been denied, revoked or suspended the program must supply, at a minimum, a copy of the following information to the secretary:

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

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

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

37.2.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

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

37.2.d. Upon the effective date of the denial, revocation or suspension the medical director of the MAT 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 a MAT program that is not licensed may be deemed adulterated.

37.2.e. If the license of a MAT program is revoked or suspended, no person named in the licensing documents of the program, including persons owning or operating the MAT program, may apply to own, license, register or operate another MAT program for five years after the date of revocation or suspension, either individually or as part of a group practice, firm, association or corporation.

37.2~~2~~.f. If a MAT program license is denied or revoked, a new application for license 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 license 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.

§69-11-38. Penalties and Equitable Relief.

38.1. Grounds for Penalties and Injunctions.

38.1.a. Any person, partnership, association or corporation which establishes, conducts, manages or operates a MAT program without first obtaining a license 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.

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

38.1.c. If the MAT program fails to timely file reports required by section 14 of this rule, the secretary may impose a civil monetary penalty not to exceed $1,000 per day.

38.1.d. If the MAT 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 MAT program's license.

38.1.e. If an owner or owners or medical director of a MAT program concurrently operates an unlicensed MAT 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.

38.1.f. If the owner of a MAT program that requires a license under this article fails to apply for a new license 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.

38.1.g. If a program physician knowingly operates, owns or manages an unlicensed MAT program that is required to be licensed pursuant to this article; knowingly prescribes or dispenses or causes to be prescribed or dispensed, controlled substances in an unlicensed MAT program that is required to be licensed; or obtains a license to operate a MAT program through misrepresentation or fraud; procures or attempts to procure a license for a MAT 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.

38.2. The secretary may deny a MAT program's application for licensure or application for renewal license; revoke or suspend a license; order an admissions ban or reduction in patient census for one or more of the following reasons:

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

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

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

38.2.d. The program has failed or refused to submit reports, comply with the documentation requirements of section 9.2.c, or make records available as requested by the secretary or his or her designee; or

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

38.3. 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 MAT program or violation of any provisions of this rule without first obtaining a license therefore in the manner hereinbefore provided.

38.3.a. The secretary may also seek injunctive relief if the establishment, conduct, management or operation of any MAT program, whether licensed, registered or not, jeopardizes the health, safety or welfare of any or all of its patients.

38.3.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:

38.3.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 MAT 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.

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

38.3.b.3. Whether there were any previous violations at the MAT program; and

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

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

§69-11-39. Administrative Due Process.

39.1. Before any MAT program license 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.

39.1.a. The notice shall be sent by certified mail to the owner(s) at the address where the MAT program concerned is located.

39.1.b. Within 30 days of receipt of the notice, the owner(s) may submit a request for an administrative hearing or an informal meeting to address and resolve the findings.

39.1.c. The MAT 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.

39.1.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.

39.1.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.

39.1.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.

§69-11-40. Administrative Appeals and Judicial Review.

40.1. Any owner of a MAT 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.

40.1.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.

40.1.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.