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OFFICE WEST VIRGINIA
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NOTICE OF RULE MODIFICATION OF A PROPOSED RULE

AGENCY: ~~Office of~~ Health ~~Facility Licensure and Certification~~ TITLE NUMBER: 64

CITE AUTHORITY: W. Va. Code 16-1-4 & 27-9-1

AMENDMENT TO AN EXISTING RULE: YES ___ NO X

IF YES, SERIES NUMBER OF RULE BEING AMENDED: _____

TITLE OF RULE BEING AMENDED: _____

IF NO, SERIES NUMBER OF RULE BEING PROPOSED: 90

TITLE OF RULE BEING PROPOSED: Regulations of Opiod Treatment Programs

THE ABOVE PROPOSED LEGISLATIVE RULES, FOLLOWING REVIEW BY THE LEGISLATIVE RULE MAKING REVIEW COMMITTEE, IS HEREBY MODIFIED AS A RESULT OF REVIEW AND COMMENT BY THE LEGISLATIVE RULE MAKING REVIEW COMMITTEE. THE ATTACHED MODIFICATIONS ARE FILED WITH THE SECRETARY OF STATE.

Martha Yeager Walker 12-21-05
Authorized Signature

$10.80

TITLE 64
LEGISLATIVE RULES
DIVISION OF HEALTH
DEPARTMENT OF HEALTH AND HUMAN RESOURCES
SERIES 90
REGULATION OF OPIOID TREATMENT PROGRAMS

§64-90-1. General.

1.1. Scope. -- This rule establishes a mechanism for regulating the provision of opioid treatment services and sets forth minimal standards for State approval of opioid treatment providers.

1.2. Authority. -- W. Va. Code §§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 in West Virginia.

§64-90-2. 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 provide opioid treatment services. These programs are exempt from Division of Health rule, "Behavioral Health Centers Licensure," 64CSR11, as long as the services offered remain solely those described within this rule. If additional services are provided, the opioid treatment program shall comply with 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, "Certification of Opioid Treatment Programs," 42 CFR 8, are hereby adopted in their entirety by reference: Provided, That to the extent there is a conflict between federal regulations or standards and the standards set forth in this rule, the more stringent standard applies.

§64-90-3. Definitions.

3.1. Administrative Withdrawal. -- An involuntary withdrawal or administrative discharge from pharmacotherapy, usually relatively brief.

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

3.3. Admissions Committee. -- A committee consisting of program administrator or his or her designee, the medical director or his or her designee and a senior counselor. The purpose of the committee is to review and track exceptions to program admissions policies and procedures.

3.4. Adverse Event or Incident. -- An event involving immediate threat to the care or safety of an individual, either staff or patient; or the possibility of serious operational or personnel problems; or the

potential to undermine public confidence in the treatment program.

3.5. Advisory Council. -- A designated group of individuals representative of staff, patients and the community appointed to serve in a non-managerial advisory capacity to the governing body.

3.6. Complaint. -- A verbal or written statement made by a patient, family member or community member alleging inadequate or inappropriate service on the part of the program, typically filed either with the program or a state agency.

3.7. Comprehensive Biopsychosocial Assessment. -- A medical and biopsychosocial evaluation of a patient completed within thirty days of admission, evaluating all aspects of the individual's physical, psychological and adaptive functioning.

3.8. Designated State Oversight Agency. -- The agency or office of state government identified by the secretary to provide regulatory oversight on behalf of the state of West Virginia; responsible for licensing, monitoring and investigating complaints or grievances regarding opioid treatment programs.

3.9. Detoxification. -- The dispensing of an opioid agonist treatment medication in decreasing doses to the patient to alleviate adverse physical or psychological effects incident to withdrawal from the continuous or substantial use of an opioid drug and as a method of bringing the patient to a drug-free state.

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

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

3.12. Grievance. -- A written or oral complaint filed by a patient alleging inadequate or inappropriate treatment by the program.

3.13. Induction. -- Initial treatment of an opioid addicted patient with opioid agonists in order to suppress signs or symptoms of withdrawal and drug cravings; usually referring to gradual increase in agonist therapy until the symptoms are regularly and reliably suppressed or controlled.

3.14. Informed Consent to Treatment. -- Written verification that the patient has been informed of the advantages and disadvantages of aspects of the treatment provided to a patient and that the patient agrees to the treatment.

3.15. Initial Assessment. -- The first medical and brief psychosocial interview or interviews with a patient that focus on the individual's eligibility or need for treatment and provides indicators for initial dosage level should admission be determined appropriate.

3.16. Initial Plan of Care. -- The treatment plan developed in conjunction with the patient describing the proposed focuses of efforts by staff and the patient to

stabilize the patient and suppress the signs or symptoms of withdrawal from opioids during the first thirty days of program participation.

3.17. Interdisciplinary Team. -- The patient, a representative of medical staff and the primary counselor; it may include family members if desired by the patient. It's purpose is to approve and coordinate the plan of care for the patient.

3.18. Maintenance Dose. -- The level of opioid replacement therapy considered to consistently suppress signs or symptoms of withdrawal and drug cravings for individuals with opioid addiction; it usually represents the end of the induction period. It is individualized for each patient and may gradually change over time.

3.19. Medical Director. -- The physician licensed within the state of West Virginia identified as having authority over and responsibility for all medical aspects of the treatment process.

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

3.21. Medication-Assisted Treatment. -- The use of medications in conjunction with a clinical program of services such as individual and family therapy to treat individuals with addictions to opioids.

3.22. Methadone. -- An opioid agonist used as replacement therapy for opioids in the addicted patient.

3.23. Opioid Addiction. -- Compulsive seeking and use of prescription or illicit narcotics in spite of negative physical and/or personal consequences.

3.24. 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.

3.25. Opioid Treatment Program. -- Programs licensed by the state of West Virginia and certified by the United States Drug Enforcement Administration and Substance Abuse and Mental Health Services Administration to provide medication-assisted therapy for individuals addicted to opioids.

3.26. Opioids. -- A class of medication or drugs used to deal with pain; they are sometimes referred to as narcotics; they include morphine, codeine, oxycontin/oxycodone, heroin and others; they operate by blocking the transmission of pain messages to the brain. Chronic use can result in addiction or physical dependence.

3.27. Orientation. -- The introduction of the patient to the policies and procedures of the opioid treatment program and to the theory and process of medication-assisted therapy.

3.28. Patient. -- The person served; consumer; patient; the individual receiving treatment.

3.29. Physician. – An individual licensed to practice medicine under W.Va. Code §30-3-1 et seq by the West Virginia Board of Medicine or under W.Va. Code

§30-14-1 et seq by the West Virginia Board of Osteopathy.

3.30. Physician Extender. -- Medical staff person other than a physician, functioning within his or her scope of practice to provide medical services to the patient. An approved physician extender has met the requirements for his or her scope of practice and has completed the training program recommended and approved by the medical director. Licensed practical nurses are excluded from consideration as physician extenders although they may work within the program in other capacities.

3.31. Plan of Care. – The treatment plan developed and coordinated by the interdisciplinary team; it follows the completion of the initial plan of care, usually after thirty days; it is reviewed at regular intervals, no less than every ninety days.

3.32. Plan of Correction. -- The written description of the actions the program intends to take to correct and prevent the reoccurrence of violations of rule and regulation identified by the designated state oversight agency during a survey or complaint investigation.

3.33. Plan of Education. -- The approved continuing education plan for the physician, counselor or physician extender to attain competence in the field of opioid treatment.

3.34. Primary Counselor. -- The individual designated by the program to serve as the patient's consultant and advisor on a regular basis; a member of the patient's interdisciplinary team.

3.35. Program Physician. -- A physician designated and approved by the medical director to prescribe and monitor medication-assisted treatment for individuals with opioid addiction. The medical director may serve as the program physician.

3.36. Relapse Prevention Plan. -- A plan of action developed by the patient in conjunction with the counselor to help the patient to deal with situations or environmental stimuli that were previously associated with abuse of opioids or other inappropriate substances.

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

3.38. State Authority/State Methadone Authority. -- The individual designated as the state's coordinator for the development and monitoring of narcotic treatment programs; the individual serves as a liaison with the appropriate federal agencies.

3.39. Take-Home Medication. -- Medication provided for unsupervised use based upon the patient's demonstrated compliance with the plan of care; it must be recommended by the primary counselor and approved by the medical director or program physician.

3.40. 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.

3.41. 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 requirement in a manner not permitted by the wording of the requirement; it may not be obtained based solely on the inability to achieve compliance.

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

§64-90-4. State Administrative Procedures.

4.1. General Licensure Provisions

4.1.a. Before establishing, operating, maintaining or advertising a medically-based opioid treatment program within the state of West Virginia, a program shall first obtain from the secretary a license authorizing the operation.

4.1.b. If the secretary determines not to issue a license, the secretary shall notify the applicant.

4.1.c. A license is valid for the program named in the application and is not transferable.

4.1.d. A program shall surrender an expired or otherwise invalid license to the secretary upon written demand.

4.2. License Application.

4.2.a. An application shall identify the service location and office or offices operated by the program.

4.2.b. A program shall submit an initial application to the secretary not less than thirty days and not more than sixty days prior to the initiation of services.

4.2.c. A program shall submit a renewal application to the secretary not less than sixty days prior to the expiration of the current license.

4.2.d. A program shall submit an amended application to the secretary if there is a change in the geographic location of a service or program.

4.2.e. An application for an initial or renewal license shall identify the governing body.

4.2.f. Applications for an initial or renewal license shall be accompanied by a non-refundable licensure fee in the following amounts:

4.2.f.1. Initial licensure fees shall be set at $250;

4.2.f.2. Programs with an average daily total census of fewer than five hundred patients shall remit a fee of $250 for each annual renewal;

4.2.f.3. Programs with an average daily total census of five hundred to one thousand patients shall remit a fee of $500 for each annual renewal;

4.2.f.4. Programs with an average daily total census of more than one thousand patients shall remit a fee of $750 for each annual renewal; and

4.2.f.5. The annual fee shall be adjusted on June 1st of each year to correspond with increases in the consumer price index.

4.2.g. After the secretary receives a complete application with required fee for a renewal license, the existing license shall not expire until the new license has been issued or denied.

4.3. Issuance.

4.3.a. The secretary shall make an inspection prior to the issuance of an initial, renewal or provisional license.

4.3.b. Following an application review and an onsite inspection or inspections with approval of subsequent plans of correction as needed, the secretary shall, if there is substantial compliance with this rule, issue a license in one of three categories:

4.3.b.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;

4.3.b.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. It 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; or

4.3.b.3. A renewal license shall be issued when a program is in substantial compliance with this rule and expires not more than one year from date of issuance.

4.4. License Amendment.

4.4.a. The program shall notify the secretary thirty days prior to a change in the name or substantial nature of the program and shall apply for a license amendment.

4.5. Waiver.

4.5.a. The secretary may grant a waiver or variance to the provisions of this rule if its application 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. The secretary may provide consultation in obtaining compliance with this rule.

§64-90-5. Governance.

5.1. Before construction or extensive renovation begins, an applicant shall submit to the secretary for approval a complete set of drawings and specifications for the architectural, structural and mechanical work.

5.2. All extensively renovated and new structures shall meet the standards of the Americans with Disabilities Act of 1990.

§64-90-6. Health and Safety.

6.1. To carry out the intent of this rule,

the secretary shall require inspections by authorized representatives.

6.2. Inspections shall include, but are not limited to:

6.2.a. Observation of service delivery;

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

6.2.c. Review of clinical and administrative records; and

6.2.d. Interviews with patients, with their consent, staff and administrators.

6.3. Each licensed program shall be inspected annually. All programs shall be accredited as required by the federal agency responsible for oversight of opioid treatment programs. The program shall submit a copy of the results of the accreditation survey to the secretary and to the state authority when they become available.

6.4. The program shall comply with any reasonable requests from the secretary to have access to the service, staff, patients (with their permission) and records of the operation of the program or services provided to patients.

6.5. Within ten working days of completion of an inspection, the secretary shall issue a report.

6.6. Based upon a program's previous substantial compliance with this rule, an onsite inspection is not always required for issuance of an amended license.

§64-90-7. Complaint Investigation.

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

7.2. The secretary may conduct unannounced inspections of programs involved in a complaint proceeding and any other investigations necessary to determine the validity of a complaint.

7.3. At the time of the investigation, the investigator shall notify the administrator of the reason for the complaint.

7.4. Within ten working days of the investigation, the secretary shall provide to the program a written report of the results of the investigation along with any violations.

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

7.6. 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.

7.7. 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.

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

§64-90-8. Reports and Records.

8.1. The secretary shall keep on file a report of any inspection or investigation.

8.2. A report shall specify the deficiency and the provision of the rule it violates.

8.3. Information in reports or records shall be available to the public except:

8.3.a. As specified in this section regarding complaint investigations;

8.3.b. If it is information of a personal nature from a patient or personnel file; or

8.3.c. If it is information required to be kept confidential by state or federal law.

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

§64-90-9. Plans of Correction.

9.1. Within ten working days after receipt of the inspection report, the program 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 program and granted by the secretary. The plan shall specify:

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

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

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

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

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

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

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

9.6. The secretary shall determine if corrections have been made.

§64-90-10. Waivers and Variances.

10.1. The secretary may grant any waivers or variances to requirements of this rule as long as:

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

10.1.b. The waiver or variance is written, approved by the secretary, and

reviewed at least annually by the designated state oversight agency.

§64-90-11. Penalties.

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

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

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

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

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

11.1.e. A program has refused to provide access to its location or records as requested by the secretary.

11.2. If a license 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.

§64-90-12. Administrative Due Process.

12.1. 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 in accordance with the Division of Health rule, "Rules of Procedure for Contested Case Hearings and Declaratory Rulings," 64CSR1, a copy of which may be obtained from the secretary of State.

§64-90-13. Designation of State Authority and Powers and Duties of State Authority.

13.1. The secretary shall designate an individual or agency within the department to serve as the state authority to facilitate oversight and technical assistance to opioid treatment programs.

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

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

13.2.b. Acting as a liaison between relevant State and federal agencies;

13.2.c. Reviewing opioid treatment guidelines and regulations developed by the federal government;

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

13.2.e. Performing both scheduled and unscheduled site visits to opioid treatment programs in cooperation with the identified state oversight office when

necessary and appropriate;

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

13.2.g. Reviewing and approving exceptions to federal and state dosage policies and procedures;

13.2.h. Receiving and referring patient appeals and grievances to the designated state oversight agency when appropriate; and

13.2.i. Working cooperatively with other relevant state agencies to determine the service need in the location of a proposed program.

§64-90-14. Federal Certification, Approval by State Authority and State Licensure.

14.1. All individuals or other entities providing medically-based opioid treatment services shall be approved by the state authority and appropriately licensed by the designated state oversight agency of the state of West Virginia: Provided, That physicians certified by the Substance Abuse and Mental Health Services Administration to provide opioid treatment in a private arena with approved medications are not required to be approved by the state authority.

14.2. The designated state oversight agency and state authority shall evaluate each program applying to provide opioid treatment services to assure that the program is in compliance with applicable state and federal standards

14.3. In order to be eligible for licensure, an opioid treatment program shall comply with all regulations, provisions and standards contained in "Certification of Opioid Treatment Programs," 42 CFR Part 8.

14.4. Hospitals licensed under "Hospital Licensure," 64CSR12, and behavioral health facilities licensed under "Behavioral Health Centers Licensure," 64CSR11, providing opioid treatment services are subject to standards contained within this rule in addition to relevant licensing requirements as specified by the secretary.

§64-90-15. Administrative Organization.

15.1. Each program shall identify a governing body.

15.2. The governing body is responsible for designation of an administrator. The administrator is responsible for the day-to-day operation of the program in a manner compliant with the laws and regulations of the United States Department of Health and Human Services, Drug Enforcement Administration and the state of West Virginia.

15.3. Duties of the administrator include:

15.3.a. Development of policies and procedures for operation of the facility;

15.3.b. Maintenance and security of the facility;

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

15.3.d. Protection of patient rights;

15.3.e. Conformity of the program with federal confidentiality regulations (42 CFR Part 2);

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

15.3.g. Management of the facility budget;

15.3.h. Implementation of governing body policy; and

15.3.i. Communication with the governing body.

15.4. The administrator shall have at minimum a bachelor's degree in an appropriate area of study and a minimum of four year's experience in substance abuse or mental health treatment.

15.5. Each program shall have 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. The advisory council shall not have access to any patient identifying information and the staff liaison to the administrator is responsible for ensuring that no identifying information is provided to the council. The advisory council shall meet at least quarterly during hours other than when patients are present in the building and shall:

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

15.5.b. Review incidents and grievances quarterly;

15.5.c. Review administrative discharges quarterly;

15.5.d. Make recommendations for operational changes or improvements;

15.5.e. Be trained in patient confidentiality regulations; and

15.5.f. Keep records of meetings and describe business conducted, members present and members absent.

15.5.g. Work to assist the 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.

§64-90-16. Facility and Clinical Environment.

16.1. Each program shall have:

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

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

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

16.1.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;

16.1.e. Sanitary and secure dosing areas;

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

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

16.2. The program may provide security personnel in lobby and parking areas (either clinic staff or contracted) if the population served or clinic environment warrant such an arrangement. If contracted staff is used, they must be trained in patient confidentiality.

§64-90-17. Staffing.

17.1. Medical Director.

17.1.a. Each program shall have a designated medical director who is a physician.

17.1.b. Physician authority over the medical aspects of treatment is mandatory. The medical director is ultimately responsible for all treatment decisions and for operation of medical aspects of the treatment program.

17.1.c. The medical director is responsible for:

17.1.c.1. Administration and supervision of all medical services; and

17.1.c.2. Ensuring that the program is in conformance with all applicable local, state, and federal regulations and rules regarding the medical treatment of opioid addiction.

17.1.d. The medical director shall be a physician licensed to practice medicine or osteopathy in the state of West Virginia. He or she shall have either:

17.1.d.1. Demonstrated experience in opioid treatment; or

17.1.d.2. A written plan to attain competence in opioid treatment within twelve months. During that time he or she shall be supervised on a regular basis by a physician with demonstrated competence in the field of opioid treatment. Consultation and supervision 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. The administrator is responsible for maintaining documentation in a file which is current and readily available at all times. The physician's written plan to attain competence shall be submitted to the state authority for approval within two weeks of employment. The state authority may request periodic documentation of continuing education during the initial twelve months and afterward if the documentation provided at the end of that period is not satisfactory. The administrator is responsible for ensuring that the plan of development is completed within the approved time lines.

17.1.e. The medical director is responsible for maintaining continuing education in the field of addictions on a

documented and ongoing basis.

17.1.f. The program may employ and use program physicians and physician extenders such as physician's assistants, nurse practitioners and registered nurses working within their scope of practice. All shall have:

17.1.f.1. One year's experience in opioid treatment settings; or

17.1.f.2. An educational plan for obtaining competence in opioid treatment methods and addictions approved by the medical director who shall certify the individual's completion of the plan when the completion occurs to the satisfaction of the medical director.

17.1.g. 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. Educational plans shall be documented and maintained by the program sponsor or administrator, who is responsible for ensuring that documentation of completion of the educational plan is present and that the medical director monitors and certifies satisfactory completion of the plan. Because the medical director is ultimately responsible for all medical services provided by the program, only the medical director can approve the educational programs and the ability of the program physician or physician extender to work independently within his or her scope of practice. The medical director shall provide an affidavit in each staff file indicating that the medical staff person has completed his or her educational program successfully and is approved to provide services on an independent basis within his or her scope of practice.

17.1.h. A licensed practical nurse shall provide services only under the direction or supervision of a registered nurse or the program physician.

17.2. Counseling Staff.

17.2.a. The program shall assign a primary counselor to each patient. The counselor shall have:

17.2.a.1. A bachelor's degree and either licensure, certification or enrollment in the process of licensure as a social worker, or certification as an addictions counselor;

17.2.a.2. A master's degree and licensure, certification or enrollment in the process of licensure or certification in the individual's chosen field, or as an addictions counselor; or

17.2.a.3. Certification or enrollment in the process of obtaining certification as an addictions counselor.

17.2.b. Ratios of primary counselor to persons served shall be adequate to allow sessions to occur as mandated and to allow persons served access to their primary counselor if more frequent contact is merited by need or requested by the patient.

17.2.c. The program shall provide direct supervision by a master's level clinical staff person who is either licensed or certified, or who has one year's direct experience in the field of opioid treatment

and two years of overall experience in a behavioral health field for counselors who are not independently certified or licensed. 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. The administrator is responsible for documentation of supervision, which shall be available for review at all times.

17.2.d. Newly employed counselors without experience in an opioid treatment program and other non-physician clinical staff without experience in an opioid treatment program shall receive initial training lasting at least twenty hours and consisting of, at a minimum, the following:

17.2.d.1. Addictions overview;

17.2.d.2. Opioid treatment and basic pharmacology and dosing;

17.2.d.3. Characteristics of the opioid dependent population;

17.2.d.4. Toxicology screening and observation of sample collection;

17.2.d.5. Program policy and procedure;

17.2.d.6. Confrontation, de-escalation and anger management;

17.2.d.7. Cultural sensitivity as necessary and appropriate;

17.2.d.8. Current strategies for identifying and treating alcohol, cocaine and other drug abuse;

17.2.d.9. Identification of co-occurring mental health or developmental disorders; and

17.2.d.10. Other clinical issues as appropriate for the population served.

17.2.e. The program may document that experienced counselors newly employed from other opioid treatment programs may be exempted from mandatory initial training.

17.2.f. 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 before seeing persons served without immediate and constant supervision.

17.2.g. The primary counselor is responsible for developing and implementing the patient's plan of care, in coordination with the medical staff. The plan of care shall address the social, environmental, psychological and familial issues maintaining the individual's maladaptive patterns of drug consumption and other high risk and/or destructive behaviors. The counselor is responsible for assisting the patient to alter life styles and patterns of behavior in order to improve the individual's ability to function adaptively in his or her family and community.

17.2.h. The program shall have available counselors qualified to deal with issues such as domestic violence, sexual abuse and anger management.

17.2.i. Policies shall ensure that

single sex groups and/or same sex counselors will be available to all patients, as needed and clinically indicated.

§64-90-18. Staff Training and Credentialing.

18.1. Each treatment program shall ensure that:

18.1.a. Doctors, nurses and other licensed or certified professional care providers maintain their current license and comply with the credentialing requirements of their own professions;

18.1.b. All clinical staff receive initial education specific to the pharmacotherapies to be used and tailored to the patient populations to be served;

18.1.c. All clinical staff receive continuing education; and

18.1.d. Detailed job descriptions are developed for credentialed and non-credentialed staff that clearly define the qualifications and competencies needed to provide specific services.

§64-90-19. Risk Management.

19.1. Each treatment program shall:

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

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

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

19.1.d. Inform each patient that:

19.1.d.1. The goal of medication therapy is stabilization of functioning;

19.1.d.2. Detoxification from opioids over thirty to one hundred eighty days is a treatment alternative to long-term maintenance;

19.1.d.3. At regular intervals, in full consultation with the patient, the program will discuss present level of functioning, course of treatment and future goals; and

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

19.2. The program shall inform the 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.

19.3. The program shall inform the patient as to federal confidentiality regulations (42 CFR Part 2) and the Health Insurance Portability and Accountability Act of 1996.

19.4. The program shall:

19.4.a. Promulgate and make available a written description of patient

rights and responsibilities;

19.4.b. Follow due process procedures for any involuntary terminations of patients; and

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

§64-90-20. Life Safety Issues.

20.1. Each treatment program shall:

20.1.a. Develop procedures to 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;

20.1.b. Maintain an up-to-date plan for emergency administration of medications in case the program must be closed temporarily, including how patients will be informed of these emergency arrangements;

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

20.1.d. 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;

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

20.1.f. Develop and maintain an up-to-date disaster plan that specifies emergency evacuation procedures, fire drills and maintenance of fire extinguishers; and

20.1.g. Establish policies and procedures that 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.

§64-90-21. Continuous Quality Improvement Policies.

21.1. Each treatment program shall:

21.1.a. Provide regular and continuous staff education;

21.1.b. Review and recertify program policies and procedures at least annually in conjunction with the advisory council;

21.1.c. Elicit ongoing input into program policies and procedures by patients in consideration of community concerns;

21.1.d. Develop and implement annual patient satisfaction surveys which shall include a review of patient satisfaction with operating hours and pricing of services;

21.1.e. Adhere to universal infection control precautions promulgated by the Center for Disease Control;

21.1.f. Measure and monitor treatment outcomes and processes including, but not limited to:

21.1.f.1. Reduction or elimination of the use of illicit opioids, illicit drugs and the problematic use of licit drugs;

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

21.1.f.3. Reduction of behaviors contributing to the spread of infectious diseases; and

21.1.f.4. Improvement of quality of life by restoration of physical and mental health and functional status including employment as appropriate.

21.2. Outcome measurements and results of patient satisfaction surveys shall be collated annually and reviewed by the governing body and the advisory council and reported to the state authority.

§64-90-22. Diversion Control Plans.

22.1. Each program shall develop a diversion control plan that is reviewed and approved by the governing body, advisory council and the state authority.

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

22.2.a. Clinical and administrative continuous monitoring of the potential for and actual diversion including an investigation, tracking and monitoring system of incidents of diversion; and

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

§64-90-23. Incident Reporting and Adverse Events.

23.1. The 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, either staff 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 events or incidents include, but are not limited to:

23.3.a. Medication errors;

23.3.b. Patient deaths;

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

23.3.d. Selling drugs on the premises;

23.3.e. Medication diversion;

23.3.f. Harassment or abuse of patients by staff; and

23.3.g. 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 program shall report any death involving drug overdose or drug-related complications to the state authority within forty-eight hours of program notification of the mortality.

§64-90-24. Patient Rights.

24.1. The 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 if any changes have occurred;

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

24.1.c. The program shall provide treatment according to accepted clinical practice;

24.1.d. The patient shall receive medications on a schedule which is most accommodating and least intrusive and disruptive for most patients;

24.1.e. The patient shall have an individual treatment plan and a periodic review of the plan;

24.1.f. The program shall provide an adequate number of competent, qualified and experienced professional staff to implement and supervise the treatment plan;

24.1.g. Patients shall be informed about potential interactions with and adverse reactions to other substances, including those reactions that might result from interactions and adverse reactions to alcohol, other prescribed or over-the-counter pharmacological agents, other medical procedures and food;

24.1.h. Patients shall be informed regarding the financial aspects of treatment, including the consequences of nonpayment of required fees;

24.1.i. Patients shall be given an assessment, acceptance into the program, or, in the case of denial of admission, a full explanation and a referral to another program based upon the results of the initial assessment;

24.1.j. Programs shall protect other patients, staff and the public from a patient who acts out. However, the program shall also 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. Patients have the right to confidentiality in accordance with federal regulations (42 CFR Part 2) and the Health Insurance Portability and Accountability Act of 1996;

24.1.l. Patients have 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. Patients have 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. Patients have 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. Those procedures shall include the following:

24.2.a. The right of patients to express verbally or in writing their dissatisfaction with or complaints about treatment received;

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

24.2.c. The right to be informed of the grievance procedure in a manner which can be understood. 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;

24.2.d. The right to receive a decision in writing with the reasoning articulated; and

24.2.e. The right to appeal the decision to the state authority or to any other appropriate state or federal agency.

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.

24.4. The patient's methadone dose shall not be changed without the patient's knowledge unless the patient signs a document waiving consent.

§64-90-25. Recordkeeping.

25.1. All records shall be maintained for a minimum of five years from the time that the documented treatment is provided.

25.2. Patient records are confidential and shall be updated in a timely manner.

25.3. Entries shall be legible and organized in an effective manner, allowing materials to be easily retrieved.

25.4. Program procedures should ensure security of all records including electronic records, if any.

25.5. Individual records shall contain:

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

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

25.5.c. An initial assessment report;

25.5.d. A narrative biopsychosocial history completed within thirty days of the patient's admission;

25.5.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; and progress notes, including documentation of current dose and other dosage data. Information in the medical record shall be entered by physicians and other licensed health professionals;

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

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

25.5.h. The initial treatment plan, any amendments to the plan, reviews of the plan and the long-term treatment plan, including any amendments to that document and reviews of the plan;

25.5.i. Documentation that services listed in the plan are available and have been provided or offered;

25.5.j. A written report of the process and factors considered in decisions impacting patient treatment (e.g., take-home medication privileges, changes in counseling sessions, changes in frequency of toxicology screens) or any other significant change in treatment, both positive and negative;

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

25.5.l. Documentation that the patient was provided with a copy of the program's rules and regulations and a copy of the patient's rights and responsibilities and that these items were discussed with her or him;

25.5.m. Consent forms, releases of information, prescription documentation, travel, employment and "take-home" documentation, etc.; and

25.5.n. A closing summary,

including reasons for discharge and any referral. In the case of death, the cause of death shall be documented.

§64-90-26. Records of Storage, Dispensing and Administering Medications.

26.1. Each program shall have policies and procedures consistent with the United States Drug Enforcement Administration's statutes and regulations.

26.2. Each medication order and dosage change shall be written on an acceptable order sheet signed by the physician.

26.3. Each dosage dispensed, prepared or received shall be recorded and accounted for by written signed notation in a manner which creates a perpetual and accurate inventory of all methadone in stock at all times.

26.4. Each dose shall be recorded on an administration sheet at the time that the dose is administered or dispensed and also on the patient's individual medication dose history.

26.5. The person administering or dispensing medications shall be qualified to do so by his or her scope of practice and shall sign or initial and date each notation.

26.6. 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.

26.7. The medication shall be totaled in milligrams daily.

26.8. Programs shall have a procedure for calibrating medication dispensing instruments consistent with the manufacturer's recommendations to ensure accurate patient dosing and substance tracking.

§64-90-27. Staff Files.

27.1. Programs shall maintain individualized personnel files as a record of employment. These files shall contain:

27.1.a. The application for employment;

27.1.b. The date of employment;

27.1.c. Documentation of orientation, internal and external training and continuing education;

27.1.d. Documentation of licensing and/or credentialing;

27.1.e. Documentation of ongoing supervision, as appropriate;

27.1.f. Detailed job descriptions;

27.1.g. Performance evaluations, done at least annually by the employee's immediate supervisor; and

27.1.h. Evidence that the employer has determined that the employee 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.

§64-90-28. Patient Admission Criteria.

28.1. The program physician shall document that treatment is medically necessary.

28.2. Criteria for admission shall be consistent with those outlined in the definition of opioid dependence in the Diagnostic and Statistical Manual of Mental Disorders (current edition). The person desiring admission must be over eighteen years of age. Exceptions may be made on extremely rare occasions by application to the state authority.

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

28.3.a. Objective evidence of current physical dependence or tolerance to an opioid with documentation of the signs and symptoms of withdrawal;

28.3.b. Onset of opioid physical dependence at least one year prior to admission with continuous use the greater part of the year; and

28.3.c. Multiple and daily self-administration of an opioid.

28.4. In addition to the admission criteria set forth in Subsection 28.2 and 28.3 of this section, the following behavioral signs which support the diagnosis shall be discussed and documented, although none are considered required for admission:

28.4.a. Unsuccessful efforts to control use;

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

28.4.c. Continual use despite harmful consequences;

28.4.d. Obtaining opiates illegally;

28.4.e. Inappropriate use of prescribed opiates;

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

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

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

28.5. The absence of physiological dependence should not be an exclusion criterion, and admission may be clinically justified. Individuals in some populations may be susceptible to relapse to opioid addiction leading to high-risk behaviors with potentially life threatening consequences. Admission of individuals with no opioid tolerance shall call for small or reduced initial doses of methadone with careful monitoring during the induction phase of treatment.

28.6. Program policies and procedures shall allow for waiving the admission criteria of physical dependence or one-year history of addiction when the person seeking admission meets one of the following criteria:

28.6.a. The person has been released from a penal facility within six months;

28.6.b. The person has been recently released from a chronic care facility and is at risk of relapse;

28.6.c. The person has been previously treated or addicted and is at risk of relapse; or

28.6.d. The person is a pregnant woman.

§64-90-29. Admissions Committee.

29.1. Exceptions to the general admissions criteria shall be documented and approved by 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. Exceptions shall be monitored and tracked annually for relevant clinical patterns and shall be submitted to the state authority or other monitoring body upon request.

§64-90-30. Multiple Program Enrollments.

30.1. The program shall have a procedure which shall ensure that no patient is enrolled in more than one opioid treatment program.

30.2. The procedure shall take into account requirements for patient confidentiality.

30.3. When practicable, the program shall obtain a release of information from the patient in order to check the records by telephone or fax 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 release of information shall state that only prior admissions may be the subject of inquiry, not contacts without admission. Results of that check shall be contained in the clinical record. This check shall be duplicated if the patient is discharged and readmitted at any time.

§64-90-31. Initial Assessment/Screening.

31.1. The initial assessment shall focus on the individual's eligibility and need for treatment and shall provide indicators for initial dosage level, if admission is determined appropriate.

31.2. A comprehensive biopsychosocial assessment shall be completed within thirty days of admission when the patient is stable and able to fully participate.

31.3. The initial assessment shall include:

31.3.a. A brief physical examination;

31.3.b. 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);

31.3.c. A determination of currently prescribed medications;

31.3.d. An evaluation of other

substances of abuse;

31.3.e. Determination of current opioid dependence;

31.3.f. Determination of length of addiction;

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

31.3.h. A full toxicology screen to identify use of other drugs including opiates, methadone, amphetamines, cocaine, barbiturates, benzodiazepines and marijuana.

31.4. Whenever possible and with patient permission, the intake 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.

31.5. Within seven days a more comprehensive medical evaluation shall be completed including:

31.5.a. A comprehensive physical evaluation;

31.5.b. A comprehensive psychiatric evaluation, including mental status examination and psychiatric history;

31.5.c. A personal and family medical history;

31.5.d. A comprehensive history of substance abuse, both personal and family;

31.5.e. A tuberculosis skin test and chest x-ray, if skin test is positive;

31.5.f. A screening test for syphilis;

31.5.g. 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);

31.5.h. A repeat full toxicology screen at fourteen days to identify use of other drugs including opiates, methadone, amphetamines, cocaine, barbiturates, benzodiazepines and marijuana; and

31.6. The program shall obtain complete medical records from other providers with patient permission.

31.7. Laboratory tests that are not directly conducted by the program may be provided:

31.7.a. By the person's primary care physician;

31.7.b. By other healthcare providers; or

31.7.c. By a medical clinic.

31.8. The 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.

31.9. Tests not directly conducted by the program at admission shall be conducted within the ninety days prior to admission.

31.10. Within thirty days, the program shall complete a full biopsychosocial

evaluation which shall be used to develop the long-term plan of care. The biopsychosocial evaluation shall integrate information obtained in the comprehensive medical evaluation.

31.11. The evaluation shall include information obtained from:

31.11.a. The patient;

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

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

31.11.d. Other appropriate and permitted collateral sources.

31.12. The psychosocial evaluation shall include information about the person's:

31.12.a. Personal strengths;

31.12.b. Individualized needs;

31.12.c. Abilities and/or interests;

31.12.d. Presenting problems including a thorough analysis of the individual's addictive behaviors such as:

31.12.d.1. Licit and illicit drugs used, including alcohol;

31.12.d.2. Amounts used;

31.12.d.3. Frequency of use;

31.12.d.4. Duration of use;

31.12.d.5. Symptoms of physical addiction;

31.12.d.6. History of treatment for addictive behaviors;

31.12.d.7. Adverse consequences of use;

31.12.d.8. Inappropriate use of prescribed substances;

31.12.e. Urgent needs, including suicide risk;

31.12.f. Previous behavioral health services, including:

31.12.f.1. Diagnostic information;

31.12.f.2. Treatment information;

31.12.f.3. Efficacy of current or previously used medication;

31.12.g. Physical health history and current status;

31.12.h. Diagnoses;

31.12.i. Mental status;

31.12.j. Current level of functioning;

31.12.k. Pertinent current and historical life situation information, including his or her:

31.12.k.1. Age;

31.12.k.2. Gender;

31.12.k.3. Employment history;

31.12.k.4. Legal involvement;

31.12.k.5. Family history;

31.12.k.6. History of abuse; and

31.12.k.7. Relationships, including natural supports;

31.12.l. Use of alcohol and tobacco;

31.12.m. Need for, and availability of, social supports;

31.12.n. Risk-taking behaviors;

31.12.o. Level of educational functioning;

31.12.p. Medications prescribed that are not a target of treatment or concern;

31.12.q. Medication allergies or adverse reactions to medications;

31.12.r. Adjustment to disabilities/disorders; and

31.12.s. Motivation for treatment.

31.13. The psychosocial assessment shall result in the preparation of a concise interpretive multidisciplinary summary that:

31.13.a. Is based on the assessment data;

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

31.13.c. Is used in the development of the individual plan of care; and

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

§64-90-32. Orientation.

32.1. Each person admitted to the program shall receive program orientation. The orientation shall be made orally at the earliest opportunity that the individual 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.

32.2. Orientation shall include:

32.2.a. An explanation of:

32.2.a.1. The rights and responsibilities of the patient;

32.2.a.2. Grievance and appeal procedures; and

32.2.a.3. Alternative treatments available for treatment of opioid addiction, whether offered by the program or not, and a description of the potential benefit, risks and costs of each. The state authority is responsible for providing informational materials to be used in discussing alternative treatments. The patient shall receive a copy of the materials for later review;

32.2.b. An explanation of the program's:

32.2.b.1. Services and activities;

32.2.b.2. Expectations and rules;

32.2.b.3. Hours of operation;

32.2.b.4. Access to after-hour services;

32.2.b.5. Confidentiality policy; and

32.2.b.6. Toxicological screening policies;

32.2.c. An explanation of any and all financial obligations, fees, and financial arrangements for services provided by the program;

32.2.d. Familiarization with the premises;

32.2.e. A description of the program's policies regarding:

32.2.e.1. Use of alcohol on or prior to entering the premises;

32.2.e.2. Smoking;

32.2.e.3. Illicit or licit drugs brought into the program; and

32.2.e.4. Weapons brought into the program;

32.2.f. Identification of the counselor assigned to the person's case and contact information for that counselor;

32.2.g. A copy of the program rules identifying the following:

32.2.g.1. Any restrictions the program may place on the patient;

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

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

32.2.h. Identification of the purpose and process of the assessment; and

32.2.i. A description of how the individual plan of care will be developed and the person's participation in it.

32.3. When applicable, an explanation of the program's services and activities include a description of any possible:

32.3.a. Sanctions;

32.3.b. Interventions;

32.3.c. Incentives; and

32.3.d. Administrative discharge criteria.

32.4. Upon admission, the patient shall also receive written documentation of the following information:

32.4.a. Signs and symptoms of overdose and when to seek emergency

assistance;

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

32.4.c. Patient's rights;

32.4.d. Confidentiality policies; and

32.4.e. A description of processes for dispensing of medication.

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

32.5.a. Information at admission in Subsection 32.4. of this section;

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

32.5.c. The anticipated benefits of treatment;

32.5.d. The nature of the recovery process;

32.5.e. HIV spectrum and other infectious diseases;

32.5.f. Potential drug interactions;

32.5.g. Self help groups, if any are available;

32.5.h. Medical issues related to detoxification from opioid agonist medication;

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

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

32.5.k. Drug safety issues;

32.5.l. Dispensing procedures; and

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

§64-90-33. Initial Plan of Care.

33.1. Within seven days of admission, the program shall develop an initial plan of care which shall guide the treatment provided to the patient during the first thirty days with the program. The plan shall include:

33.1.a. Completion of program orientation;

33.1.b. Ongoing education regarding addiction, HIV/aids, hepatitis and communicable diseases;

33.1.c. Consistent program attendance, both for dosing and counseling sessions;

33.1.d. Elimination of withdrawal symptoms and opioid craving;

33.1.e. Cessation of illicit drug use; and

33.1.f. Other issues unique to the needs of the individual.

33.2. Patients are frequently in poor physical health and may require other health care. Programs without primary care onsite shall refer patients for appropriate laboratory tests and follow-up on results.

§64-90-34. Admissions.

34.1. The admissions and initial dosing decision ultimately rests with the medical director or his or her designated program physician.

34.2. The admissions physical examination may be delegated to an experienced medical professional working within the scope of his or her licensure and directly supervised by the medical director or an approved program physician.

34.3. The admissions assessment shall be conducted by a master's level, experienced professional staff member working within his or her scope of practice or by a bachelor's level practitioner with two years of experience performing psychosocial assessments in behavioral health or one year's experience performing assessments in an opioid treatment program.

34.4. The admission and initial dosing of the patient may take place only after the patient is seen by a program physician, or physician extender who:

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

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

34.4.c. Has completed his or her plan of development.

34.5. 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. The physician or physician extender and patient shall both sign and date that the review occurred.

34.6. Whenever possible, the patient shall be admitted only after observation by and an interview with the program physician. Under unusual circumstances, an approved physician extender may conduct the interview and observation and obtain telephone or fax orders from the physician to initiate treatment; however, the patient admitted under those circumstances must be seen by the physician within three working days of admission for verification of appropriate admission and treatment.

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

§64-90-35. Dosage Principles.

35.1. The dose of methadone or other medications shall be individually determined on the basis of good clinical judgment after review by a physician or other professional practitioner with prescribing privileges for the medication in question.

35.2. 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.

35.3. Dosages shall ultimately:

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

35.3.b. Reduce or eliminate drug cravings; and

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

35.4. The initial full-day dose of medication shall be based on the physician's evaluation of the history and condition of the patient.

35.5. The usual initial dose of methadone should be from 20 to 30 milligrams. The reasons for exceeding an initial dose of 30 milligrams need to be documented in the clinical chart and should not exceed 40 milligrams unless the physician or prescribing professional documents in the record that 40 milligrams did not suppress opiate abstinence symptoms after a three-hour period of observation.

35.6. When dispensing opioid agonists, the program shall:

35.6.a. Ensure that the program physician:

35.6.a.1. Orders the medication and/or dosage change; and

35.6.a.2. Signs for the medication and/or dosage change;

35.6.b. Ensure that each dose is recorded:

35.6.b.1. In the individual record of the patient; and

35.6.b.2. Using a method to ensure that an accurate inventory of all medication in stock is available.

35.7. The program physician or other approved physician extender shall meet with each patient prior to prescribing the initial dose as described in Subsection 34.6. of this section. The program physician or a physician extender shall then meet with the patient as follows:

35.7.a. During the first month, 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;

35.7.b. Only the program physician may approve changes in dosage or take-home privileges; and

35.7.c. The program physician or approved physician extender shall meet with the patient annually to perform a medical screening and to discuss the possibility of consideration of titration of medications. The discussion shall be documented along with the individual's decision to continue medications at current levels or to begin a slow titration process.

35.8. The program is responsible for proper medication documentation which shall include:

35.8.a. The signature or initials of the qualified person administering medication;

35.8.b. The exact number of milligrams of the substance dispensed; and

35.8.c. The daily totals of the substance dispensed.

35.9. The maintenance dose must be individually determined. There shall be no use of standardized scales or protocols of medication increase or adjustment. 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.

35.10. Dosage adjustment shall be guided by outcomes criteria, which shall be documented and include:

35.10.a. Cessation of withdrawal symptoms;

35.10.b. Cessation of illicit opioid use as documented by:

35.10.b.1. Negative drug tests; and

35.10.b.2. Reduction of drug-seeking behavior;

35.10.c. Establishment of a blockade dose of an agonist;

35.10.d. Absence of problematic craving as documented by:

35.10.d.1. A subjective report;

35.10.d.2. Clinical observations; and

35.10.e. Absence of signs and symptoms of too large an agonist dose after an interval adequate for the patient to develop complete tolerance to the blocking dose.

35.11. The program shall have a mechanism through which the patient can discuss dosing with appropriate staff members regularly and upon request. This mechanism shall be clearly described to the patient during orientation and admission and at least annually thereafter. The description shall be documented and initialed and dated by the patient.

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

35.13. 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.

35.14. The program shall have the capability of obtaining medication blood levels when clinically indicated.

35.15. The state authority is responsible for development of practice guidelines for alternative treatments such as buprenorphine as they become available. The guidelines shall be in conformance with any federal guidelines available. The program is responsible for remaining in conformity with practice guidelines as issued by the state

authority.

§64-90-36. Admission for Detoxification.

36.1. Programs shall offer detoxification services as an admission alternative. All potential patients shall be offered long-term detoxification as an admission alternative; however, programs may choose to offer short-term detoxification for those patients who desire such a service.

36.2. Short-term detoxification services shall be defined as those projected to last fewer than thirty days. Unsupervised doses of medication may not be permitted to those patients admitted for short-term detoxification except through an exception procedure with the state authority.

36.3. Long-term detoxification services shall be defined as those projected to last more than thirty, up to one hundred eighty or more days, depending on clinical need. Frequency of access to unsupervised-medications shall be determined by the program physician but shall never exceed the frequency allowed to individuals in maintenance treatment. Violations of program policy regarding take-home doses and program compliance shall be considered by the physician and team in a manner consistent with, or more stringently than, violations of policy with regard to maintenance take-homes.

§64-90-37. Counseling.

37.1. Because so many opioid dependent patients also abuse other illicit or prescription substances, counseling is essential to promote and guide the patient to a more productive life style of abstinence from illicit medications or drugs.

37.2. The primary counselor is responsible for developing and implementing the patient's plan of care, in coordination with the medical staff. The plan of care shall address the social, environmental, psychological and familial issues maintaining the individual's maladaptive patterns of drug consumption and other high risk and/or destructive behaviors. The counselor is responsible for assisting the patient to alter life styles and patterns of behavior in order to improve the individual's ability to function adaptively in his or her family and community.

37.3. The clinical staff caseload ratio shall:

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

37.3.b. Allow the program to provide adequate:

37.3.b.1. Psychosocial assessment;

37.3.b.2. Treatment planning; and

37.3.b.3. Individualized counseling; and

37.3.c. Allow for regularly scheduled counseling sessions. Counseling sessions are defined as face-to-face interactions in a private location between the patient and the primary counselor. Sessions shall be offered:

37.3.c.1. At least weekly during the first ninety days of treatment;

37.3.c.2. At least twice per month during the remainder of the first year of treatment; and

37.3.c.3. At least monthly thereafter.

37.4. Ratios of primary counselor to persons served shall be adequate to allow sessions to occur as described in Subdivision 37.3.c. of this subsection and to allow persons served access to their primary counselor if more frequent contact is merited by need or is requested by the patient.

37.5. 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 as a factor in his or her decision although justified lack of participation (such as for reasons of employment) shall not be held against the patient in the take-home decision.

§64-90-38. Long-Term Plans of Care.

38.1. When the patient reaches thirty days in treatment, his or her plan of care shall be reviewed and revised by the patient and his or her individual counselor with input as appropriate from medical staff. This review and revision shall be in writing and placed in the case record within thirty-five days of admission.

38.2. Careful discussion shall be held with the patient regarding the patient's continued desire to remain in the program on a maintenance schedule of medication. Alternatives such as medically-supervised withdrawal shall be presented to the patient at the time of the review of the initial plan of care. The patient shall sign and date a statement indicating that he or she wishes to remain within the program in a maintenance format. If he or she wishes to enter medically-supervised withdrawal, the plan of care shall reflect that choice. If at any time a patient in good standing wishes to re-enter a maintenance program, that he or she shall do so in consultation with medical staff.

38.3. The revised plan of care shall be developed in conjunction with the patient and shall be individualized to meet his or her needs. It shall include at a minimum:

38.3.a. Regular attendance and participation in the program, both medical and counseling aspects, as determined necessary by the staff and patient;

38.3.b. The identification of "triggers" for misuse of substances;

38.3.c. The development and use of coping strategies for each "trigger";

38.3.d. The development of a detailed relapse prevention plan;

38.3.e. Meaningful follow-up on any identified mental health issues;

38.3.f. Follow-up on medical or physical issues as necessary;

38.3.g. A vocational evaluation,

formal or informal, and a plan to achieve financial stability and independence;

38.3.h. Abstinence from use of illicit substances or abuse of prescription substances; and

38.3.i. Other individual or familial issues as relevant and appropriate.

38.4. After the plan is developed and approved by the patient, the patient shall receive a copy.

38.5. The plan of care shall be reviewed by the patient and staff at least each ninety days. Reviews shall be written and detailed. The review shall encompass each of the objectives identified on the plan. At the time of the review, the patient shall again be presented with the option of medically-supervised withdrawal. Continued stay in the program is the right of the patient who remains in good standing as defined in policy by the governing body. At no time should such a patient feel pressured to enter a program of withdrawal over his or her objections. Programs shall make every effort to retain patients in treatment as long as clinically appropriate, medically necessary, and acceptable to the patient.

38.6. Treatment programs shall provide opportunities for family involvement in therapy.

§64-90-39. Counseling and Other Documentation.

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

39.2. The documentation shall include a description of:

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

39.2.b. The patient's current condition;

39.2.c. Significant events occurring since prior contact;

39.2.d. The assessment of patient status; and

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

39.3. 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.

§64-90-40. Toxicology Screens.

40.1. 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.

40.2. Drug screening procedures shall be individualized and shall include:

40.2.a. At least eight random drug screens per year for each person receiving methadone maintenance services. The program shall test new patients upon admission and at approximately fourteen days of treatment, then monthly through the remainder of the first year;

40.2.b. More frequent collection and analysis of samples during medically-

supervised or other types of withdrawal;

40.2.c. Collection of observed specimens on an unannounced basis when using urine as a screening mechanism if the staff believes that observation is necessary based on individual behavior or need. 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; and

40.2.d. Toxicological analysis for drugs of abuse, including, but not limited to:

40.2.d.1. Opiates including oxycodone at common levels of dosing;

40.2.d.2. Methadone and any other medication used by the program as an intervention;

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

40.2.d.4. Cocaine;

40.2.d.5. Methamphetamine/amphetamines; and

40.2.d.6. Other drugs as determined by community standards, regional variation or clinical indication (e.g., carisoprodol, barbiturates).

40.3. Marijuana shall be included in the testing process on a random basis at least three times per year. Positive marijuana screens shall be carefully clinically evaluated and shall in most cases result in reduction in take-home privileges unless other action is considered appropriate by the medical director or program physician and primary counselor.

40.4. 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.

40.5. 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. The individual may return to the clinic for dosing during the same day if the breathalyzer results reach acceptable limits.

40.6. The results of toxicological testing shall be used to assist clinical staff in making informed-decisions regarding take-home medication privileges; however, clinical decisions about take-homes or discharge shall not be based solely on toxicological test reports but shall be made using all the clinical data available.

40.7. Programs shall document both the results of toxicological tests and the follow-up therapeutic action taken in the patient record.

40.8. 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.

40.9. The 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 absorption, metabolism and elimination of opiates.

40.10. 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:

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

40.10.b. The prescribing physician is aware that the patient is enrolled in an opioid treatment program.

40.11. If the 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 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.

40.12. Absence of methadone or other program-prescribed medications shall be considered evidence of possible medication diversion and evaluated by the physician and interdisciplinary team accordingly.

40.13. As appropriate and necessary, the state authority shall develop guidelines for frequency of toxicological screening for alternative treatment modalities such as buprenorphine.

§64-90-41. Unsupervised Approved Use (Take-Home Medications).

41.1. The program shall have a policy regarding medication schedules which takes into account each patient's best interests as well as the interests of the public at large (e.g., preventing diversion, ensuring safe storage and security of medication, preventing overdoses). Policies shall not create unnecessary barriers for patients continuing in treatment.

41.2. The interdisciplinary team shall make recommendations to the physician regarding take-home medications for each patient. The physician shall make the final decision regarding approval of medications and shall approve any changes in take-home privileges in the patient record.

41.3. Programs shall consider the following criteria in determining patient eligibility for "take-home" medications:

41.3.a. Cessation of illicit drug use;

41.3.b. Regularity of program attendance;

41.3.c. Length of time and level of treatment in medication therapy (ability to

responsibly self-medicate);

41.3.d. Absence of known recent criminal activity (especially drug dealing);

41.3.e. Absence of serious behavioral problems;

41.3.f. Absence of abuse of drugs including excessive use of alcohol;

41.3.g. Other special needs of the patient, such as split dosing, physical health needs, pain treatment, etc.;

41.3.h. Capacity to safely store "take-home" medication within the patient's home;

41.3.i. Stability of the home environment and social relationships;

41.3.j. Patient's work, school, or other daily-life activity schedule; and

41.3.k. Hardship experienced by the patient in traveling to and from the program.

41.4. The program physician may approve temporary unsupervised take-home medication for documented family or medical emergencies or other exceptional circumstances. Patterns of emergency take-home provision shall be tracked and monitored by the program and available for review by regulatory bodies. Guest dosing at a nearby clinic is preferred whenever possible.

41.5. The program shall have policies and procedures that address the transfer of persons served from one clinic to another.

41.6. The amount of take-home medication shall be determined by the program physician in consultation with the interdisciplinary team and shall not exceed:

41.6.a. A single dose each week during the first ninety days of treatment except in those weeks in which a holiday falls, causing the program to be closed, in which case, two doses may be permitted. The single dose shall be that provided to supply the patient during the single day per week the clinic may be closed, barring holidays. If the clinic is open seven days per week, no take-home doses shall be permitted during the first thirty days of treatment, then one per week for the remaining sixty days of the first ninety-day period except for holidays during which the clinic is closed. No clinic shall be open less than six days per week on an ongoing basis;

41.6.b. Two doses per week in the next ninety days of treatment;

41.6.c. Three doses per week in the third ninety days of treatment;

41.6.d. A maximum six-day supply of take-home medication in the remaining months of the first year in treatment;

41.6.e. A maximum thirteen-day supply during the second year in treatment; or

41.6.f. A maximum one-month supply of take-home medication:

41.6.f.1. After two years of continuous treatment; and

41.6.f.2. With monthly visits

made by the patient.

41.7. The state authority may approve exceptional unsupervised-medication dosages on a case-by-case basis with application by the program physician.

41.8. As appropriate and necessary, the state authority shall develop guidelines for take-home (unsupervised) medications for alternative treatments such as buprenorphine. The program is responsible for documentation of adherence to the specified guidelines.

§64-90-42. Medication Security.

42.1. The program shall have policies ensuring responsible handling and secure storage of "take-home" medication in child-proof and tamper-resistant containers. Each patient must demonstrate the ability to provide secure storage for take-home medications.

42.2. The program shall inform patients of their rights and responsibilities in writing in ensuring the security of opioid medications.

42.3. The program shall establish a mechanism for monitoring medications to prevent diversion. The policy may include provisions for random call backs of individuals with more than one week of take-home dosage and accompanying random toxicology screens. Frequency of call backs and toxicology screens shall be individually determined by the multidisciplinary team.

§64-90-43. Concurrent Alcohol and Polysubstance Abuse.

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

43.2. The program shall ensure that staff are trained and knowledgeable regarding current effective strategies for treating alcohol, cocaine and other drug abuse.

43.3. Ongoing multi-drug use is not necessarily a reason for discharge unless the patient refuses recommended, more intensive levels of care. The multidisciplinary team shall consider the patient's condition and address the situation from a clinical perspective.

43.4. The 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.

§64-90-44. Special Populations.

44.1. Mental Health Needs.

44.1.a. The program shall ensure that patients with mental health needs are identified through the evaluation process and referred to appropriate treatment.

44.1.b. The program shall monitor patients during withdrawal to identify the emergence of symptoms of mental illness.

44.1.c. The program shall establish linkages with mental health providers in the community.

44.1.d. The program may provide psychotropic medication management onsite by appropriately trained medical professionals. Plans of care shall describe the goals of psychotropic medication management and shall be reviewed regularly, as specified at Subsection 38.5. of this rule. Medical documentation shall describe regular contact with the prescribing physician and/or physician extender with appropriate prescription privileges for the distinct purpose of monitoring psychotropic medications that were prescribed.

44.2. HIV Patients.

44.2.a. The 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. The program shall ensure that physicians 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-assisted therapy for either maintenance or withdrawal in a program setting. The 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 patient permission. If the 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. The program shall establish agreements and develop procedures to coordinate with agents of the criminal justice system on behalf of patients.

44.5. Pregnant Patients.

44.5.a. Pregnant women seeking and needing treatment shall be enrolled in the program.

44.5.b. The 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 that 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. 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. Ensure that if a pregnant patient elects to withdraw from methadone, that withdrawal is not initiated by the clinic before fourteen weeks and after thirty-two weeks gestation, that regular fetal assessments are performed as appropriate for fetal age, and that withdrawal is supervised by a physician experienced in addiction medicine.

44.5.e. The 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 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.

§64-90-45. Administrative Withdrawal.

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

45.2. Administrative withdrawal may result from:

45.2.a. Non-payment of fees. The 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 be humane;

45.2.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; or

45.2.c. Incarceration or other confinement; however, it is the program's responsibility to work with law enforcement and corrections personnel in order to avoid mandatory withdrawal whenever possible.

45.3. Efforts shall be documented regarding referral or transfer of the patient to a suitable, alternative treatment program.

§64-90-46. Medical Withdrawal.

46.1. Medical withdrawal occurs as a voluntary and therapeutic withdrawal agreed upon by staff and patient. In some cases the withdrawal may be against the advice of clinical staff (against medical advice).

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

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

46.4. If the patient leaves the program abruptly against medical advice, the program may readmit the patient within thirty 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.

46.5. The 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.

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

46.7. For either withdrawal, the program shall have in place a detailed relapse prevention plan developed by the counselor in conjunction with the patient and given to the patient in writing prior to the administration of the final dose.

§64-90-47. Detoxification Programs.

47.1. Detoxification treatment means the dispensing of an opioid agonist treatment medication in decreasing doses to the persons served to alleviate adverse physical or psychological effects incident to withdrawal from the continuous or substantial use of an opioid drug and as a method of bringing the patient to a drug-free state within that period.

47.2. Detoxification is a time-limited, planned withdrawal from medication therapy after a maintenance dose of an opioid agonist is achieved as documented by the program physician. The estimated time of withdrawal shall be specified by the physician and documented; however, it may be modified at any time. Any extension shall be briefly documented in the clinical record.

47.3. Detoxification shall be clearly offered as a treatment option at admission to the program and the patient shall sign and date acknowledgment of receipt of the

notification.

47.4. When appropriate, the program shall have cooperative agreements with the criminal justice system to encourage detoxification services to persons who are:

47.4.a. Incarcerated; or

47.4.b. On probation and/or parole and required to become abstinent.

47.5. The program shall have procedures for providing detoxification services to persons prior to their incarceration in criminal justice system facilities if possible and foreseeable.

47.6. The program physician, or a physician extender working within the scope of his or her practice and directly supervised by the physician, shall provide onsite medical supervision and oversight of the detoxification program.

47.7. For persons projected to be involved in detoxification for six months or less, the program must offer the patient:

47.7.a. A minimum of two counseling sessions per week for the first month; and

47.7.b. A minimum of two counseling sessions each month thereafter.

47.8. For persons involved in detoxification for fourteen days or less, the program must offer a minimum of four counseling sessions per week.

47.9. Exceptions or refusal to participate in the program shall be documented and tracked by the program.

47.10. The program physician shall determine on an individualized basis the appropriate dosage of opioid agonist medication to ensure stabilization during detoxification. No standardized routines or schedules of increase or decrease of medications may be used.

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

47.12. In detoxification programs of thirty days or less duration, the program shall have a policy that does not allow more than one unsupervised or take-home medication per week for persons served. If the program operates on a seven day per week basis, no take-home, unsupervised-medications shall be allowed.

47.13. In detoxification programs of more than thirty days duration, the program shall have a policy that allows the persons served to have the opportunity for take-home medications.

47.14. In detoxification programs of more than thirty days duration, based on the clinical judgment of the program physician, the quantity of unsupervised-medication shall not exceed:

47.14.a. One unsupervised dose per week during the first ninety days of treatment except in a week in which a holiday falls causing the program to be closed. In those weeks, two doses may be allowed; or

47.14.b. Two unsupervised doses per week during the second ninety days of treatment.

47.15. The program shall have a policy regarding detoxification from opioid agonist medication that shall include:

47.15.a. Individualized determination of a schedule of detoxification that is:

47.15.a.1. Well tolerated by the patient; and

47.15.a.2. Consistent with sound medical practices;

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

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

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

47.15.e. Provision for continuing care after the last dose of methadone.

47.16. Counseling services provided in conjunction with detoxification services shall be designed to:

47.16.a. Explore other modalities of care, including drug and alcohol treatment following discharge;

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

47.16.c. Identify triggers for relapse and a coping plan for dealing with each, detailed and in writing and given to the patient prior to discharge. The plan shall be developed in conjunction with the patient.