

**WEST VIRGINIA
SECRETARY OF STATE
NATALIE E. TENNANT
ADMINISTRATIVE LAW DIVISION**

Form #3

Do Not Mark In This Box

2012 AUG 31 PM 12:23

STATE OF WEST VIRGINIA
SECRETARY OF STATE

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

AGENCY: Health & Human Resources TITLE NUMBER: 69

CITE AUTHORITY: §9-2-6, §16-1-4; §279-1

AMENDMENT TO AN EXISTING RULE: YES NO

IF YES, SERIES NUMBER OF RULE BEING AMENDED: _____

TITLE OF RULE BEING AMENDED: _____

IF NO, SERIES NUMBER OF RULE BEING PROPOSED: 7

TITLE OF RULE BEING PROPOSED: Regulations of Opioid Treatment Programs

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.

Rocco S. Fualto

Authorized Signature

QUESTIONNAIRE

(Please include a copy of this form with each filing of your rule: Notice of Public Hearing or Comment Period; Proposed Rule, and if needed, Emergency and Modified Rule.)

DATE: August 31, 2012

TO: LEGISLATIVE RULE-MAKING REVIEW COMMITTEE

FROM: (Agency Name, Address & Phone No.) Health & Human Resources

LEGISLATIVE RULE TITLE: Regulation of Opioid Treatment Programs 69CSR7

1. Authorizing statute(s) citation WV Code §§9-2-6, 16-1-4, 27-9-1

2. a. Date filed in State Register with Notice of Hearing or Public Comment Period:
comment period began on July 31st, 2012

b. What other notice, including advertising, did you give of the hearing?
n/a

c. Date of Public Hearing(s) *or* Public Comment Period ended:
comment period ran from July 31 to August 31, 2012

d. Attach list of persons who appeared at hearing, comments received, amendments, reasons for amendments.

Attached _____ No comments received X

- e. Date you filed in State Register the agency approved proposed Legislative Rule following public hearing: (be exact)

n/a

- f. Name, title, address and phone/fax/e-mail numbers of agency person(s) to receive all *written correspondence* regarding this rule: (Please type)

DHHR, Secretary's Office
One Davis Square, Suite 100, East
Charleston, WV 25301
phone: 304 558-0684

- g. **IF DIFFERENT FROM ITEM 'f'**, please give Name, title, address and phone number(s) of agency person(s) who wrote and/or has responsibility for the contents of this rule: (Please type)

3. If the statute under which you promulgated the submitted rules requires certain findings and determinations to be made as a condition precedent to their promulgation:

- a. 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.

n/a

b. Date of hearing or comment period:

comment period ran from July 31st to August 31st 2012

c. On what date did you file in the State Register the findings and determinations required together with the reasons therefor?

n/a

d. Attach findings and determinations and reasons:

Attached n/a

69 CSR 7

Department of Health and Human Resources
Office of Health Facilities Licensure and Certification

Brief Summary

The provisions of *W.Va. Code §16-1-4* require that the Secretary of the Department of Health and Human Resources regulate and license all opioid treatment centers in this state. The rules were previously known as *Regulation of Opioid Treatment Programs*, 64 CSR 90, effective April 11, 2008. After extensive amendments to *W.Va. Code § 16-1-4* during the 2012 Legislative Session, new rules were created that repeal and replace 64 CSR 90 and reflect the required changes.

The rule establishes the administrative framework of an opioid treatment program and sets forth the requirements for ownership, staffing, operation and licensing. It specifies training criteria for medical and non-medical staff; provides minimum requirements for admission to an opioid treatment program; establishes the necessary steps for a patient to receive opioid treatment medications once admitted; and outlines the basic medical treatment, counseling and other opportunities available to a patient.

The rule requires monthly drug testing for all patients; encourages a program where the amounts of drugs provided during medication therapy are reduced over time; and establishes individualized treatment plans of care for each patient. It also requires consultation and coordination with the prescription medication database maintained by the Board of Pharmacy, periodic medical assessments and reviews, and peer review analyses.

Statement of Circumstances

This rule is being revised and will be reviewed for applicability at least every five years.

FISCAL NOTE FOR PROPOSED RULES

Rule Title: 69CSR7 - Regulation of Opioid Treatment Programs

Type of Rule: x Legislative Interpretive Procedural

Agency: Health and Human Resources

Address: One Davis Square
Suite 100 East
Charleston, WV 25301

Phone Number: 304-558-0488 Email: Rose.R.Lowther-Berman@wv.gov

Fiscal Note Summary

Summarize in a clear and concise manner what effect this measure will have on costs and revenues of state government.

This rule establishes the regulation of opioid treatment services and sets forth minimal standards for state approval of opioid treatment programs as defined in this rule. This rule governs all aspects of the regulation of opioid treatment programs, as defined by this rule, which are located in West Virginia. This rule repeals and replaces 64 CSR 90, effective April 11, 2008.

The Office of Health Facility Licensure and Certification (OHFLAC) already regulates Opioid Treatment Programs, therefore there is no fiscal impact.

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	Fiscal Year		
	2013 Increase/Decrease (use "-")	2014 Increase/Decrease (use "-")	Fiscal Year (Upon Full Implementation)
1. Estimated Total Cost	0	0	0
Personal Services			
Current Expenses			
Repairs and Alterations			
Equipment			
Other			
2. Estimated Total Revenues	0	0	0

3. Explanation of above estimates (including long-range effect):

Please include any increase or decrease in fees in your estimated total revenues.

Memorandum

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.

Date

7/31/12

Agency

Department of Health and Human Resources

Authorized Representative

[Signature]

Rocco S. Fucillo
Cabinet Secretary

TITLE 69
LEGISLATIVE RULE
DEPARTMENT OF HEALTH AND HUMAN RESOURCES
SERIES 7
REGULATION OF OPIOID TREATMENT PROGRAMS

RECEIVED
2012 AUG 31 PM 12:23SECRETARY OF HEALTH AND HUMAN RESOURCES
STATE OF WEST VIRGINIA**§69-7-1. General.**

1.1. Scope. -- This rule establishes the regulation of opioid treatment services and sets forth minimal standards for state approval of opioid treatment programs as defined in this rule.

1.2. Authority. -- W.Va. Code §9-2-6, §16-1-4 and §27-9-1.

1.3. Filing Date. --

1.4. Effective Date. --

1.5. Purpose -- This rule governs all aspects of the regulation of opioid treatment programs, as defined by this rule, which are located in West Virginia. This rule repeals and replaces 64CSR90, effective April 11, 2008.

§69-7-2. Application and Enforcement.

2.1. Application. -- This rule applies to all for-profit programs and not-for-profit programs approved by the state of West Virginia to operate as an opioid treatment program as defined in this rule. These programs are exempt from the Department of Health and Human Resources rule entitled "Behavioral Health Centers Licensure," 64CSR11, so long as the services offered remain solely those described within this rule. If additional services are provided, the opioid treatment program shall comply with all other applicable licensure laws and rules.

2.2. Enforcement. -- This rule is enforced by the Secretary of the Department of Health and Human Resources. The Secretary shall designate an office of the Department to act in his or her stead.

2.3. 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 CFR Part 8, are hereby adopted in their entirety by reference. To the extent there is a conflict between federal regulations or standards and the provisions of this rule, the more stringent standard applies.

§69-7-3. Definitions.

3.1. Accreditation -- The process of review and acceptance of an opioid treatment program by an accreditation body.

3.2. Accreditation Body -- A body approved by the Substance Abuse and Mental Health Services Administration (hereinafter SAMHSA) under 42 CFR §8.3 to accredit opioid treatment programs that use opioid treatment medications.

3.3. Accreditation Elements -- The elements or standards that are developed and adopted by an accreditation body and approved by SAMHSA.

3.4. Accreditation Survey -- An onsite review and evaluation of an opioid treatment program by an accreditation body for the purpose of determining compliance with the federal opioid treatment standards.

3.5. Addiction -- A disease characterized by the individual's pursuing reward and/or relief by substance use and/or other behaviors. Addiction is characterized by impairment in behavioral control, craving, inability to consistently abstain, and diminished recognition of significant problems with one's behaviors and interpersonal relationships; likely to involve cycles of relapse and remission.

3.6. Administrative Withdrawal -- A brief, involuntary withdrawal or administrative discharge from pharmacotherapy.

3.7. Administrator -- An individual designated by the governing body to be responsible for the day-to-day operation of the opioid treatment program.

3.8. 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, which is responsible for developing, 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.

3.9. Advanced Alcohol and Drug Abuse Counselor (AADC) -- An alcohol and drug abuse counselor that is certified by the West Virginia Certification Board for Addiction & Prevention Professionals as demonstrating a high degree of competence in the addiction counseling field.

3.10 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 opioid treatment program facility; or the potential to undermine public confidence in the opioid treatment program.

3.11. 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.

3.12. Alcohol and Drug Abuse Counselor (ADC) -- A counselor certified by the West Virginia Certification Board for Addiction & Prevention Professionals for specialized work with patients who have substance abuse problems

3.13. Approved Authorities -- Programs or authorities that publish practice or treatment guidelines, standards or protocols that the secretary has approved for use by opioid treatment 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); and any other program or authority approved by the secretary.

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

3.15. Complaint -- A verbal or written statement made by a patient, family member or community member and filed with the program administrator or a state agency alleging inadequate or inappropriate service on the part of an opioid treatment program.

3.16. Comprehensive Bio-Psychosocial Assessment -- A medical and bio-psychosocial evaluation of a patient completed within thirty days of admission that evaluates all aspects of the individual's physical, psychological and adaptive functioning.

3.17. Controlled Substances Monitoring Program Database -- The database maintained by the West Virginia Board of Pharmacy pursuant to W.Va. Code §60A-9-3 that monitors and tracks certain prescriptions written or dispensed by physicians or pharmacies in West Virginia.

3.18. Co-Occurring Disorders -- The combination of current or former substance use disorders and any other Axis I or Axis II mental disorders recognized by the *Diagnostic and Statistical Manual of Mental Disorders* (DSM-IV) published by the American Psychiatric Association.

3.19. Counseling Session -- A face-to-face interaction in a private location between a patient and a primary counselor. Counseling sessions may be private, individual sessions, with only the patient and a counselor, or group sessions, in which the counselor works with one or more patients on similar issues.

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

3.21. Detoxification Treatment -- The dispensing of an opioid treatment medication to a patient in decreasing doses to alleviate adverse physical or psychological effects incident to withdrawal from the continuous or substantial use of an opioid drug. Detoxification utilizes the process of dose tapering from maintenance medication as a method of bringing the individual to a drug-free state within a desired period of time.

3.22. Dispense -- The preparation and delivery of an opioid treatment medication in an appropriately labeled and suitable container to a patient by an opioid treatment program. For purposes of this rule, the term 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.*

3.23. Diversion Control Plan -- A required plan developed by the opioid treatment program to minimize the diversion of methadone or other medications to illicit use.

3.24. Facility -- The physical building in which an opioid treatment program is provided.

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

3.26. For-Cause Inspection – An inspection by any federal or state agency or accreditation body of an opioid treatment program that may be operating in violation of federal or state opioid treatment standards, may be providing substandard treatment or may be serving as a possible source of diverted medications.

3.27. Governing Body -- The person or persons identified as being legally responsible for the operation of the opioid treatment program. A governing body may be a board, a single entity or owner or a partnership.

3.28. Grievance -- A written or oral complaint filed by a patient with the program administrator or the state agency alleging inadequate or inappropriate treatment by the opioid treatment program.

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

3.30. Induction -- Initial treatment of an opioid addicted patient with opioid treatment medication in order to suppress signs or symptoms of withdrawal and drug cravings. Induction usually includes a gradual increase in opioid treatment medication therapy until the symptoms are regularly and reliably suppressed or controlled.

3.31. Induction Period – The period of time during which a patient receives an induction of opioid treatment medication.

3.32. Informed Consent to Treatment -- Written acknowledgement and verification by a patient stating that the patient has been informed of the advantages and disadvantages of all aspects of the treatment provided to the patient and that the patient agrees to the treatment.

3.33. Initial Assessment -- The first medical interview and initial screening of a patient that focus on the individual's eligibility or need for admission and treatment. The initial assessment provides indicators for initial dosage level should admission be determined appropriate, and forms the basis for the individualized treatment plan of care.

3.34. Interdisciplinary Team -- A representative of the medical staff of the opioid treatment program, and the patient's primary counselor, all 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.

3.35. Long-Term Detoxification Treatment – Detoxification treatment for a period more than 30 days but not in excess of 180 days.

3.36. Maintenance Dose -- The level of opioid treatment medication considered medically necessary to consistently suppress signs or symptoms of opioid withdrawal and drug cravings for individuals with opioid addiction. A maintenance dose is generally administered at the end of the induction period. The dose is individualized for each patient and may gradually change over time.

3.37. Medical Director -- The physician licensed within the state of West Virginia who assumes responsibility for administering all medical services performed by the opioid treatment program, either by

performing them directly or by delegating specific responsibility to authorized program physicians and health care professionals functioning under the medical director's direct supervision.

3.38. Medical and Rehabilitative Services – Treatment and recovery services such as medical evaluations, counseling and rehabilitative and other social programs intended to help patients in opioid treatment programs become and/or remain productive members of society.

3.39. Medical Withdrawal -- The gradual voluntary and therapeutic withdrawal of a patient from opioid replacement therapy, agreed upon by the patient and staff. Medical withdrawal may occur against medical advice.

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

3.41. Methadone -- A medication of the opioid agonist type, which can be used as replacement therapy for opioids for an addicted patient.

3.42. Opiate Addiction – A cluster of cognitive, behavioral and physiological symptoms in which the individual continues use of opiates despite significant opiate-induced problems. Opiate dependence is characterized by repeated self-administration that usually results in opiate tolerance, withdrawal symptoms and compulsive drug-taking. Dependence may occur with or without the physiological symptoms of tolerance and withdrawal.

3.43. Opioid Treatment Medication – Any medication that is approved by the United States Food and Drug Administration under section 505 of the Federal Food, Drug and Cosmetic Act, 21 USC 355, for use in the treatment of opiate addiction.

3.44. Opioid Agonists -- Substances that bind to and activate the opiate receptors resulting in analgesia and pain regulation, respiratory depression and a wide variety of behavioral changes. As used in this rule, the term "opioid agonist" does not include partial agonist medications used as an alternative to opioid agonists in the treatment of opioid addiction.

3.45. Opioid Drug -- Any drug having an addiction-forming or addiction-sustaining liability similar to morphine or being capable of conversion into a drug having such addiction-forming or addiction-sustaining liability. Opioids include heroin, morphine, codeine, Oxycontin®, oxycodone and other medications that block the transmission of pain messages to the brain.

3.46. Opioid Treatment Program ("program") -- A program or practitioner engaged in the treatment of individuals with opioid dependence through on-site administration or dispensing of an opioid treatment medication in the form of an opioid agonist or partial opioid agonist . As used in this rule, the term "opioid treatment program" does not include programs or practitioners that issue prescriptions for partial opioid agonist medications.

3.47. Opioid Treatment Services -- Treatment and services provided by an opioid treatment program that uses opioid treatment medications as a part of its treatment modality. Opioid treatment services may be provided through intensive outpatient, residential or hospital settings. Treatment may include medical maintenance, medically supervised withdrawal and detoxification, various levels of medical, psychosocial and other types of care, detoxification treatment, short-term detoxification treatment, long-term detoxification treatment and maintenance treatment.

3.48. Orientation -- The introduction of a patient to the policies and procedures of the opioid treatment program and to the theory and process of recovery-based, medication-assisted therapy.

3.49. Partial Opioid Agonist -- A medication that is used as an alternative to opioid agonists in the treatment of opioid addiction. At certain dosages, a partial agonist can both activate and block the effects of opioid medications or receptors, thereby assisting in control of opioid addiction. Partial agonists bind to the receptors and activate them, but not to the same degree as full agonists. Buprenorphine is an example of a partial opioid agonist.

3.50. Patient -- An individual consumer who undergoes treatment in an opioid treatment program.

3.51. 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. The peer review committee shall include at least one physician licensed in the state of West Virginia.

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

3.53. Physician -- An individual licensed to practice medicine by the West Virginia Board of Medicine pursuant to W.Va. Code §30-3-1, *et seq.*, or osteopathic medicine by the West Virginia Board of Osteopathy pursuant to W.Va. Code §30-14-1, *et seq.*

3.54. Physician Extender -- A medical staff person other than a physician, functioning within his or her scope of practice to provide medical services to patients admitted to opioid treatment programs. An approved physician extender must meet the requirements for his or her scope of practice and complete the certification or training programs recommended and approved by the medical director of the opioid treatment program. Physician extenders approved for employment at an opioid treatment program include advanced practice registered nurses or physician assistants. Registered nurses and licensed practical nurses are not authorized to act as physician extenders in an opioid treatment program, although they may work within the program in other capacities.

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

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

3.57. Positive Drug Test -- A test that results in the presence of any drug or substance listed in subdivision 41.2.e. of this rule or any other drug or substance prohibited by the opioid treatment 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.

3.58. Primary Counselor -- The individual designated by the opioid treatment 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.

3.59. Program Physician -- One or more physicians designated and approved by the medical director to prescribe and monitor medication-assisted treatment for patients admitted to an opioid treatment program. At least one program physician must be present or on call during all hours of operation. The medical director may serve as the program physician.

3.60. Program Sponsor -- The person named in the application for certification and licensure of an opioid treatment program who is responsible for the operation of the opioid treatment program, and who assumes responsibility for all of its employees, including any practitioners, agents or other persons providing medical, rehabilitative or counseling services at the program. The program sponsor need not be a licensed physician, but shall employ a licensed physician for the position of medical director.

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

3.62. 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.

3.63. Recovery Model -- A recovery initiative that focuses on various dimensions that support recovery from opioid addiction, including health, home, individual purpose and community relationships and services.

3.64. Relapse Prevention Plan -- A plan of action developed by a patient and his or her 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.

3.65. Secretary -- The Secretary of the West Virginia Department of Health and Human Resources or his or her designee.

3.66. Short-Term Detoxification Treatment -- Detoxification treatment for a period not in excess of 30 days.

3.67. State Authority or State Methadone Authority -- The agency or individual designated by the Governor to exercise the responsibility and authority of the state for governing the treatment of opiate addiction with an opioid drug. The state authority shall act as the state's coordinator for the development and monitoring of narcotic treatment programs and shall serve as a liaison with the appropriate federal agencies. The Bureau for Behavioral Health and Health Facilities has been designated by the Governor as the state methadone authority for the state of West Virginia.

3.68. State Oversight Agency -- The agency or office of state government identified by the secretary to provide regulatory oversight of opioid treatment programs on behalf of the state of West Virginia. The designated state oversight agency is responsible for licensing, monitoring and investigating complaints or grievances regarding opioid treatment programs. The Office of Health Facility Licensure and Certification is the agency designated by the Secretary to provide regulatory oversight on behalf of the state of West Virginia.

3.69. Substance -- Alcohol, controlled substances as defined by W.Va. Code §60A-2-208 or §60A-2-210, or anything consumed for its psychoactive effect, whether or not designed for human consumption.

3.70 Substance Abuse – The inappropriate use of any medication, alcohol or other substance that results in or contributes to the person becoming addicted to the substance contrary to accepted medical or social standards.

3.71. Substance Abuse and Mental Health Services Administration (SAMHSA) – The agency under the United States Department of Health and Human Services responsible for the accreditation and certification of opioid treatment programs and that provides leadership, resources, programs, policies, information, data, contracts and grants for the purpose of reducing the impact of substance abuse and mental or behavioral illness.

3.72. 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.

3.73. Titration – The gradual decreasing of doses of an opioid treatment medication to the point of elimination of the use of the medication in the withdrawal process.

3.74. Toxicology Screen -- Urine drug screens or other approved medical screening processes designed to monitor and evaluate the patient’s initial need for treatment and subsequent progress in treatment.

3.75. Variance -- A formal agreement between the state authority or designated oversight agency and the program that allows the program to comply with the intent of a regulatory rule, policy or standard in a manner not otherwise permitted by the rule, policy or standard. A variance may not be obtained based solely on the inability to achieve compliance.

3.76. Waiver -- A formal, time-limited agreement between the designated oversight agency and the opioid treatment program that suspends a rule, policy or standard for a specific situation so long as the health and safety of patients are better served in the situation by suspension of the rule, policy or standard than by enforcement.

§69-7-4. State Authority; Powers and Duties.

4.1. The secretary shall designate an individual or agency within the department to serve as the state authority to provide technical assistance to opioid treatment programs and the state oversight authority. The Governor has designated the Bureau for Behavioral Health and Health Facilities as the state methadone authority, as that authority is defined in this rule.

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

4.2.a. Facilitate the development and implementation of rules, regulations, standards and best practice guidelines to assure the quality of services delivered by opioid treatment programs;

4.2.b. Act as a liaison between relevant state and federal agencies;

4.2.c. Review opioid treatment guidelines, rules, regulations and recovery models for individualized treatment plans of care developed by the federal government and other nationally recognized authorities approved by the secretary;

4.2.d. Assure delivery of technical assistance and informational materials to opioid treatment programs as needed;

4.2.e. Perform both scheduled and unscheduled site visits to opioid treatment programs in cooperation with the identified state oversight office when necessary and appropriate;

4.2.f. Consult with the federal government regarding approval or disapproval of requests for exceptions to federal regulations, where appropriate;

4.2.g. Review and approve exceptions to federal and state dosage policies and procedures;

4.2.h. Receive and refer patient appeals and grievances to the designated state oversight agency when appropriate; and

4.2.i. Work cooperatively with other relevant state agencies to determine the services needed and the location of a proposed opioid treatment program.

§69-7-5. State Oversight Agency.

5.1. The secretary has designated the Office of Health Facility Licensure and Certification within the Department of Health and Human Resources to act as the state oversight agency, as that agency is defined in this rule. The Office of Health Facility Licensure and Certification shall provide regulatory oversight, licensing and inspection of opioid treatment programs.

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

5.2.a. Develop and implement rules, regulations, standards and best practice guidelines regarding the licensure and oversight of opioid treatment programs;

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

5.2.c. Issue initial, amended and renewed licenses to an opioid treatment program upon a determination that the program is qualified;

5.2.d. Perform both scheduled and unscheduled site visits to opioid treatment programs when necessary and appropriate;

5.2.e. Monitor the activities of all opioid treatment programs to ensure compliance with all state and federal requirements;

5.2.f. Receive and act upon patient complaints, appeals and grievances;

5.2.g. Inspect all allegations of misconduct, rule or regulation violations, unauthorized activities or other conduct that may affect the health, safety or well-being of patients or employees of an opioid treatment program;

5.2.h. Assist an opioid treatment program in developing a plan of improvement in order to correct any noted violations or deficiencies;

5.2.i. Revoke or suspend the license of an opioid treatment program in accordance with the applicable administrative proceedings; and

5.2.j. Perform all other necessary actions related to the licensing, monitoring, investigatory and oversight of opioid treatment programs.

§69-7-6. Certification, Approval and Exemptions.

6.1. Unless otherwise exempted by this rule, all individuals or other entities operating as an opioid treatment program shall meet the requirements of applicable federal and state statutes, rules and regulations; shall be approved by the state authority and shall be appropriately licensed by the designated state oversight agency. In particular, in order to be eligible for licensure, an opioid treatment program shall comply with all federal regulations, provisions and standards contained in "Certification of Opioid Treatment Programs," 42 CFR Part 8, as amended.

6.2. Hospitals that are licensed under "Hospital Licensure," 64CSR12, and behavioral health facilities that are licensed under "Behavioral Health Centers Licensure," 64CSR11, and which provide opioid treatment services as defined in this rule are subject to the provisions of this rule and to all other relevant federal and state licensing requirements as specified by the secretary.

6.3. An opioid treatment 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.

6.4. Federal agencies operating opioid treatment programs may agree to cooperate voluntarily with state agencies regarding visits or inspections of federal facilities and an exchange of reports.

§69-7-7. Licensure, Fees and Costs.

7.1. Before establishing, operating, maintaining or advertising a opioid treatment program within the state of West Virginia, an opioid treatment program shall:

7.1.a. Hold current, valid certification from the Substance Abuse and Mental Health Services Administration (SAMHSA);

7.1.b. Be registered and qualified by the United States Department of Health and Human Services under the Controlled Substances Act to dispense opioid drugs in the treatment of opioid addiction;

7.1.c. Be approved by the state authority for operation of an opioid treatment program in this state;

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

7.1.e. Obtain from the secretary a license authorizing the operation of the opioid treatment program and facility.

7.2. License Application.

7.2.a. The program sponsor of an opioid treatment program shall submit an application for an opioid treatment program license to the secretary not less than thirty days and not more than 60 days prior to the anticipated initiation of services.

7.2.b. All applications for an initial or renewed license shall include the following:

7.2.b.1. The name and address of the program sponsor;

7.2.b.2. The name and address of the opioid treatment program;

7.2.b.3. The service location and office or offices operated by the program;

7.2.b.4. Documentation of all current federal accreditations, certifications and authorizations;

7.2.b.5. A description of the organizational structure of the opioid treatment program, including identification of the governing body, the advisory council and peer review committee; and

7.2.b.6. The applicable filing fee.

7.3. License Fees and Inspection Costs.

7.3.a. All applications for an initial or renewed license shall be accompanied by a non-refundable license 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 and renewal fees are as follows:

7.3.a.1. Initial license fee - \$250;

7.3.a.2. Renewal fee - fewer than 500 patients - \$250 plus adjustment;

7.3.a.3. Renewal fee - 500 to 1,000 patients - \$500 plus adjustment;

7.3.a.4. Renewal fee - more than 1,000 patients - \$750 plus adjustment.

7.3.b. An opioid treatment program shall pay for the cost of the initial inspection made by the secretary prior to issuing a license. The cost of the initial inspection is \$400, and shall be billed to the applicant by the secretary within five business days after the inspection. The cost of the initial inspection must be paid in full by the applicant before a license may be issued.

7.4. Initial Inspection and Issuance of License.

7.4.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 opioid treatment program and facility in order to determine whether the program has satisfied all of the federal and state requirements for licensure.

7.4.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 sponsor of the deficiencies. The program sponsor may submit one or more written plans of correction demonstrating compliance with the corrections required. The secretary may conduct follow-up inspections if required.

7.4.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 subdivision 7.3.b. of this section, the secretary shall issue a license in one of three categories:

7.4.c.1. An initial license, valid for six 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.

7.4.c.2. A provisional license shall be issued when a program seeks a renewal license and is not in substantial compliance with this rule but does not pose a significant risk to the rights, health and safety of a patient. A provisional license expires not more than six months from date of issuance, and shall be consecutively reissued only upon action of the secretary, unless the provisional recommendation is that of the state fire marshal.

7.4.c.3. A renewal license shall be issued when an opioid treatment program is in substantial compliance with this rule and expires not more than one year from date of issuance.

7.4.d. A license is valid for the opioid treatment program named in the application and is not transferable.

7.5. Denial of License.

7.5.a. The secretary may deny an application for an initial or renewed license if:

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

7.5.a.2. The opioid treatment program will not be or is not operated in accordance with federal or state opioid treatment standards;

7.5.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 relevant records or information; or

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

7.5.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.

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

7.5.d. An opioid treatment program may protest the denial of a new or renewed license pursuant to the administrative procedures included in this rule.

7.6. Renewed or Amended Licenses.

7.6.a. The program manager of an opioid treatment program shall submit an application for a renewed license to the secretary not less than sixty 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.

7.6.b. The program sponsor shall notify the secretary thirty 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.

7.7. Administrative Due Process.

7.7.a. Any person aggrieved by an order or other action by the secretary based on this rule may request in writing a hearing by the secretary.

7.7.b All hearings shall be conducted in accordance with the Department of Health and Human Resources rule, "Rules of Procedure for Contested Case Hearings and Declaratory Rulings," 64CSR1, a copy of which may be obtained from the Secretary of State.

§69-7-8. Facility Construction or Renovations.

8.1. Before construction or extensive renovation of an opioid treatment program facility begins, the program sponsor 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.

8.2. The secretary shall advise the program sponsor whether approval has been granted within ten working days from the date of receipt of the plans. 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 sponsor the opportunity to correct any deficiencies. Construction or extensive renovation of a facility may not begin until the secretary has issued final approval of the plans.

8.3. All opioid treatment program facilities shall comply with the current standards of the Americans with Disabilities Act of 1990, as amended.

8.4. All opioid treatment program facilities must meet all other requirements of applicable federal or state regulatory or oversight agencies.

§69-7-9. Annual Inspections.

9.1. 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.

9.2. 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 authority when they become available.

9.3. 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:

9.3.a. Observation of service delivery;

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

9.3.c. Review of clinical and administrative records;

9.3.d. Interviews with patients, with patient consent, staff and administrators; and

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

9.4. The opioid treatment program shall comply with any reasonable requests from the secretary to have access to the service, staff, patients (with their permission), 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.

9.5. Within ten 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.

9.6. 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.

§69-7-10. For-Cause Inspections; Complaints.

10.1. The secretary may at any time inspect an opioid treatment 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 opioid treatment standards; may be providing substandard treatment; or may be serving as a possible source of diverted medications.

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

10.3. The secretary may conduct unannounced inspections of an opioid treatment program named in a complaint and any other investigations deemed necessary to determine the validity of a complaint.

10.4. At the time of any on-site investigation activities, the investigator shall notify the program sponsor or administrator of the general reason for the investigation.

10.5. Within ten 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.

10.6. The secretary may permit the opioid treatment 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 program in order to assist with a plan of correction.

10.7. The secretary may take disciplinary measures, impose a fine, 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 opioid treatment program is a threat to the health, welfare and safety of its patients or employees, the secretary may issue an order immediately closing the facility pursuant to applicable administrative procedures.

10.8. The secretary shall provide to the complainant a description of any corrective action the opioid treatment program is required to take and of any disciplinary action the secretary may take.

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

10.10. 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.

10.11. The secretary may suspend or revoke a license of an opioid treatment program for violating the prohibitions of this section.

§69-7-11. Plans of Correction.

11.1. Within ten 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 variance is requested by the opioid treatment program and granted by the secretary. The plan of correction shall specify:

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

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

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

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

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

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

11.5. The opioid treatment program shall immediately correct a violation that severely risks the health or safety of a patient or other persons.

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

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

§69-7-12. Waivers and Variances.

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

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

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

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

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

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

§69-7-13. Penalties.

13.1. The secretary may deny any application for licensure or licensure renewal as an opioid treatment program; revoke or suspend a license; and/or order an admissions ban or reduction in patient census for one or more of the following reasons:

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

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

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

13.1.d. The opioid treatment program has failed or refused to submit reports or make records available as requested by the secretary; or

13.1.e. An opioid treatment program has refused to provide access to its location or records as requested by the secretary.

13.2. If a license for an opioid treatment program has been revoked, the secretary may stay the effective date of the revocation if the program can show that the stay is necessary to ensure appropriate referral and placement of patients.

§69-7-14. Reports and Records.

14.1. Inspection Reports.

14.1.a. The secretary shall keep on file a report of any inspection, survey or investigation of an opioid treatment 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.

14.2.a. The opioid treatment program shall submit statistical reports to the secretary on reporting dates established by the secretary. The reporting dates shall be at least semi-annual.

14.2.b. Within ninety days of the reporting dates established by the secretary the opioid treatment program shall file a statistical report with the secretary which includes the following information:

14.2.b.1. The total number of patients;

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

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

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

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

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

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

14.2.b.6.B. Completion of a program of detoxification;

14.2.b.6.C. Voluntary withdrawal prior to completion of all requirements of detoxification as determined by the opioid treatment program;

14.2.b.6.D. Successful completion of the individualized treatment plan of care of care; or

14.2.b.6.E. An unexplained reason;

14.2.b.7. Statistics demonstrating program compliance with the random drug testing requirements of subdivision 16.2.a. of this rule;

14.2.b.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.b.9. Confirmation that the random drug tests were performed at least monthly for all program participants;

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

14.2.b.11. The number of expulsions from the opioid treatment program.

§69-7-15. Administrative Organization of Opioid Treatment Programs.

15.1. Each opioid treatment program shall identify a program sponsor, a governing body, an administrator, an advisory council and a peer review committee.

15.2. Program Sponsor.

15.2.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 opioid treatment medications in the treatment of opioid addiction.

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

15.2.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.

15.3. Governing Body.

15.3.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.

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

15.4. Program Administrator.

15.4.a. The administrator of the opioid treatment program shall have at minimum a bachelor's degree in an appropriate area of study and a minimum of four years of experience in the field of substance abuse or a master's degree in an appropriate professional area of study and a minimum of four years of experience in the field of behavioral health.

15.4.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, and the laws and rules of the State of West Virginia.

15.4.c. Duties of the administrator include:

15.4.c.1. Development of policies and procedures for operation of the facility;

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

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

15.4.c.4. Protection of patient rights;

15.4.c.5. Conformity of the program with federal confidentiality regulations, namely, 42 CFR Part 2;

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

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

15.4.c.8. Implementation of governing body policy; and

15.4.c.9. Communication with the governing body.

15.5. Advisory Council.

15.5.a. Each opioid treatment program shall have an advisory council comprised of a designated group of 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 and/or advocates.

15.5.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.

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

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

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

15.5.c.3. Review administrative discharges quarterly;

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

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

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

15.5.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.

15.6. Peer Review Committee.

15.6.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, preferably with documented training and experience in the field of addiction treatment.

15.6.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 twenty (20) randomly chosen active clinical files. The survey shall be documented on a form approved by the secretary.

15.6.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.

15.6.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.

15.6.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.

§69-7-16. Medication Security.

16.1. Each opioid treatment program shall have 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. The policies and procedures shall include measures that:

16.1.a. Ensure responsible handling and secure storage of all medications kept at the facility.

16.1.b. Ensure responsible documentation of all medications received, stored, administered and dispensed at the facility.

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

16.2. Each opioid treatment program shall have 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:

16.2.a. Ensure responsible handling and secure storage of take-home medication in child-proof and tamper-resistant containers.

16.2.b. Require each patient to demonstrate the ability to provide secure storage for take-home medications.

16.2.c. Inform patients of their rights and responsibilities in writing in ensuring the security of opioid medications.

16.3. The opioid treatment program shall establish policies and procedures for monitoring medications to prevent diversion. The policies and procedures may include random call backs of individuals with more than one week of take-home dosage, required clinic attendance, random toxicology screens and random medication counts.

16.3.a. All patients shall undergo random toxicology screens at least monthly.

16.3.b. Frequency of call backs, random toxicology screens and medication counts shall be individually determined for each patient by the interdisciplinary team.

§69-7-17. Facility and Clinical Environment.

17.1. 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.

17.2. Each opioid treatment program facility shall have:

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

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

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

17.2.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;

17.2.e. Sanitary and secure dosing areas;

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

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

17.3. 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.

§69-7-18. Staffing.

18.1. Medical Director.

18.1.a. Each opioid treatment program shall have a designated medical director. The medical director shall be a physician licensed to practice medicine or osteopathy in the state of West Virginia and shall have either:

18.1.a.1. Demonstrated experience in opioid treatment; or

18.1.a.2. A written plan to attain competence in opioid treatment within a probationary time period as provided in subdivision 18.1.b of this section.

18.1.b. The medical director may submit a written plan to attain competence in opioid treatment to the state authority for approval at least two weeks (14 days) prior to employment at an opioid treatment program.

18.1.b.1. The time frame for completion of the plan may not exceed twelve 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.

18.1.b.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 opioid treatment.

18.1.b.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 physician and the supervised physician.

18.1.b.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 is also responsible for ensuring that the plan of development is completed within the approved time lines.

18.1.b.5. The state 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.

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

18.1.c.1. All opioid treatment decisions;

18.1.c.2. Operation of all medical aspects of the treatment program;

18.1.c.3. Administration and supervision of all medical services;

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

18.1.c.5. Obtaining and maintaining his or her continuing medical education in the field of addiction on a documented and ongoing basis;

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

18.1.c.7. Determining the ability of the program physicians or physician extenders to work independently within the applicable scope of practice.

18.2 Professional Medical Staff.

18.2.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 and 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 advanced practice registered nurses and physician's assistants as physician extenders.

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

18.2.b.1. A minimum of one year's experience in opioid treatment settings; or

18.2.b.2. Active enrollment in a plan of education for obtaining competence in opioid treatment methods and addiction 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.

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

18.2.d. During all hours of operation when medication is being administered, every opioid treatment program shall have present and on duty at the facility at least one of the following actively-licensed health care professionals:

18.2.d.1. Physician assistant;

18.2.d.2. Advanced practice registered nurse;

18.2.d.3. Registered nurse; or

18.2.d.4. Licensed practical nurse operating within his or her scope of practice.

18.2.e. Plans of Education.

18.2.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.

18.2.e.2. The program sponsor or the 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; ensure that completion of any plan of education is documented and maintained in the personnel files; and ensure that the medical director monitors and certifies satisfactory completion of each plan of education.

18.2.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. The affidavit shall be maintained in the personnel file of each professional medical staff person who has completed a plan of education.

18.3. Counseling Staff.

18.3.a. Counseling through an opioid treatment program shall be provided by a program counselor who is qualified by education, training or experience to assess the psychological and sociological background of patients, to contribute to the appropriate treatment plan for the patient and to monitor patient progress.

18.3.b. As long as medication is not being administered a mental health professional or a health care professional, as identified in subdivision 18.2.d. of this section, shall be present and on duty at the opioid treatment center to provide counseling during all hours of operation. The opioid treatment program shall assign a primary counselor to each patient.

18.3.c. Any counselor employed by an opioid treatment program shall have one or more of the following qualifications:

18.3.c.1. A bachelor's degree and either licensure or certification as a social worker, or certification as an addiction counselor;

18.3.c.2. A graduate degree with either licensure and certification in the individual's chosen field or as an addiction counselor;

18.3.c.3. Certification as an addiction counselor;

18.3.c.4. A bachelor's degree in a relevant human services field, practicing under the supervision of an advanced alcohol and drug counselor (AADC); Provided, that the individual practicing with a bachelor's degree under supervision applies for certification as an alcohol and drug counselor within three years of the date of employment as a counselor; or

18.3.c.5. An advanced degree and actively working towards licensure or certification in a chosen field under the supervision of a licensed or certified professional in that field and/or under the supervision of an AADC.

18.3.d. Each opioid treatment program's policy and procedures shall establish ratios of primary counselors to persons served that are adequate to allow sessions to occur as mandated and will allow persons served access to a primary counselor.

18.3.e. An opioid treatment program shall employ or retain an AADC to supervise unlicensed and/or uncertified counselors in the core competencies required by an applicable certification board. At a minimum, the supervisor shall provide at least one hour of supervision per twenty hours of direct service. Supervision may be group in nature, but must consist of case consultation and discussion and/or clinical training rather than administrative oversight.

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

18.3.g. 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 twenty hours and consisting of, at a minimum, the following:

18.3.g.1. Addiction overview;

18.3.g.2. Opioid treatment, detoxification protocols, recovery models and basic pharmacology and dosing;

18.3.g.3. Characteristics of the opioid dependent population;

18.3.g.4. Toxicology screening and observation of sample collection;

18.3.g.5. Program policy and procedure;

18.3.g.6. Confrontation, de-escalation and anger management;

18.3.g.7. Cultural sensitivity as necessary and appropriate;

18.3.g.8. Current strategies for identifying and treating alcohol, cocaine and other drug abuse;

18.3.g.9. Identification of co-occurring behavioral health or developmental disorders; and

18.3.g.10. Other clinical issues as appropriate for the population served.

18.3.h. An experienced counselor newly employed from another opioid treatment program may request an exemption from the mandatory initial training required by this rule. The administrator of the opioid treatment program shall document in the personnel file any exemption granted and the basis for the exemption.

18.3.i. Counselors with less than one year of full time experience in the field of opioid treatment shall accompany an experienced counselor at all times for a minimum of two weeks (14 days) before seeing persons served without immediate and constant supervision.

18.4. Unlicensed Clinical Staff and Volunteers.

18.4.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 policies and procedures which specify the roles and responsibilities of each unlicensed employee and volunteers. 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.

18.4.a.1. All employees and volunteers shall be screened through criminal and protective services background checks prior to being hired or permitted on the premises of an opioid treatment program facility. No person who has a history of one or more convictions for a felony crime may be an employee or volunteer of an opioid treatment program.

18.4.a.2. An opioid treatment program may apply to the secretary for a written waiver of employment restrictions on a case-by-case basis. The secretary, in his or her sole discretion, may waive any employment restriction if the circumstances appear reasonable and just in accordance with subdivision 19.6.g of this rule.

18.4.b. An opioid treatment program shall designate a supervisor for each separate service or program. A supervisor may be responsible for more than one program. All unlicensed clinical staff and volunteers shall receive regular supervision and be provided with assistance, directions for activity and support.

§69-7-19. Staff Training and Credentialing.

19.1. Each opioid treatment program shall ensure that all doctors, physician assistants, advanced practice registered nurses, licensed practical nurses, counselors 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 and these rules.

19.2. Clinical staff of an opioid treatment program may include employees and/or independent contractors. 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 facility, the patient populations to be served and is consistent with the requirements of

applicable federal or state laws, rules, regulations or guidelines. Documentation of all completed education and training courses or programs shall be maintained in the personnel file of each staff member or volunteer.

19.3. Each opioid treatment 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's job description or responsibilities.

19.4. Within ten days of the date any new clinical staff member or volunteer begins working at an opioid treatment 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 facility. Documentation of the completed orientation and confidentiality training shall be included in the personnel file of each staff member or volunteer.

19.5. The opioid treatment program shall ensure that all policies and procedures regarding employment practices, training and credentialing are consistent with federal and state statutes, rules and regulations.

19.6. Each opioid treatment program shall maintain confidential individual personnel files for every clinical staff member or volunteer. The files shall be secured in a confidential manner with limited access. Personnel files shall contain, at a minimum:

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

19.6.b. Documentation of the date of employment;

19.6.c. Identifying information and emergency contacts;

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

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

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

19.6.g. Detailed job descriptions; and

19.6.h. Evidence that the opioid treatment program has determined that the employee, independent contractor or volunteer has never been convicted of a felony and/or documentation of a waiver from the state authority allowing the program to employ an individual with a history of a felony conviction.

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

§69-7-20. Risk Management.

20.1. Each opioid treatment program shall:

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

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

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

20.1.d. Inform each patient that:

20.1.d.1. The goal of medication assisted therapy is recovery, stabilization of functioning and establishment of a drug-free lifestyle;

20.1.d.2. Detoxification from opioids over thirty to one hundred eighty days is a treatment alternative to an ongoing, recovery-oriented plan of care, and that under the detoxification protocol:

20.1.d.2.A. The strength of maintenance doses of methadone should decrease over time;

20.1.d.2.B. The detoxification treatment should be limited to a defined period of time; and

20.1.d.2.C. The participant is required to work towards a drug-free lifestyle;

20.1.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

20.1.d.4. A patient may choose to withdraw from or be maintained on the medication as he or she desires unless medically contraindicated in accordance with the patient's plan of care.

20.2. Each opioid treatment 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.

20.3. Each opioid treatment program shall inform every patient as to federal confidentiality regulations (42 CFR Part 2) and the Health Insurance Portability and Accountability Act of 1996, as amended.

20.4. Each opioid treatment program shall:

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

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

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

§69-7-21. Life Safety Policies and Procedures.

21.1. Each opioid treatment program shall develop and maintain policies and procedures regarding the appropriate and safe administration of medications and other medical treatment. The policies and procedures shall:

21.1.a. 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;

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

21.1.c. Ensure that there is appropriately trained staff on duty at all times who are proficient in cardiopulmonary resuscitation and management of opiate overdose; and

21.1.d. Ensure that each opioid treatment medication used by the opioid treatment program is administered and dispensed 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.

21.2. Each opioid treatment program shall develop and maintain policies and procedures regarding safe and effective access to the facility and staff. The policies and procedures shall:

21.2.a. Provide twenty-four hour, seven day per week access to designated program staff so that patient emergencies may be immediately addressed and dosage levels verified;

21.2.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;

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

21.2.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.

§69-7-22. Continuous Quality Improvement Policies, Diversion Control Plan.

22.1. Each opioid treatment program shall maintain current quality assurance and quality control plans that include provisions for:

22.1.a. Regular and continuous staff education;

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

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

22.1.d. Development and implementation of annual patient satisfaction surveys that include a review of patient satisfaction with operating hours and pricing of services;

22.1.e. Adherence to universal infection control precautions promulgated by the Center for Disease Control; and

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

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

22.1.f.2. Reduction or elimination of associated criminal activities;

22.1.f.3. Reduction of the patient's behaviors contributing to the spread of infectious diseases; and

22.1.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.

22.2. The opioid treatment 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.

22.3. An opioid treatment 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 opioid treatment program for carrying out the diversion control measures and functions described in the DCP.

22.3.a. The diversion control plan shall be reviewed and approved by the governing body, advisory council, peer review council and the state authority.

22.3.b. Diversion control plans shall minimize the diversion of methadone or other opioid treatment medications to illicit use. The plan shall include:

22.3.b.1. Clinical and administrative continuous monitoring of the potential for and actual diversion of medications, including an investigation, tracking and monitoring system of incidents of diversion; and

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

§69-7-23. Incident Reporting and Adverse Events.

23.1. Each opioid treatment program shall develop policies and procedures for comprehensively documenting, investigating, taking corrective action and tracking instances of adverse events or incidents.

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

23.2.a. Immediate threat to the care or safety of an individual, whether it be a staff member, visitor or patient;

23.2.b. The possibility of serious operational or personnel problems; or

23.2.c. The potential to undermine public confidence in the treatment program.

23.3. The adverse events or incidents may include:

23.3.a. Agency medication errors;

23.3.b. Potentially lethal patient suicide attempts;

23.3.c. Patient deaths;

23.3.d. Harm to family members or others from ingesting a patient's medication;

23.3.e. Selling drugs on the premises;

23.3.f. Medication diversion;

23.3.g. Harassment or abuse of patients by staff; or

23.3.h. Violence.

23.4. Adverse events or incidents shall be reviewed on a quarterly basis by the advisory council which may choose to make recommendations to the administration or the governing body regarding improvements in the process to prevent further incidents.

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

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

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

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

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

23.6. The opioid treatment program shall report any death involving drug overdose or drug-related complications to the state authority and the state oversight agency within forty-eight hours of the program receiving notification of the mortality.

§69-7-24. Patient Rights.

24.1. Each opioid treatment program shall have policies and procedures which guarantee the following rights to patients:

24.1.a. The patient has the right to be informed, both verbally and in writing, of clinic 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;

24.1.b. The patient shall receive treatment provided in a fair and impartial manner regardless of race, sex, age, sexual orientation and/or religion;

24.1.c. The patient shall 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;

24.1.d. The patient shall 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;

24.1.e. The patient shall be informed that random drug testing of all patients shall be conducted during the course of treatment at least monthly or as deemed necessary by the opioid treatment program, 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 test result;

24.1.f. The patient shall be entitled to participate in an opioid treatment program that provides an adequate number of competent, qualified and experienced professional staff to implement and supervise the individualized treatment plan of care;

24.1.g. The patient shall 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;

24.1.h. The patient shall be informed about the financial aspects of treatment, including the consequences of nonpayment of required fees;

24.1.i. The patient shall 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 program based upon the results of the initial assessment;

24.1.j. 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;

24.1.k. The patient has the right to confidentiality in accordance with federal regulations, 42 CFR Part 2, and the Health Insurance Portability and Accountability Act of 1996, as amended;

24.1.l. The patient has the right 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;

24.1.m. The patient has the right to give informed consent prior to being involved in research projects and the right to retain a copy of the informed consent form; and

24.1.n. The patient has the right 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.

24.2. The program shall have patient grievance procedures which shall be displayed in the patient care area. The procedures should be published, posted 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:

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

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

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

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

24.3. 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.

§69-7-25. Patient Records.

25.1. Each opioid treatment 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 drugs approved for use in treatment of opioid addiction.

25.2. 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 eighteen years.

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

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

25.5. Information in the patient medical records shall be entered only by physicians and other licensed health professionals. Entries shall be legible and organized in an effective manner, allowing materials to be easily retrieved.

25.6. Opioid treatment program procedures should ensure security of all records including electronic records, if any.

25.7. Individual patient records shall contain:

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

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

25.7.c. An initial assessment report;

25.7.d. A narrative bio-psychosocial history completed within thirty days of the patient's admission;

25.7.e. Medical reports including results of the physical examination; past and family medical history; review of systems; laboratory reports, including results of required toxicology screens; results obtained from the Controlled Substances Monitoring Program database; and progress notes, including documentation of current dose and other dosage data;

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

25.7.g. Dates and results of case conferences for patients;

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

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

25.7.j. 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 toxicology screens; results from the Controlled Substances Monitoring Program database); documentation of whether the patient was offered or accepted a detoxification treatment plan option; or any other significant change in treatment, both positive and negative;

25.7.k. Documentation that the opioid treatment program made a good faith effort to review whether the patient is enrolled in any other opioid treatment program;

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

25.7.m. 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 were discussed with the patient;

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

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

§69-7-26. Admissions Committee.

26.1. 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.

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

26.3. Exceptions to the admission criteria include, but are not limited to:

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

26.3.b. Circumstances where a physician did not observe or interview the patient at all.

26.4. 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 authority or other monitoring body upon request.

§69-7-27. Pre-Admission Assessment; Admission Criteria.

27.1 Each opioid treatment program shall maintain current 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.

27.2. Any person seeking admittance to the opioid treatment program shall undergo a pre-admission initial assessment in order to determine whether the person meets the criteria for admission to an opioid treatment program. The initial assessment, consisting of a physical examination 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 Diagnostic and Statistical Manual for Mental disorders (DSM-IV).

27.3. The initial physical examination shall include documentation of:

27.3.a. A brief physical examination;

27.3.b. The patient's immediately relevant health history (e.g., 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);

27.3.c. A determination of currently prescribed medications;

27.3.d. An evaluation of other substances of abuse;

27.3.e. Determination of current opioid dependence;

27.3.f. Determination of length of addiction;

27.3.g. A toxicology screen to determine immediate use of opiates;

27.3.h. An initial drug test and full toxicology screen to identify whether the patient is using other drugs, including opiates, methadone, amphetamines, cocaine, barbiturates, benzodiazepines, marijuana or other drugs or substances as determined by community standards, regional variation or clinical indication (e.g., carisopodol) to determine whether the individual is opioid addicted and to determine whether the patient is presently receiving methadone for an opioid addiction from another opioid treatment program;

27.3.i. An inquiry to and report from the Controlled Substances Monitoring Program; and

27.3.j. An inquiry whether the patient is enrolled in any other opioid treatment program.

27.4. The person desiring admission for treatment through the use of an opioid treatment medication must be at least eighteen years of age. Exceptions may be made on extremely rare occasions by application to the state authority.

27.5. All admissions shall include documentation regarding medical necessity and program eligibility for opioid treatment that includes:

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

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

27.5.c. Evidence of an onset of opioid physical dependence of at least one year prior to admission with continuous use the greater part of the year; or

27.5.d. Evidence of multiple and daily self-administration of an opioid.

27.6. The following behavioral signs which support the diagnosis of opioid addiction shall be discussed and documented, although none are considered required for admission:

27.6.a. Unsuccessful efforts to control use;

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

27.6.c. Continual use despite harmful consequences;

27.6.d. Obtaining opiates illegally;

27.6.e. Inappropriate use of prescribed opiates;

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

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

27.6.h. One or more unsuccessful attempts at gradual removal of physical dependence on opioids (detoxification) using methadone or other appropriate medications.

27.7. 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 opioid addiction, leading to high-risk behaviors with potentially life threatening consequences.

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

27.8.a. The person is currently addicted to an opioid drug, as evidenced by a positive test for either opioids or methadone, and the person became addicted at least one year before admission for treatment;

27.8.b. There are objective symptoms of withdrawal, or

27.8.c. There is objective evidence that the individual qualifies under the provisions of subsection 27.9 of this section.

27.9. Admission to the opioid treatment program may be allowed to the following groups with a high risk of relapse without the necessity of a positive test or the presence of objective symptoms:

27.9.a. The person is a pregnant woman with a history of opioid abuse;

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

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

27.9.d. The person is an HIV patient with a history of intravenous drug use.

27.10. A patient enrolled in an opioid treatment program shall not be permitted to obtain treatment in any other opioid treatment program except in exceptional circumstances and only as provided in section 28 of this rules.

27.11. 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:

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

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

27.11.c. Has completed a plan of development.

27.12. 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 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.

27.13. The program physician or physician extender shall review the accumulated data directly with the individual and confirm a diagnosis of opioid addiction of sufficient severity to warrant admission to the opioid treatment 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.

27.14. The program physician shall ensure that each patient voluntarily chooses maintenance treatment and that all relevant facts concerning the use of opioid treatment drugs are clearly and adequately explained to the patient. The program physician shall ensure that each newly admitted patient provides informed written consent to treatment.

27.15. 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.

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

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

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

§69-7-28. Multiple Program Enrollments.

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

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

28.1.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 opioid treatment program in which the patient is enrolled and at the opioid treatment program that provides the additional treatment.

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

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

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

§69-7-29. Orientation.

29.1. Every person admitted to an opioid treatment 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 at the time the decision is made to admit the patient, regardless of his or her condition.

29.2. Orientation shall include the following:

29.2.a. An explanation of the rights and responsibilities of the patient;

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

29.2.c. An explanation of the services and activities provided by the opioid treatment program, including:

29.2.c.1. Expectations and rules;

29.2.c.2. Hours of operation;

29.2.c.3. Access to after-hour services;

29.2.c.4. Confidentiality policy;

29.2.c.5. Toxicological screening and random testing policies;

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

29.2.c.7. Interventions;

29.2.c.8. Incentives; and

29.2.c.9. Various discharge criteria;

29.2.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;

29.2.e. An explanation of any and all financial obligations of the patient, all fees charged by the opioid treatment program, and any financial arrangements for services provided by the opioid treatment program;

29.2.f. Familiarization with the opioid treatment programs facility and premises;

29.2.g. A description of the opioid treatment program's policies regarding:

29.2.g.1. Use of alcohol on or prior to entering the premises;

29.2.g.2. Smoking;

29.2.g.3. Illicit or licit drugs brought into the program; and

29.2.g.4. Weapons brought into the program;

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

29.2.i. A copy of the opioid treatment program rules identifying the following:

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

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

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

29.2.j. An explanation of the purpose and process of the initial and subsequent medical and psychological assessments;

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

29.2.l. An explanation of alternative methods that are available for treatment of opioid addiction, whether offered by the program or not, and the potential benefits, risks and costs of each treatment.

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

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

29.3.b. A formal agreement of informed consent to be signed by the patient and a copy retained by him or her;

29.3.c. Patient's rights;

29.3.d. Confidentiality policies;

29.3.e. The program's processes for dispensing medication; and

29.3.f. Information on alternative methods available for treatment of opioid addiction and the potential benefits, risks and costs of each treatment. The state authority is responsible for providing informational materials to be used in discussing alternative treatments.

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

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

29.4.b. The nature of addictive disorders including the great likelihood that addiction is a relapsing disease and is likely to have grave medical and social consequences if not treated on an ongoing basis;

29.4.c. The anticipated benefits of treatment;

29.4.d. The nature of the recovery process;

29.4.e. HIV spectrum and other infectious diseases;

29.4.f. Potential drug interactions;

29.4.g. Self-help groups, if any are available;

29.4.h. Medical issues related to detoxification from opioid treatment medications;

29.4.i. The special risk of withdrawal from methadone and detoxification to pregnant women and the fetus (as appropriate);

29.4.j. Characteristics of the medications administered and/or prescribed by the program;

29.4.k. Drug safety issues;

29.4.l. Dispensing procedures; and

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

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

§69-7-30. Required Services.

30.1. Each opioid treatment program shall provide adequate medical, counseling, vocational, educational, recovery and other assessment and treatment services. These services must be available at the primary facility and the program sponsor or administrator must be able to document that these services are fully and reasonably available to patients.

30.2. Each opioid treatment program shall require every patient to undergo a complete, fully documented physical evaluation by a program physician or a primary care physician, or an authorized health care professional under the supervision of a program physician, before admission to the opioid treatment program. The full medical examination, including the results of serology and other tests, must be completed within fourteen days following admission.

30.3. Each patient accepted for treatment at an opioid treatment program shall be assessed 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.

30.4. Within seven days of the admission of a patient, the opioid treatment program shall complete a post-admission initial assessment and an initial individualized treatment plan of care.

30.5. Random drug testing of all patients shall be conducted during the course of treatment at least monthly. Each opioid treatment program must provide adequate testing or analysis for drugs of abuse in accordance with generally accepted clinical practice.

30.6. Each opioid treatment program must provide adequate substance abuse counseling to each patient as clinically necessary and at the minimum levels as required by subsection 31.8. of this rule. Counseling shall be provided by a program counselor, who is 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.

30.7. Each opioid treatment 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 opioid treatment program or by referral to appropriate healthcare providers. Services rendered to pregnant patients shall comply with the requirements of section 44 of this rule.

30.8. Each opioid treatment program must provide counseling on preventing exposure to, and the transmission of, human immunodeficiency virus (HIV) disease 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 44 of this rule.

30.9. Services provided by an opioid treatment 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 addiction 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.

§69-7-31. Counseling.

31.1. Each opioid treatment program shall provide substance abuse counseling to every patient as is clinically necessary. Counseling sessions should encourage and guide the patient to a lifestyle that that does not include abuse of prescribed or illicit medications, drugs or other substances.

31.2. The counseling shall be provided by a counselor, who is qualified by education, training or experience 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. 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 and/or destructive behaviors.

31.3. The primary counselor is responsible for assisting the patient in altering life styles 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 and/or destructive behaviors.

31.4. Each opioid treatment program shall provide counseling on matters indirectly related to substance addiction including, but not limited to:

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

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

31.5. Each opioid treatment program shall develop and implement policies which ensure that single sex groups and/or same sex counselors will be available to all patients, as needed and clinically indicated.

31.6. Each opioid treatment 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.

31.7. Ratios of primary counselor to persons served shall be adequate to allow sessions to occur as described in this section and to allow persons served access to their primary counselor if more frequent contact is merited by need or is requested by the patient. The ratio of individual and group therapy sessions must be individually determined by the specific needs of the patient. The clinical staff caseload ratio shall:

31.7.a. Reflect an appropriate clinical mix of sex, race and ethnicity representatives of the population served;

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

31.7.c. Allow for regularly scheduled, documented individual counseling sessions.

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

31.8.a. At least weekly during the first ninety days of treatment;

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

31.8.c. At least monthly thereafter.

31.9. The counseling program shall provide for mandatory and documented weekly counseling of any patient who has a positive drug test and is required by §41.3 of this rule to undergo additional counseling. The counseling sessions shall be no less than thirty minutes to a patient with a counselor who is licensed, certified or enrolled in the process of obtaining licensure 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.

31.10. Exceptions to frequency of counselor to patient contact shall be clearly justified by program documentation. The program physician or prescribing professional 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.

§69-7-32. Post-Admission Assessment and Initial Plan of Care.

32.1. Upon admission to an opioid treatment program, each patient shall undergo an initial post-admission assessment and the opioid treatment 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.

32.2. Post Admission Assessment.

32.2.a. The initial post-admission assessment shall consist of a comprehensive medical evaluation, which shall include, but not be limited to:

32.2.a.1. A comprehensive physical evaluation;

32.2.a.2. A comprehensive psychiatric evaluation, including mental status examination and psychiatric history;

32.2.a.3. A personal and family medical history;

32.2.a.4. A comprehensive history of substance abuse, both personal and family;

32.2.a.5. A tuberculosis skin test and chest X-ray, if skin test is positive;

32.2.a.6. A screening test for syphilis; and

32.2.a.7. Other tests as necessary or appropriate (e.g., CBC, EKG, chest X-ray, pap smear, hepatitis B surface antigen and hepatitis B antibody, HIV testing).

32.2.b.. A repeat, full toxicology screen may be completed at fourteen days after admission to identify whether the patient is using other drugs or substances, including opiates, methadone, amphetamines, cocaine, barbiturates, benzodiazepines and marijuana.

32.2.c. The initial post-admission assessment may include laboratory tests conducted by the opioid treatment program or by other reliable sources.

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

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

32.2.c.3. Tests not directly conducted by the opioid treatment program at admission shall have been conducted within the ninety days prior to admission in order to be considered a valid assessment of the patient.

32.3. Initial Individualized Treatment Plan of Care.

32.3.a. Within seven days of the admission of a patient, the opioid treatment program, in conjunction with the patient, shall develop an initial individualized treatment plan of care. Whenever possible and with patient permission, the development process shall include a non-addicted family member or significant other to assist in provision of accurate information and a full understanding and retention of instructions given to the patient.

32.3.b. The initial individualized treatment plan of care shall include:

32.3.b.1. Completion of program orientation;

32.3.b.2. Ongoing education regarding addiction, HIV/AIDS, hepatitis and communicable diseases;

32.3.b.3. Consistent program attendance, both for dosing and counseling sessions;

32.3.b.4. Elimination of withdrawal symptoms and opioid craving;

32.3.b.5. Cessation of illicit drug use; and

32.3.b.6. Resolution of other issues unique to the needs of the individual.

§69-7-33. Comprehensive Bio-Psychosocial Evaluation.

33.1. Within thirty days after admission, or when the patient is stable and able to fully participate, the program shall complete a full bio-psycho-social evaluation which shall be used to develop the long-term plan of care. The bio-psycho-social evaluation shall integrate information obtained in the comprehensive medical evaluation.

33.2. The bio-psycho-social evaluation shall include information obtained from:

33.2.a. The patient;

33.2.b. Family members, when applicable or permitted;

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

33.2.d. Other appropriate and permitted collateral sources.

33.3. The bio-psycho-social evaluation shall include information about the person's:

33.3.a. Personal strengths;

33.3.b. Individualized needs;

33.3.c. Abilities and/or interests;

33.3.d. Presenting problems, including a thorough analysis of the individual's addictive behaviors 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 addictive behaviors; adverse consequences of use; inappropriate use of prescribed substances; and urgent needs, including suicide risk;

33.3.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;

33.3.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;

33.3.g. Use of alcohol and tobacco;

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

33.3.i. Risk-taking behaviors;

33.3.j. Level of educational functioning;

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

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

33.3.m. Adjustment to disabilities/disorders; and

33.3.n. Motivation for treatment.

33.4. The patient's counselor shall review the bio-psychosocial assessment and prepare a concise, interpretive multidisciplinary summary that:

33.4.a. Is based on the assessment data;

33.4.b. Describes and evaluates the level and severity of the individual's addictive behaviors;

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

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

§69-7-34. Individualized Treatment Plan of Care.

34.1. Within thirty days after admission of a patient, the opioid treatment 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 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.

34.2. The individualized treatment plan of care shall be reviewed by the patient and staff at least each ninety days. Reviews shall be written and detailed. The quarterly review shall address each of the objectives identified on the initial individualized treatment plan of care; document all treatment, counseling, medications and other services rendered to the patient; and document the patient's progress towards recovery.

34.3 The initial and quarterly individualized treatment plans of care shall be developed by the patient and the patient's counselor, with input as appropriate from medical staff. 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.

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

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

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

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

- 34.4.d. The development and use of coping strategies for each “trigger”;
- 34.4.e. The development of a detailed relapse prevention plan;
- 34.4.f. Meaningful follow-up on any identified behavioral health issues;
- 34.4.g. Follow-up on medical or physical issues as necessary;
- 34.4.h. A vocational evaluation, formal or informal;
- 34.4.i. A plan to achieve financial stability and independence;
- 34.4.j. A requirement that the patient abstain from use of illicit substances or abuse of prescription substances;
- 34.4.k. Documentation of other individual or familial issues as relevant and appropriate and the proposed means of addressing such issues;
- 34.4.l. The success of the patient’s treatment, initiatives and goals;
- 34.4.m. The results from initial, monthly and random drug tests; and
- 34.4.n. Such other information as recommended by the guidelines and recovery model utilized for the patient.

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

34.6. Each opioid treatment 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.

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

34.7.a. Opioid treatment 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.

34.7.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.

34.7.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 methadone should decrease over time, the treatment will be limited to a defined period of time and that the participant is required to work toward a drug-free lifestyle.

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

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

34.7.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.

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

§69-7-35. Documentation of Patient Contact.

35.1. The primary counselor or medical staff is responsible for documentation of significant contact with each patient, which shall be filed in the patient's record.

35.2. The documentation shall include a description of:

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

35.2.b. The patient's current condition;

35.2.c. Significant events occurring since prior contact;

35.2.d. The assessment of patient status; and

35.2.e. A plan for action or further treatment.

35.3. Each entry shall be completed within twenty-four hours of the contact and shall be clearly dated and initialed or signed by the staff person involved.

§69-7-36. Medication Storage, Administration and Documentation.

36.1. Each opioid treatment program shall have policies and procedures consistent with the United States Drug Enforcement Administration's statutes and regulations regarding the storage, administration and documentation of medications.

36.2. Administration of Medications.

36.2.a. The policies and procedures of an opioid treatment program shall require all personnel dispensing opioid agonists to adhere to federal and state laws, rules and to protocols and guidelines from approved authorities.

36.2.b. Each opioid treatment program shall calibrate medication dispensing instruments consistent with the manufacturer's recommendations to ensure accurate patient dosing and substance tracking.

36.2.c. Each opioid treatment program shall ensure that opioid 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 opioid drugs.

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

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

36.3. Each opioid treatment program shall maintain current procedures adequate to ensure that all opioid 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.

36.4. Documentation.

36.4.a. Each opioid treatment program is responsible for proper documentation of medications stored, administered or dispensed.

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

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

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

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

36.4.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 methadone in stock at all times.

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

36.4.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.

36.4.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.

36.5. Patient Meetings and Screening.

36.5.a. Each opioid treatment program shall have the capability of obtaining medication blood levels when clinically indicated through random drug testing of all patients and on a required monthly basis.

36.5.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 eight to twelve substances, including the substance prescribed by the program.

36.5.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 for follow-up medical and drug screenings, if required, and to discuss the possibility of consideration of titration of medications.

36.5.d. In addition to the meetings and screenings required by subdivision 36.5.c. of this subsection, the program physician, approved physician extender or a registered nurse shall meet with the patient at least every six months for further follow-up medical and drug screenings, if required, and to discuss the patient's current status or condition, treatment and any related issues.

36.5.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.

36.6. Approved Medications.

36.6.a. An opioid treatment program shall use only those opioid 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 opioid addiction.

36.6.b. The state authority is responsible for development of 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 opioid treatment program is responsible for remaining in conformity with practice guidelines as issued or approved by the state authority.

36.7. Dosage.

36.7.a. Each opioid treatment 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.

36.7.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.

36.7.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 to 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.

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

36.7.d.1. Cessation of withdrawal symptoms;

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

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

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

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

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

36.7.e.1. Prevent the onset of subjective and/or objective signs of opioid abstinence syndrome for twenty-four hours or more;

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

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

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

36.8. Methadone.

36.8.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.

36.8.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.

36.8.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.

§69-7-37. Unsupervised Take-Home Medications.

37.1. Each opioid treatment program shall have 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 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 not create unnecessary barriers for patients continuing in treatment.

37.2. 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. An opioid treatment 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.

37.3. All opioid treatment 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 clinics may be closed.

37.4. 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.

37.5. In determining which patients may be permitted unsupervised use of medications, the physician shall consider the following criteria in determining whether a patient is responsible in handling opioid drugs for unsupervised use:

37.5.a. Cessation of illicit drug use;

37.5.b. Absence of recent abuse of drugs (opioid or non-narcotic), including alcohol;

37.5.c. Regularity of clinic attendance;

37.5.d. Absence of serious behavioral problems at the program;

- 37.5.e. Absence of known recent criminal activity, including drug dealing;
- 37.5.f. Stability of the patient's home environment and social relationships;
- 37.5.g. The length of time the patient has been in medication-assisted maintenance treatment;
- 37.5.h. Assurance that take-home medication can be safely stored within the patient's home;
- 37.5.i. Whether the rehabilitative benefit the patient derives from decreasing the frequency of clinic attendance outweighs the potential risks of diversion;
- 37.5.j. The ability of the patient to responsibly self-medicate;
- 37.5.k. Other special needs of the patient, such as split dosing, physical health needs, pain treatment, etc.;
- 37.5.l. Patient's work, school, or other daily-life activity schedule; and
- 37.5.m. Hardship experienced by the patient in traveling to and from the program.
- 37.6. 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.
- 37.7. Each opioid treatment program shall maintain current procedures adequate to identify the theft or diversion of take-home medications, including labeling containers with the opioid treatment 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.
- 37.8. 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 plans 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:
- 37.8.a. During the first 90-day period of treatment, no take-home doses shall be permitted during the first thirty 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;
- 37.8.b. In the second 90-day period of treatment, the take-home supply is limited to two (2) doses per week;
- 37.8.c. In the third 90-day period of treatment, the take-home supply is limited to three (3) doses per week;
- 37.8.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;

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

37.8.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 opioid treatment program.

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

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

37.11. Patients participating in the unsupervised take-home medication plan are subject to the provisions of §41 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 reduction of medication or a discharge from the program.

37.12. 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 opioid treatment program, included in the patient records and be made available for review by regulatory bodies.

37.13. Guest dosing at a nearby clinic is preferred whenever possible and shall be documented in the patient's chart and individualized treatment plan of care. Each opioid treatment program shall have policies and procedures that address the transfer of patients from one opioid treatment clinic to another.

37.14. The state authority may approve exceptional unsupervised-medication dosages, including alternative medications, on a case-by-case basis upon application for an exemption by the program physician. Any authorization for exceptions shall be consistent with guidelines and protocols of approved authorities.

§69-7-38. Detoxification Program.

38.1. In addition to recovery-oriented opioid treatment services, each opioid treatment program shall provide both long-term and short-term detoxification recovery treatment services. The program physician or a physician extender shall provide onsite medical supervision and oversight of the detoxification treatment program.

38.2. 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.

38.3. Patients with two or more unsuccessful detoxification episodes within a one year period must be assessed by the opioid treatment program physician for other forms of treatment. A program shall not admit a patient for more than two detoxification treatment episodes in one year.

38.4. 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 acknowledgment that under the detoxification protocol the strength of maintenance doses of methadone should decrease over time; that the treatment should be limited to a defined period of time in accordance with national guidelines; and that the patient is required to work toward a drug-free lifestyle.

38.5. The estimated time of time of titration 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 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 of care and chart.

38.6. The program physician shall determine on an individualized basis the appropriate dosage of opioid 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.

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

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

38.9 The opioid treatment program shall have a policy regarding recovery-oriented detoxification treatment from opioid treatment medication that shall include:

38.9.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;

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

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

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

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

38.10. The opioid treatment 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 opioid treatment program shall have cooperative agreements with the criminal justice system to encourage detoxification treatment services to persons who are incarcerated or on probation and/or parole and are required to become abstinent.

38.11. Short-Term Detoxification Treatment Services.

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

38.11.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 opioid treatment 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.

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

38.12. Long-Term Detoxification Treatment Services.

38.12.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.

38.12.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.

38.12.c. In a detoxification program of more than 30days' duration, the opioid treatment 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:

38.12.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 opioid treatment program to be closed, two doses may be allowed;

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

38.12.c.3. Three unsupervised doses per week during the third 90 days of treatment; and

38.12.c.4. A maximum 6 day supply of take-home medication in the remaining months of the first year of treatment.

38.13. Counseling services.

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

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

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

38.13.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.

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

38.13.c. For a patient projected to be involved in detoxification treatment services for six months or less, the opioid treatment 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.

§69-7-39. Administrative Withdrawal.

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

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

39.2.a. Non-payment of fees. The opioid treatment 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;

39.2.b. Disruptive conduct or behavior considered to have an adverse effect on the program, 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, and/or flagrant noncompliance resulting in an observable, negative impact on the program, staff and other patients; and

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

39.3. The opioid treatment 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.

§69-7-40. Medical Withdrawal.

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

40.2. The opioid treatment program shall supply a schedule of dose reduction well tolerated by the patient.

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

40.4. If the patient leaves the opioid treatment program abruptly against medical advice, the program may readmit the patient within 30 days without a formal reassessment procedure. The program shall document attempting to assist the patient in any issues which may have triggered his or her abrupt departure.

40.5. The opioid treatment 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.

40.6. Female patients shall have a negative pregnancy screen prior to the onset of either administrative or medically-supervised withdrawal.

40.7. For either withdrawal, 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.

§69-7-41. Toxicology Screens.

41.1. All patients in the opioid treatment program shall undergo monthly drug testing. Random drug testing of all patients shall be conducted during the course of treatment at least monthly.

41.2. Collection and Testing.

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

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

41.2.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.

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

41.2.d.1. A patient receiving methadone maintenance services must have at least twelve random drug screens per year. The patient shall be tested upon admission; at approximately fourteen days

of treatment; and then monthly through the remainder of the time the patient remains in the treatment program;

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

41.2.d.3. When using urine as a screening mechanism, if patient behavior or need indicates to the staff that observation is necessary, the opioid treatment program may collect observed specimens on an unannounced basis. Collection shall be done in a manner that assures respect for the patient and minimizes the chance of adulterating or substituting another individual's urine.

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

41.2.e.1. Opiates including oxycodone at common levels of dosing;

41.2.e.2. Methadone or any other medication used by the program as an intervention for that patient;

41.2.e.3. Benzodiazepines (including testing procedures that detect diazepam, clonazepam, alprazolam and lorazepam);

41.2.e.4. Cocaine;

41.2.e.5. Meth-amphetamine/ amphetamines;

41.2.e.6. Tetrahydrocannabinol, delta-9-tetrahydrocannabinol, dronabinol or other similar substances; or

41.2.e.7 Other drugs or substances as determined by community standards, regional variation or clinical indication, such as carisoprodol or barbiturates.

41.2.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.

41.2.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 .02 Blood Alcohol Content (BAC). The individual may return to the clinic for dosing during the same day if the breathalyzer results reach acceptable limits.

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

41.2.i. Each opioid treatment program shall ensure that physicians demonstrate competence in 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.

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

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

41.2.j.2. The prescribing physician is aware that the patient is enrolled in an opioid treatment program.

41.2.k. If a patient refuses the release of information to contact his or her physician but can produce prescriptions and/or other evidence of legitimate prescription (such as current medication bottles, 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 medication-assisted treatment. The program physician shall make the ultimate decision as to the patient's continuing care in the clinic and the circumstances of that care.

41.2.l. Nothing contained in this rule shall preclude any opioid treatment program from administering any additional drug tests it determines are necessary.

41.3. Test Results

41.3.a. A positive test is a test that results in the presence of any drug or substance listed in subdivision 41.2.e of this rule, or any other drug or substance prohibited by the opioid treatment 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.

41.3.b. A positive drug test result after the first six months in an opioid treatment program shall result in the following:

41.3.b.1. Upon the first positive drug test result, the opioid treatment program shall:

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

41.3.b.1.B. Immediately revoke the take-home methadone privilege for a minimum of thirty days;

41.3.b.2. Upon a second positive drug test result within six months of a previous positive drug test result, the opioid treatment program shall:

41.3.b.2.A. Provide mandatory and documented weekly counseling to the patient of no less than thirty minutes, which shall include weekly meetings with a counselor who is licensed, certified or enrolled in the process of obtaining licensure or certification in compliance with the rules on staff at the opioid treatment program;

41.3.b.2.B Immediately revoke the take-home methadone privilege for a minimum of sixty days; and

41.3.b.2.C. Provide mandatory documented treatment interdisciplinary team meetings with the patient.

41.3.b.3. Upon a third positive drug test result within a period of six months the opioid treatment program shall:

41.3.b.3.A. Provide mandatory and documented weekly counseling to the patient of no less than thirty minutes, which shall include weekly meetings with a counselor who is licensed, certified, or enrolled in the process of obtaining licensure or certification in compliance with the rules on staff at the opioid treatment program;

41.3.b.3.B Immediately revoke the take-home methadone privilege for a minimum of one hundred twenty days; and

41.3.b.3.C Provide mandatory and documented treatment 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;

41.3.b.4. Upon a fourth positive drug test within a six month period, the patient shall be immediately discharged from the opioid treatment program, or, at the option of the patient, shall immediately be provided the opportunity to participate in a 21-day detoxification plan, followed by immediate discharge from the opioid treatment program. Testing positive solely for tetrahydrocannabinol, delta-9-tetrahydrocannabinol, dronabinol or similar substances shall not serve as a basis for discharge from the program.

41.3.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 methadone 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.

41.3.d. Absence of methadone prescribed by the program for the patient is evidence of possible medication diversion. Whenever there is evidence of possible medication diversion, the patient shall be re-evaluated by the physician and interdisciplinary team and the individualized treatment plan of care shall be adjusted, if needed, accordingly.

§69-7-42. Controlled Substances Monitoring Program Database.

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

42.2. Program physicians shall access the database:

42.2.a. At the patient's intake;

42.2.b. Before the administration of methadone or other treatment in an opioid treatment program;

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

42.2.d. Prior to any take-home medication being granted;

42.2.e. After any positive drug test; and

4.2.f. At each 90 day treatment review.

42.3. The 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.

§69-7-43. Concurrent Alcohol and Polysubstance Abuse.

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

43.2. The opioid treatment program shall ensure that its staff is fully trained and knowledgeable regarding current effective strategies for treating alcohol, cocaine and other drug abuse.

43.3. 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.

43.4. Each opioid treatment 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.

§69-7-44. Special Populations.

44.1. Behavioral Health Needs.

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

44.1.b. At all phases of treatment, the opioid treatment program shall monitor patients during detoxification withdrawal and recovery for indications of symptoms of behavioral illness.

44.1.c. Each opioid treatment program shall establish linkages with behavioral health providers in the community.

44.1.d. Each opioid treatment 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.

44.2. HIV Patients.

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

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

44.3. Pain Patients.

44.3.a. Each opioid treatment program shall ensure that physicians practicing at the facility are knowledgeable in the management of opioid dependence 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.

44.3.b. Each opioid treatment program shall ensure continuity of care and communication between programs or physicians regarding patients receiving treatment in both an opioid treatment 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.

44.4. Criminal Justice.

44.4.a. Each opioid treatment program shall establish agreements and develop procedures to coordinate with agents of the criminal justice system on behalf of patients insofar as permitted by patient confidentiality requirements.

44.5. Pregnant Patients.

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

44.5.b. The opioid treatment 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.

44.5.c. If not available elsewhere, the program shall offer a 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.

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

44.5.d.1. If clinically appropriate, maintain patients who become pregnant during treatment on the pre-pregnancy dosage, if effective, and apply the same dosing principles as used with any other non-pregnant patient;

44.5.d.2. Ensure that the initial methadone 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;

44.5.d.3. Monitor the dose carefully, moving rapidly to supply increased or split dose if it becomes necessary; and

44.5.d.4. If a pregnant patient elects to withdraw from methadone, ensure that withdrawal is not initiated by the clinic before fourteen weeks and after thirty-two weeks gestation; perform regular fetal assessments as appropriate for fetal age; and require that withdrawal is supervised by a physician experienced in addiction medicine.

44.5.e. The opioid treatment program shall ensure appropriate referral for follow-up and primary care for the mother and infant.

44.5.f. If a pregnant patient is discharged, the opioid treatment program shall identify the physician to whom the patient is being discharged and this information shall be retained in the clinical record.

44.5.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 the training.

44.5.h. The program shall offer reproductive health education to all patients and appropriate referrals for contraceptive services as necessary.