OKLAHOMA DEPARTMENT OF MENTAL HEALTH
AND SUBSTANCE ABUSE SERVICES

Post Office Box 53277
Oklahoma City, OK 73152
(405) 522-3908

Title 450

Chapter 70

Standards and Criteria for Opioid Substitution Treatment Programs

Effective July 1, 2008

Authority: Oklahoma Board of Mental Health and Substance Abuse Services; 43A O.S. § 3-601 et. seq.

History: Added at 24 OK Reg 2634, effective 07/12/07.

Unofficial Copy

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SUBCHAPTER 1. GENERAL PROVISIONS

450:70-1-1. Purpose

This chapter is to set forth rules regulating program requirements, activities, and services which are not specific to levels of care and sets forth the standards and criteria used in the certification of facilities and organizations providing opioid substitution treatment programs. The rules regarding the certification process, including, but not limited to, the application process, fees, and administrative sanctions are found in OAC 450:1, Subchapters 5 and 9.

450:70-1-2. Definitions

The following words or terms, when used in this chapter, shall have the following meaning, unless the context clearly indicates otherwise:

"Accreditation" means the process of review and acceptance by a nationally recognized accreditation body.

"Accreditation body" means a body that has been approved by SAMHSA to accredit opioid treatment programs using opioid agonist treatment medications.

"Administer" The direct application of a prescription drug by ingestion or any other means to the body of a patient by a licensed practitioner, or the patient at the direction of, or in the presence of, a practitioner.

"Administrative withdrawal" means a patient's medically supervised withdrawal involving the gradual tapering of dose of medication over time, coinciding with the patient's usually involuntary discharge from medication assisted treatment. Administrative withdrawal typically results from non-payment of fees, violent or disruptive behavior, incarceration or other confinement.

"Approved narcotic drug" means a drug approved by the United States Food and Drug Administration for maintenance and/or detoxification of a person physiologically addicted to opioid drugs.

"American Society of Addiction Medicine Patient Placement Criteria" or "**ASAM PPC"** means the most recent clinical guide published by the American Society of Addiction Medicine to be used in matching patients to appropriate levels of care.

"**Biopsychsocial assessment"** means in-person interviews conducted by a treatment professional designed to elicit historical and current information regarding the behavior and experiences of a patient, and are designed to provide sufficient information for problem formulation, intervention planning, case management needs, and formulation of appropriate substance abuse-related treatment and service planning.

"Buprenorphine" means a partial agonist, Schedule III narcotic approved for use in opioid addiction treatment, marketed as Subutex or Suboxone when combined with naloxone.

"Central registry" A document or database to which an OSTP shall report patient identifying information about individuals who are applying for or undergoing medically supervised withdrawal or maintenance treatment on an approved opioid agonist to a central record system approved by the Commissioner or designee.

"Certification" means the process by which ODMHSAS or SAMHSA determine that an OSTP is qualified to provide opioid treatment under applicable State and Federal standards.

"Certified opioid substitution treatment program" means an opioid substitution treatment program with all current, required state and federal, current, valid certifications.

"Chain of custody" means the process of protecting items so that movement, possession and location are secure and documented and there is no possibility for altering or otherwise tampering with the item.

"Chronic pain disorder" means an ongoing condition or disorder consisting of chronic anxiety, depression, anger and changed lifestyle, all with a variable but significant level of genuine neurologically based pain. The pain becomes the main focus of the patient's attention, and results in significant distress and dysfunction.

"Clinical supervision" means an organized process by which knowledgeable and skilled supervisors systematically and routinely provide ongoing and in-depth review of direct service providers' performance.

"Comprehensive maintenance treatment" is:

(1) Dispensing or administering an approved opioid agonist medication at stable dosage levels for a period in excess of 21 days to a patient for opioid addiction, and

(2) Providing medical, clinical and educational services to the patient with opioid addiction.

"Continuing care plan" means a written plan of recommendations and specific referrals for implementation of continuing care services, including medications, shall be prepared for each patient meeting the ASAM Patient Placement Criteria dimensional continued service criteria. Continuing care plans shall be developed with the knowledge and cooperation of the patient. This continuing care plan may be included in the discharge summary. The patient's response to the continuing care plan shall be noted in the plan, or a note shall be made that the patient was not available and why. In the event of the death of a patient, a summary statement including this information shall be documented in the record.

"Co-occurring disorder" or "**COD"** means any combination of mental health and substance abuse symptoms or diagnoses as determined by the current Diagnostic and Statistical Manual of Mental Disorders that affect a patient.

"Co-occurring disorder capability" means the organized capacity within any type of program to routinely screen, identify, assess, and provide properly matched interventions to patients with co-occurring disorders. Co-occurring disorder capable programs address co-occurring disorders diagnosis in policy and procedures, assessment, treatment planning, program content, and transition planning.

"Clinical Opioid Withdrawal Scale" or **"COWS"** means a well validated, standardized assessment instrument for evaluating the severity of a patients withdrawal through the identification of objective and subjective symptoms and the severity of these symptoms.

"**Courtesy Dosing"** means the act of dosing a methadone patient from another clinic on a short term basis due to emergency or other extra ordinary circumstance.

"Critical incident" means an occurrence or set of events inconsistent with the routine operation of an approved treatment facility, or the routine care of a patient. Critical incidents specifically include but are not necessarily limited to the following: adverse drug events; self destructive behavior; deaths and injuries (including

automobile accidents) to the patient, patient family, staff and visitors; medication errors; neglect or abuse of a patient; fire; unauthorized disclosure of information; damage to or theft of property belonging to a patient or an approved treatment facility; other unexpected occurrences; or events potentially subject to litigation. A critical incident may involve multiple individuals or results.

"CSAT" means Center for Substance Abuse Treatment.

"**Cultural competency**" means the ability to recognize, respect, and address the unique needs, worth, thoughts, communications, actions, customs, beliefs and values that reflect an individual's racial, ethnic, religious, sexual orientation, and/or social group.

"DEA" means Drug Enforcement Administration.

~~"**Methadone detoxification treatment"** means the process of dispensing or administering of an opioid agonist treatment medication in decreasing doses to an individual to alleviate adverse physical or psychological effects related to withdrawal from the continuous or sustained use of an opioid drug and as a method of bringing the individual to a drug-free state.~~

"**Discharge planning"** means the process, beginning at admission of determining a consumer's continued need for treatment services and developing a plan to address ongoing consumer recovery needs.

"**Diskette"** means a compressed wafer form of methadone intended to be dissolved in water for consumption. For the purposes of this chapter methadone diskettes will not be considered to be the same as tablet methadone.

"Dispense" means preparing, packaging, compounding and labeling for delivery, a prescription drug in the course of professional practice to an ultimate user by the lawful order of a physician.

"**Diversion"** means the unauthorized or illegal transfer of an opioid agonist treatment medication.

"**Diversion control plan"** or **"DCP"** means documented procedures to reduce the possibility that controlled substances are used for any purpose other than legitimate use.

"Drug dispensing area" means the specified and secured location established by the OSTP for dispensing opioid agonist drugs to the patients. The area shall be secure, meet all appropriate standards and be the only location within the facility where drugs are dispensed.

"Drug stocks" means the inventory of drugs stored and secured by the clinic, available for use in opioid agonist treatment.

"Drug test" means the assessment of an individual to determine the presence or absence of illicit or nonprescribed drugs or alcohol or to confirm maintenance levels of treatment medication(s), by a methodology approved by the OSTP medical director based on informed medical judgment and conforming to State and Federal law. This may include blood testing, oral-fluid and urine testing.

"**DSM**" means the most current edition of the Diagnostic and Statistical Manual of Mental Disorders published by the American Psychiatric Association.

"Exception request process" means a process recording the justification of the need to make a change in treatment protocol for an opioid patient and submitted to SAMHSA using form SMA-168.

"Facility" means any program authority, hospital, school, building, house or retreat, authorized by law to have the care, treatment or custody of the mentally ill or drug-or alcohol-dependent persons including, but not limited to, public or private hospitals, community mental health centers, clinics, satellites, institutions, organizations or agencies provided that the facility shall not mean a child guidance center operated by the State Department of Health.

"FDA" Federal Food and Drug Administration.

"Federal opioid treatment standards" means the established standards of SAMHSA, CSAT and the DEA that are used to determine whether an OSTP is qualified to engage in opioid treatment.

"**HIPAA"** means Healthcare Insurance Portability and Accountability Act.

"ICIS" means Integrated Client Information Services.

"**Individualized treatment planning"** means the ongoing process by which a clinician and the patient identify and rank problems, establish agreed upon goals, and decide on the treatment process and resources to be utilized.

"Interim maintenance treatment" means maintenance treatment provided in conjunction with appropriate medical services while a patient is awaiting transfer to a program that provides comprehensive maintenance treatment.

"Liquid methadone" means a liquid concentrate of methadone meant to be mixed with water for ingestion.

"Lock box" means a container with a combination lock or key lock entry system for securing take home medications. The box must have the ability to lock and should be secure enough to thwart access by children.

"Long-term care facilities" means a facility or institution that is licensed, certified or otherwise qualified as a nursing home or long term care facility by the state in which methadone treatment services are rendered. This term includes skilled, intermediate, and custodial care facilities which operate within the terms of licensure.

"Long-term detoxification treatment" means detoxification treatment for a period of more than 30 days but less than 180 days.

"Medical and rehabilitative services" means services such as medical evaluations, counseling, and rehabilitative and other social programs (e.g., vocational and educational guidance, employment placement), intended to help patients in an OSTP to become and/or remain productive members of society.

"Medical director" means a physician, licensed to practice medicine in Oklahoma, who assumes responsibility for the administration of all medical services performed by an OSTP, either by performing them directly or by delegating specific responsibility to authorized program physicians and healthcare professionals functioning under the medical director's direct supervision, unless otherwise indicated in this chapter. This includes ensuring the program is in compliance with all federal, state, and local laws and regulations regarding the medical treatment of addiction to an opioid drug.

"Medical withdrawal" means a condition created by administering an opioid agonist treatment medication in decreasing doses to an individual to alleviate adverse physical or psychological effects of withdrawal from the continuous or sustained use of an opioid drug and as a method of bringing the individual to a drug-free state.

"**Medication unit"** means a facility established as part of, but geographically

separate from, an OSTP from which licensed private practitioners or community pharmacists dispense or administer an opioid agonist treatment medication or collect samples for drug testing or analysis.

"**Methadone detoxification treatment"** means the process of dispensing or administering of an opioid agonist treatment medication in decreasing doses to an individual to alleviate adverse physical or psychological effects related to withdrawal from the continuous or sustained use of an opioid drug and as a method of bringing the individual to a drug-free state.

"Non-oral methadone" means an injectable form of methadone not allowed for use by an OSTP,

"**ODMHSAS"** means the Oklahoma Department of Mental Health and Substance Abuse Services.

"**Oklahoma Administrative Code**" or "**OAC**" means the publication authorized by 75 O.S. § 256 known as The Oklahoma Administrative Code, or, prior to its publication, the compilation of codified rules authorized by 75 O.S. § 256(A) (1) (a) and maintained in the Office of Administrative Rules.

"Oklahoma state-issued identification card" means a photo identification card issued by the Oklahoma Department of Motor Vehicles for use in identification.

"**Opiate drug"** means any of a class of drugs also called narcotics derived from the opium poppy or containing opium and with analgesic or sedative effects that can form sustain or enhance addiction and physical dependency.

"Opioid addiction" means a cluster of cognitive, behavioral, and physiological symptoms in which an individual continues use of opioids despite significant opioid-induced problems. Opioid dependence is characterized by repeated self-administration resulting in opioid tolerance, withdrawal symptoms, and compulsive drug-taking. Dependence may occur with or without the physiological symptoms of tolerance and withdrawal.

"Opioid agonist" means a drug that has an affinity for and stimulates physiologic activity at cell receptors in the central nervous system normally stimulated by opioids. Methadone is an opioid agonist.

"Opioid agonist treatment medication" means a prescription medication, such as methadone, buprenorphine or other substance scheduled as a narcotic under the Federal Controlled Substances Act (21 U.S.C. Section 811) that is approved by the U.S. Food and Drug Administration for use in the treatment of opiate addiction or dependence.

"Opioid antagonist" means a drug that binds to cell receptors in the central nervous system that normally are bound by opioid psychoactive substances and that blocks the activity of opioids at these receptors without producing the physiologic activity produced by opioid agonists. Naltrexone is an opioid antagonist.

"Opioid dependence" see opioid addiction.

"Opioid drug" means any of a class of drugs also called narcotics, having an addiction-forming or addiction-sustaining liability similar to morphine. Originally a term for synthetic narcotics only, but for the purposes of this chapter and unless otherwise specified, currently used to describe both opium based and synthetic narcotics. These drugs have analgesic or sedative effects.

"**Opioid partial agonist"** means a drug that binds to, but incompletely activates,

opiate receptors in the central nervous system, producing effects similar to those of an opioid agonist but, at increasing doses, does not produce as great an agonist effect as do increased doses of an agonist. Buprenorphine is a partial opioid agonist.

"Opioid treatment" means the dispensing of an opioid agonist treatment medication, along with a comprehensive range of medical and rehabilitative services, when clinically necessary, to an individual to alleviate the adverse medical, psychological, or physical effects incident to opioid addiction. This term encompasses detoxification treatment, short-term detoxification treatment, long-term detoxification treatment, maintenance treatment or comprehensive maintenance treatment, interim maintenance treatment and treatment provided in medication units, long term care facilities or hospitals.

"Opioid Substitution Treatment Program (OSTP)" An organization which has been certified by ODMHSAS to provide opioid treatment whose certification has not been suspended, revoked, or surrendered to the department.

"Pain management" means the successful management of chronic pain or a chronic pain disorder.

"Paraprofessional" means a person who does not have an academic degree related to the scope of treatment or support services being provided but performs prescribed functions under the general supervision of that discipline.

"Patient-based planning" means an organized and systematic method of basing treatment and services on the needs of current and prospective patients.

"Patient record" or **"medical record"** means the collection of written information about a patient's evaluation or treatment that includes the intake data, evaluation, treatment or service plan, description of treatment or services provided, medications as prescribed, continuing care plan, and discharge information on an individual patient.

"Parenteral" means injected, infused or implanted, used to describe drug administration other than oral or anal.

"**Peak test"** see Peak and Trough.

"Peak and trough test" means a therapeutic monitoring of serum methadone levels to determine the most appropriate dosing strategy for the individual patient, requiring at least two blood samples be drawn. The initial sample taken immediately prior to the daily dose and twenty four hours after the previous day's dose allowing the lowest level or "trough" to be identified. The second sample taken four hours after dosing allows the highest level or "peak" to be identified.

"Program physician" A licensed physician who provides medical treatment and counsel to the patients of an OSTP while under the supervision of the medical director.

"Program sponsor" A person named in the application for an OSTP permit who is responsible for the operation of the OSTP and who assumes responsibility for all its employees, including any practitioners, staff, or other persons providing medical, rehabilitative, or counseling services at the program or any of its medication units. The program sponsor need not be a licensed physician but shall employ a licensed physician for the position of medical director.

"SAMHSA" means the Substance Abuse and Mental Health Services Administration.

"Sentinel event" means a type of critical incident that is an unexpected

occurrence involving the death or serious injury to a consumer, or risk thereof. Serious injury specifically includes loss of limb or function. The phrase “or risk thereof” includes a variation in approved processes which could carry a significant chance of a serious adverse outcome to a consumer. These events signal the need for an immediate investigation and response. Sentinel events include, but are not limited to: suicide, homicide, criminal activity, assault and other forms of violence, including domestic violence or sexual assault, and adverse drug events (including medication overdoses by patients and associates of patients) resulting in serious injury or death.

"Short-term detoxification treatment" means detoxification treatment for a period not in excess of 30 days.

"State Methadone Authority" or "SMA" is the agency designated by the Governor or other appropriate official designated by the Governor to exercise the responsibility and authority within the State or Territory for governing the treatment of opioid addiction with an opioid drug. For Oklahoma it is the The Oklahoma Department of Mental Health and Substance Abuse Services.

"**STD"** means sexually transmitted disease.

"**Street outreach"** means methods of direct intervention/prevention with high risk populations for HIV, HCV, tuberculosis and other infectious and communicable diseases.

"**Tablet methadone"** means methadone in a tablet form intended to be taken orally. For the purposes of this chapter diskettes will not be considered to be tablet methadone.

"Take-home privilege or take home medication" means one or more doses of an opioid agonist treatment medication dispensed to a patient for use off the premises.

"Therapeutic hour(s)" means the amount of time in which the patient was engaged with a treatment professional in identifying, addressing, and/or resolving those issues that have been identified in that patients treatment plan. This time frame can be no less than thirty (30) minutes.

"Transient consumer" means a methadone patient from another geographic location requiring “courtesy dosing”.

"**Treatment professional"** means any person allowed to provide alcohol and drug counseling, or is under supervision pursuant to the Licensed Alcohol and Drug Counselors Act, or otherwise exempt by law.

"**Trough test"** see Peak and Trough.

"Urine analysis or **UA"** means a urine sample taken to determine if metabolites are present indicating the use of drugs.

"Withdrawal treatment" means either administrative withdrawal, or medical titration and withdrawal from any drug or medication until the patient has achieved a drug free state.

450:70-1-3. Meaning of verbs in rules

The attention of the facility is drawn to the distinction between the use of the words "shall," "should," and "may" in this chapter:

(1) **"Shall"** is the term used to indicate a mandatory statement, the only acceptable method under the present standards.

(2) **"Should"** is the term used to reflect the most preferable procedure, yet allowing for the use of effective alternatives.

(3) **"May"** is the term used to reflect an acceptable method that is recognized but not necessarily preferred.

450:70-1-4. Applicability

(a) This chapter is applicable to all substance abuse treatment facilities and organizations providing opioid substitution treatment, opioid detoxification or opioid maintenance including but not limited to counseling, rehabilitation services and substance abuse treatment services including methadone maintenance treatment, short term detoxification treatment, long term detoxification treatment or interim maintenance treatment which are statutorily required to be certified and approved by the ODMHSAS, the Alcohol and Drug Abuse Prevention, Training and Rehabilitation Authority [43A O.S. § 3-601,(c).

(b) Any conviction for a violation of any rule in this Part which has been promulgated pursuant to the provisions of 43A O.S. § 3-601 shall be a felony [43A O.S. § 3-601(B)].

450:70-1-5. Compliance review of standards and criteria

The standards and criteria in this chapter shall be annually reviewed by the ODMHSAS. Compliance with these standards and criteria may be determined by a review of the following:

(1) Progress notes,

(2) Policy and Procedures,

(3) Review of all facility records,

(4) Interviews with staff and patients, and

(5) Investigations, site visits, treatment protocols, patient records, clinical service manuals and certification reviews.

SUBCHAPTER 2. FACILITY INFRASTRUCTURE REQUIRMENTS

450:70-2-1. Physical facility environment and safety

(a) All facilities providing opioid substitution treatment service shall have written policies and procedures intended to ensure the safety and protection of all persons within the facility's physical environment (property and buildings, leased or owned).

(b) These policies and procedures shall include, but are not limited to:

(1) Meeting all fire and safety regulations, code and statutory requirements of federal, state, tribal, or local government. All OSTPs shall have an annual fire and safety inspection from the State Fire Marshal, tribal, or local authorities; and shall maintain a copy of said inspection and attendant correspondence regarding any deficiency.

(2) An emergency preparedness plan to provide effective utilization of resources to best meet the physical needs of patients, visitors, and staff during any disaster (including, but not limited to; fire, flood, tornado, explosion, prolonged loss of heat, light, water, and/or air conditioning).

(A) This plan shall include procedures facilitating the transfer of patients in the event the OSTP is unable to open.

(B) This plan shall be evaluated annually, and revised as needed.
(3) A designated Safety Officer.
(4) Staff training and orientation regarding the location and use of all fire extinguishers and first aid supplies and equipment and an emergency preparedness plan.
(5) Emergency evacuation routes and shelter areas shall be prominently posted in all areas.
(6) Fire alarm systems shall have visual signals suitable for the deaf and hearing-impaired.
(7) There shall be emergency power to supply lighting to pre-selected areas of the facility.
(8) The maintenance of facility grounds to provide a safe environment for consumers (specific to age group[s] served), staff and visitors.
(9) Storage of dangerous substances (toxic or flammable substances) in locked, safe areas or cabinets.
(10) A written plan for the protection and preservation of consumer records in the event of a disaster.

450:70-2-2. Hygiene and sanitation

OSTPs shall provide:
(1) Lavatories and toilet facilities in a minimum ratio of one per twenty persons.
(2) Sewerage discharge into a municipal sewerage system or collected, treated and disposed of in an independent sewerage system.
(3) Solid waste disposal through public systems or in a manner approved by the local agency having jurisdiction and the Oklahoma State Department of Health or Department of Environmental Quality, as necessary.
(4) Water obtained from an approved public water supply or tested at least quarterly and treated as necessary, thereby maintaining a determination as an approved water supply by the authority having jurisdiction and the Oklahoma Department of Health or Department of Environmental Quality, as indicated by the building permit.
(5) The facility shall have proof of regular inspections and treatment by a licensed pest control operator.
(6) House-keeping services so that a hygienic environment is maintained in the facility.

SUBCHAPTER 3. FACILITY RECORD SYSTEM

PART 1. RECORD SYSTEM

450:70-3-1. Purpose.

All OSTPs shall document and maintain records as described in Subchapter 3.

450:70-3-2. Patient record system

(a) Each OSTP shall maintain an organized system for the content, confidentiality, storage retention and disposition of patient records.
(b) The OSTP shall have written policies and procedures concerning patient records

which define required documentation within the patient record.
(c) Patient records shall be maintained in a locked and secure manner.
(d) The OSTP shall maintain identification and filing systems which enable prompt record location and accessibility by treatment professionals.
(e) Patient records shall be maintained in the facility where the individual is being treated or served. In the case of temporary office space or satellites, records may be maintained in the main (permanent) office and transported in secured lock boxes to and from temporary offices or satellites, when necessary. Patient records may be permanently maintained at the OSTP's administrative offices; however, a working copy of the patient record for the purposes of documentation and review of services provided must be maintained at the site in which the patient is receiving treatment.
(f) The OSTP shall have policies which govern the storage, retention, and disposition of patient records. These policies shall be compatible with protection of patient's rights against confidential information disclosure, and compliant with applicable state and federal law.

450:70-3-3. Patient records, basic requirement

(a) Patient records shall be developed and maintained to ensure that all appropriate individuals have access to relevant clinical and other information regarding the patient. The patient record shall communicate information in a manner that is organized, clear, complete, current and legible. All patient records shall contain the following:

(1) Entries in patient records shall be legible, signed with first name or initial, last name, and dated by the person making the entry;
(2) The patient shall be identified by name and unique identifier on each sheet in the patient record, readily identifiable, on both sides of each page if both sides are used;
(3) A signed consent for treatment shall be obtained and placed in the record before any person can be admitted into treatment at an OSTP;
(4) A signed consent for follow-up shall be obtained and placed in the record before any contact after discharge can be made;
(5) An intake and admission assessment;
(6) A biopsychsocial assessment;
(7) Case management needs assessment;
(8) Treatment planning;
(9) Documentation of progress notes;
(10) A discharge biopsychsocial assessment;
(11) A continuing care plan;
(12) Consultation reports;
(13) Psychological or psychometric testing;
(14) Records and reports from other entities;
(15) Medication records;
(16) A discharge summary;
(17) Referral and transfer;
(18) Consultation reports;
(19) Psychological or psychometric testing;
(20) Records and reports from other entities;
(21) Medication records; and

(22) Referrals and transfers.

(A) The OSTP shall refer patients to other resources when the individual has treatment or service needs the facility does not provide.

(B) The OSTP shall maintain a directory of currently available resources, which shall, at a minimum, contain the "ODMHSAS Yellow Pages."

(C) The transferring program must supply patient medical records necessary in response to a written request and a valid consent form within fifteen (15) days of receipt and in compliance with all applicable state and federal law.

(i) The program shall furnish copies of medical records requested, or a summary or narrative of the records, including records received from a physician or other health care provider involved in the care or treatment of the patient, pursuant to a written consent for release of the information, except if the physician determines that access to the information would be harmful to the physical, mental, or emotional health of the patient, and the program may delete confidential information about another patient or family member of the patient who has not consented to the release.

(ii) The information shall be furnished by the program within fifteen (15) days after the date of receipt of the request.

(iii) If the program denies the request, in whole or in part, the program shall furnish the patient a written statement, signed and dated, stating the reason for the denial. A copy of the statement denying the request shall be placed in the patient's record.

450:70-3-4. Confidentiality of drug or alcohol abuse or mental health treatment information

Confidentiality policy, procedures and practices must comply with federal and state law, guidelines, and standards, and with OAC 450:15-3-20.1 and OAC 450:15-30-60.

~~All facilities shall have policy and procedures protecting the confidential and privileged nature of mental health and substance abuse treatment information in compliance with state and federal law and which contain at a minimum:~~

~~(1) An acknowledgment that all mental health and substance abuse treatment information, whether recorded or not, and all communications between a physician or psychotherapist and a consumer are both privileged and confidential and will not be released without the written consent of the consumer or the consumer's legally authorized representative;~~

~~(2) An acknowledgment that the identity of a consumer who has received or is receiving mental health or substance abuse treatment services is both confidential and privileged and will not be released without the written consent of the consumer or the consumer's legally authorized representative;~~

~~(3) A procedure to limit access to mental health and substance abuse treatment information to only those persons or agencies actively engaged in the treatment of the patient and to the minimum amount of information necessary to carry out the purpose for the release;~~

~~(4) A procedure by which a consumer, or the consumer's legally authorized representative, may access the consumer's mental health and substance abuse~~

~~treatment information;~~
~~(5) An acknowledgement that certain state and federal law exceptions to disclosure of mental health and drug or alcohol abuse treatment information without the written consent of the consumer or the consumer's legally authorized representative exist and the facility will release information as required by those laws and~~
~~(6) A procedure by which to notify a consumer of his or her right to confidentiality.~~
~~(7) Compliance with 450:18-7-3.1 shall be determined by a review of facility policy and procedures; facility forms; consumer record reviews; interviews with staff and consumers; and any other supporting facility documentation.~~

PART 3. INTAKE AND ADMISSION ASSESSMENT

450:70-3-5. Intake assessment and record content

(a) All OSTPs shall assess each individual for appropriateness for admission, ensuring the individual is placed in the least restrictive level of care.
(b) Each OSTP shall ensure that patients are admitted to short or long term detoxification treatment by a program physician, who determines that such treatment is appropriate for the specific patient by applying current and established DSM diagnostic and ASAM placement criteria.
(c) The OSTP shall have written policy and procedure stating the program shall require each patient to undergo a complete, fully documented history and physical examination by a program physician or physician with a valid Oklahoma license before admission to the opioid treatment program. A full medical examination, including the results of serology and other tests, must be completed within fourteen (14) days following admission.
(d) Patients who have had a complete history and physical including laboratory tests within the past three months may be admitted to the OSTP without a new medical examination and laboratory tests, unless the program physician requests it. The admitting program shall obtain copies of these results within fifteen (15) days of admission. If records are not obtained within fifteen (15) days, the program shall conduct a complete history and physical.
(e) The OSTP shall have written policy and procedure stating any drugs approved for use in treating opioid dependency when used by an OSTP for persons with a history of addiction, or physiologic dependence, shall only be used in treating persons with a history of addiction of two (2) years or more as verified by the medical director or a program physician through medical examination; or persons with a one (1) year history of addiction and written documentation from an agency at which another type of addiction treatment was attempted or accomplished. Such documentation shall be received prior to admission to the program and/or induction of any drug uses as a part of an opioid substitution treatment regimen.
(f) Any patient seeking admission while under the influence, or undergoing withdrawal of alcohol or drugs shall be assessed prior to admission for medical needs. The written criteria to be used for medical needs assessment shall be approved by the OSTP Medical Director and meet state and federal requirements regarding standards0 of care.

(g) Using a standardized and accepted instrument (such as the COWS Scale) no patient shall be admitted to opioid substitution treatment unless symptoms of opioid dependency are present including:

(1) Elevated resting pulse rate;
(2) Increased sweating;
(3) Increased restlessness;
(4) Variation in pupil size;
(5) Bone and/or joint pain;
(6) Runny nose and/or tearing;
(7) Gastrointestinal distress;
(8) Tremors;
(9) Increased yawning;
(10) Increased anxiety or irritability; or
(11) Presence of “gooseflesh”.

(h) The OSTP shall have written policy and procedure stating the patient record shall contain adequate documentation of any prescription drug, including methadone, that a patient may be taking, including the name of the drug, the prescription number, the dose, the reason for prescribing, the name of the prescribing doctor, the pharmacy's name and telephone number, the date it was prescribed, and the length of time the patient is to be taking the drug. A release of information to the prescribing physician either by mail, facsimile or other acceptable electronic means allowing the medical director to coordinate treatment and discuss medications.

(i) The OSTP shall have written policy and procedure stating that if clinically appropriate, the program physician may waive the requirement of a one (1)-year history of opioid addiction for,

(1) A patient within six (6) months of release from a correctional institution;
(2) A patient with a pregnancy verified by the program physician; or
(3) A patient having previously received opioid substitution treatment and within two (2) years of discharge from an OSTP.

(j) The OSTP shall have written policy and procedure stating that patients with two (2) or more unsuccessful detoxification episodes within a twelve (12) month period must be assessed by the medical director or a program physician for identification of need for other forms of treatment. An OSTP shall not admit a patient for more than two (2) detoxification treatment episodes in one (1) year.

(k) The OSTP shall have written policy and procedure stating any person under the age of eighteen (18) years of age requesting maintenance treatment shall have written documentation of two (2) unsuccessful attempts at short-term detoxification or drug-free treatment within a twelve (12) month period to be considered eligible for maintenance treatment.

(1) Such documentation shall be received prior to admission to the program or the induction of any drug used as a part of an opioid substitution treatment regimen.
(2) No person under eighteen (18) years of age may be admitted to maintenance treatment unless a parent, legal guardian or otherwise legally responsible adult designated by the relevant state authority consents in writing to such treatment.

(l) The OSTP shall have written policy and procedure outlining the requirement for the

reporting of persons receiving opioid substitution treatment to the ODMHSAS. This report to the Central Registry shall be made in a form requested by the Commissioner or designee and within twenty-four (24) hours of admission, change of medical status or discharge of any patient.

(m) The OSTP shall have written policy and procedure stating the admission requirements for opioid substitution treatment programs.

(n) All applicants for opioid substitution treatment shall sign a written consent for opioid treatment in the primary language of the applicant.

(o) The patient intake information shall contain, but not be limited to, the following:

(1) Date of initial contact requesting services;

(2) Identification information, including Patient's name, home address, and telephone number;

(3) Referral source;

(4) Mental status examination and findings;

(5) History and physical information;

(6) Family to be notified in case of emergency; and

(7) If the facility reports on ICIS, the ICIS intake data core content.

(p) All OSTPs shall document and assess all patients for appropriateness of admission taking into account the patient's needs as identified by, but not limited to:

(1) Acute intoxication and withdrawal potential;

(2) Biomedical conditions and complications;

(3) Emotional and behavioral conditions and complications;

(4) Readiness to change;

(5) Relapse potential; and

(6) Recovery environment.

(q) The OSTP shall have a written policy and procedure that shall be made available to all patients, outlining rehabilitation services. Minimum services include:

(1) Individual counseling until the patient is fully stabilized and as indicated in this chapter;

(2) Group and family counseling for spouses, parents, or significant others and as indicated in this chapter;

(3) Vocational or educational counseling and referral and as indicated in this chapter; and

(4) Referral for additional services as outlined by the individualized treatment plan.

(r) The OSTP shall have written policy and procedure requiring the patient to be informed of all services that are available through the agency; and of all policies and procedures that may impact the patient's treatment.

(s) The OSTP shall have written policy and procedure requiring the patient be informed of the following upon admission:

(1) The progression of opioid addiction and the patient's assessed stage of opioid addiction;

(2) The goal and benefits of opioid treatment;

(3) The signs and symptoms of overdose and when to seek emergency assistance;

(4) The characteristics of opioid agonist treatment medication, including common side-effects and potential interaction effects with non-opioid

agonist treatment medications and/or illicit drugs;
(5) The requirement for staff members to report suspected or alleged abuse or neglect of a child or an incapacitated or vulnerable adult;
(6) The requirement for staff members to comply with the confidentiality requirements of 42 CFR Part 2 and 45 CFR parts 160 and 164;
(7) Drug screening and urinalysis procedures;
(8) Take-home medication requirements;
(9) Testing and treatment available for HIV, HCV, tuberculosis and other communicable diseases;
(10) The process for a patient to file a grievance with the agency for any reason, including involuntary discharge, and to have the client's grievance handled in a fair and timely manner; and
(11) The process for a patient to file a grievance with the ODMHSAS Patient Advocate office agency for any reason, including involuntary discharge.

(t) The OSTP shall have written policy and procedure requiring the OSTP to see that an individual who requires administration of opioid agonist treatment medication only for relief of chronic pain is:
(1) Identified during the physical examination or assessment;
(2) Not admitted for opioid agonist medication treatment; and
(3) Referred to appropriate medical services.

(u) The OSTP shall have written policy and procedure requiring treatment by a multi-disciplinary team of medical practitioners; including specialists in addiction medicine and pain management, for physically dependent or addicted patients with a chronic pain disorder. The OSTP shall coordinate with the physician treating the patient for pain.

(v) The OSTP shall have written policy and procedure requiring the facility to ensure that, if, during the assessment or physical examination, a determination is made that a patient may have a mental disorder, the patient is referred for assessment and treatment of the mental disorder. The OSTP will have written procedures including all required consents, for communication and collaboration with the patient's behavioral health professional to monitor and evaluate interactions between the client's opioid agonist treatment medication and any medications used to treat the patient's mental disorder.

(w) The OSTP shall have written policy and procedure requiring the OSTP to ensure that, if, during the assessment or physical examination, a determination is made that a patient may have a medical condition requiring intervention, the patient is referred for assessment and treatment of the medical condition. The OSTP will have written procedures including all required consents, for communication and collaboration with the patient's health professional to monitor and evaluate interactions between the patient's opioid agonist treatment medication and medications used to treat the patient's medical condition.

(x) The OSTP shall have written policy and procedure allowing the medical director to refuse the admission and/or opioid treatment to any patient if, in the reasonable clinical judgment of the medical director, the person would not benefit from such treatment. Prior to such a decision, appropriate staff should be consulted and the reason(s) for the decision must be documented by the medical director.

(y) The OSTP shall have written policy and procedure requiring the patient must present a valid form of photo identification which can include; valid driver's license from the State of residence, United States passport, military identification card, or state-issued identification card containing a photograph of the patient from the State of residence, Tribal ID card with photograph, or other identification approved by the State Methadone Authority. Photocopies shall be obtained upon admission and the copy must be maintained in the patient's record. The program shall document in the patient's file attempts to induce the patient to obtain state identification.

(z) OSTPs shall develop and maintain written policies and procedures that are adequate to ensure that the following dosage form and initial dosing requirements are met:

(1) Methadone shall be administered or dispensed only in oral form and shall be formulated in such a way as to reduce its potential for parenteral abuse.

(2) For each new patient enrolled in a program, the initial dose of methadone shall not exceed thirty (30) milligrams and the total dose for the first day shall not exceed forty (40) milligrams, unless the program physician documents in the patient's record that forty (40) milligrams did not suppress opiate abstinence symptoms. Any increase above forty (40) milligrams shall be based on the physician's medical judgment and documented in the chart.

(aa) Facilities must ensure that a patient's refusal of a particular service does not preclude the patient from accessing other needed mental health or substance abuse services. Should the treatment professional determine the patient's needs cannot be met within the facility, clinical documentation of assessments and referrals for the patient shall contain, at a minimum:

(1) Date of initial contact requesting services;

(2) Identification information, including Patient's name, home address and telephone number;

(3) Referral source;

(4) Mental status examination and results;

(5) History and physical;

(5) Family to be notified in case of emergency;

(6) If the facility reports on ICIS, the ICIS intake data core content;

(7) A continuing care plan;

(8) What agency was contacted; and

(9) Where and why the individual was referred.

450:70-3-6. Intake and assessment, process requirements

Written policies and procedures governing the intake and assessment process shall specify the following:

(a) The information to be obtained on all applicants or referrals for admission;

(b) The procedures for accepting referrals from outside agencies or organizations;

(c) The records to be kept on all applicants;

(d) Any prospective patient data to be recorded during the intake process;

(e) The procedures to be followed when an applicant or a referral is found ineligible for admission; and

(f) The procedures and policies for the purpose of admitting and assessing persons with special needs or disabilities.

PART 5. BIOPSYCHSOCIAL ASSESSMENT

450:70-3-7. Biopsychsocial assessment

(a) All OSTPs shall complete a biopsychsocial assessment which gathers sufficient information to assist the patient in developing an individualized treatment plan. The OSTP shall utilize the current edition of the Addiction Severity Index (ASI) or develop a biopsychsocial assessment which contains, but not be limited to, the following:

(1) Identification of the patient's strengths, needs, abilities, and preferences problem;
(2) Presenting problem and history of the presenting problem;
(3) Previous treatment history, including opioid substitution therapy:
  (A) Mental health,
  (B) Substance abuse, and
  (C) Domestic violence, to include batterer's treatment or victim services;
(4) Health history and current biomedical conditions and complications;
(5) Alcohol and drug use history;
(6) History of trauma;
(7) Family and social history, including family history of alcohol and drug use;
(8) Educational attainment, difficulties, and history;
(9) Cultural and religious orientation;
(10) Vocational, occupational and military history;
(11) Sexual history, including HIV, AIDS and STD at-risk behaviors;
(12) Marital or significant other relationship history;
(13) Recreational and leisure history;
(14) Legal history;
(15) Present living arrangement;
(16) Economic resources;
(17) Level of functioning;
(18) Current support system;
(19) Current medications, if applicable and shall include obtainable information regarding the name of prescribing physician, name of medication, strength and dosage, and length of time consumer was on the medication;
(20) Patient's expectations in terms of service; and
(21) Assessment summary or diagnosis, and signature of the assessor and date of the assessment.

(b) The assessment shall be completed as soon as possible after admission and by the end of fourth (4th) visit.

(c) In the event of a consumer re-admission after one (1) year of the last biopsychsocial assessment, a new biopsychsocial assessment shall be completed. If readmission occurs within one (1) year after the last biopsychsocial assessment, an update shall be completed.

PART 7. TREATMENT PLANNING

450:70-3-8. Individualized treatment planning

(a) Upon completion of the admission evaluation, an individualized treatment plan shall be developed. The individualized treatment plan shall include, but not be limited to:

(1) Presenting problems or diagnosis;
(2) Strengths, needs, abilities, and preferences of the patient;
(3) Goals for treatment with specific, measurable, attainable, realistic and time-limited;
(4) Type and frequency of services to be provided;
(5) Primary person responsible for providing services;
(6) Description of patient's involvement in, and responses to, the treatment plan, and his or her signature and date;
(7) Discharge criteria, other than the discharge criteria required by the level of care;
(8) Specific date for each planned treatment plan review and update, no less than at each phase change;
(9) Any other item required by state of federal law;
(10) Projected length of treatment;
(11) Medication Protocol;
(12) Measurable long and short term treatment goals;
(13) Primary and supportive services to be utilized with the patient;
(14) Type and frequency of therapeutic activities in which patient will participate;
(15) Documentation of the patient's participation in the development of the plan; and
(16) Staff who will be responsible for the patient's treatment.

(b) The treatment plan shall be based on the patient's presenting problems or diagnosis, intake assessment, biopsychsocial assessment, and expectations of their recovery.
(c) Treatment plans shall be dated and signed by the patient and the primary service provider. A list of the treatment team members who participate in providing services shall be included on the treatment plan.
(d) Unless otherwise indicated by this chapter, frequency of services shall be determined by mutual agreement between the facility treatment team and the patient.
(e) Time frames for completion of treatment plans from the date and time of admission shall be by the sixth (6th) visit.
(f) The treatment plan shall contain review and update of the treatment plan according to the time frame required by the treatment plan; and further, is required by any of the following situations:

(1) Change in goals and objectives based upon patient's documented progress, or identification of any new problem;
(2) Change in primary counselor assignment;
(3) Change in frequency and types of services provided;
(4) Critical incident reports; or
(5) Sentinel events.

PART 9. PROGRESS NOTES

450:70-3-9. Progress notes

Unless defined otherwise by level of care, substance abuse treatment services and any issues related to treatment shall be reflected by written documentation in the patient's record and shall include the following:

(1) date;
(2) start and stop time for each timed treatment session;
(3) signature of the staff person providing the service and date of signature;
(4) credentials of the staff person providing the service;
(5) when service is provided by a paraprofessional, signatures of the paraprofessional and a credentialed staff person;
(6) specific problems(s), goals and objectives addressed (problem must be identified on master treatment plan, or the assessment);
(7) interventions used to address problem(s), goals and objectives;
(8) progress made toward goals and objectives, or lack of;
(9) patient response to the session or intervention;
(10) any new problem(s), goals and objectives identified during the session; and
(11) Patient's name and unique identifier.

PART 11. DISCHARGE

450:70-3-10. Discharge assessment

(a) All consumers shall be assessed for biopsychsocial appropriateness of discharge from each level of care taking into account the consumers needs as identified by, but not limited to:

(1) Presenting problem(s) at intake;
(2) Initial condition and condition of consumer at discharge;
(3) Medication summary, when appropriate;
(4) Treatment and services provided, and a summary of treatment outcomes and results;
(5) The continuing care plan may be included in the discharge summary;
(6) The signature of the staff member completing the summary, and the date;
(7) Acute intoxication and/or withdrawal potential;
(8) Biomedical conditions and complications;
(9) Emotional, behavioral or cognitive conditions and complications;
(10) Readiness to change;
(11) Relapse, continued use or continued problem potential; and
(12) Recovery/living environment.

(b) A discharge summary shall be entered in each patient's record within fifteen (15) days of discharge.

SUBCHAPTER 4. SERVICES SUPPORT AND ENHANCEMENT

PART 1. STAFF SUPPORT

450:70-4-1. Purpose

The purpose of this subchapter is to set forth components which support and enhance treatment services provided to consumers by OSTP staff and employees.

450:70-4-2. Clinical supervision

(a) All facilities shall provide clinical supervision for those delivering direct services and shall be provided by persons qualified to provide clinical supervision as determined by state licensure or certification.

(b) All facilities shall have written policy and procedures, operational methods, and documentation regarding clinical supervision for all direct treatment staff and service staff. These policies shall include, but are not limited to:

(1) Credentials required for the clinical supervisor;

(2) Specific frequency for case reviews with treatment and service providers;

(3) Methods and time frames for supervision of individual, group, and educational treatment services; and

(4) Written policy and procedures defining the program's plan for appropriate counselor-to-patient ratio, and a plan for how exceptions may be handled.

(c) Ongoing clinical supervision should address:

(1) The appropriateness of treatment selected for the patient;

(2) Treatment effectiveness as reflected by the patient meeting their individual goals; and

(3) The provision of feedback that enhances the clinical skills of direct service staff and treatment professionals.

450:70-4-3. Staff privileging

(a) Each OSTP shall have policy and procedure for documenting and verifying the training, experience, education, and other credentials of treatment professionals prior to their providing clinical or treatment services.

(b) Each OSTP shall have written policy and procedures and operational methods for evaluating the professional qualifications of treatment professionals providing treatment services, including those who perform staff privileging evaluations and the verification process, and the granting of privileges.

(c) All treatment professionals shall be documented as privileged prior to performing treatment services.

(d) The evaluation and verification of professional qualifications includes, but is not limited to, the review and verification of:

(1) Professional degree(s) via official college transcript(s);

(2) Professional licensure(s);

(3) Professional certification(s);

(4) Professional training;

(5) Professional experience; and

(6) Other qualifications as set forth in the position's job description.

(e) Each OSTP shall minimally perform an annual review of current licensure, certifications, and current qualifications for privileges to provide specific treatment services.

(f) Initial training and ongoing training updates for all personnel employed by the treatment facility covers at a minimum:

(1) Rights of the patients served;

(2) Person and family centered services;

(3) The prevention of violence in the workplace;
(4) Confidentiality requirements;
(5) Cultural competency; and
(6) Expectations regarding professional conduct.

450:70-4-4. Staffing

(a) The OSTP shall have written policy and procedure requiring at least two (2) staff members be present on the premises during dispensing hours. At least one (1) of the staff members shall be appropriately licensed to dispense approved opioid agonist or partial agonist drugs.

(b) The OSTP shall have written policy and procedure to ensure that only appropriately trained and licensed medical personnel shall be allowed access to, transportation of, dispensing of, administration of, or responsibility for opioid medications.

(1) Access to medication deliveries to an OSTP shall be received, secured and inventoried by program personnel specifically designated for this task.

(2) Acceptance of delivery of narcotic substances must be made only by a licensed practitioner employed at the OSTP or other authorized individuals designated in writing who must sign for the narcotics. Staff who are currently or previously dependent on narcotic drugs are not allowed to perform this function,

(3) The OSTP shall have one staff member to have primary responsibility for receiving, securing and inventorying medications.

(4) The OSTP also shall identify additional program personnel who have authority to receive, store and inventory the medication at times when the individual designated to have primary responsibility is not available.

(5) The OSTP shall maintain a written list of all designated personnel who have been authorized to receive, store and inventory the medication. This list shall be updated whenever a change in designated personnel occurs.

(c) Transportation of opioid medications by OSTP staff shall also:

(1) Be limited to OSTP patients in residential treatment or jail, and

(2) always done with an appropriate chain of custody form, such as the one available through the Division of Pharmacologic Therapies within SAMHSA.

(d) The OSTP shall have written policy and procedure requiring the Medical Director be present, on site for two hours each week during normal dispensing hours for every one hundred (100) patients admitted to an OSTP.

(e) The OSTP shall have written policy and procedure requiring each person engaged in the treatment of opioid addiction to have sufficient education, training, and/or experience to enable that person to perform the assigned duties and functions. This includes specific training in opioid related treatment options. All physicians, nurses, and other licensed professional care providers, including addiction counselors, must comply with the credentialing requirements of their respective professions. Hiring preference may be given to staff with addiction and/or opioid treatment specific licenses and certifications.

(1) All direct service and medical staff shall receive training relevant to service delivery in an opioid treatment setting.

(2) Each staff member shall have documentation in a personnel file of participation in fourteen (14) clock hours of such training during each two

(2) year period.
(3) It is recommended that all physicians have, or be in the process of obtaining, specialty certification and/or licensure related to opioid treatment.
(f) The OSTP shall have written policy and procedure requiring opioid agonist treatment medications be administered or dispensed only by a practitioner licensed and registered under the appropriate State and Federal laws to administer or dispense opioid drugs.
(g) The facility shall maintain documentation verifying the qualifications for the treatment professionals.
(h) Staff shall be, at least, twenty one (21) years old (excluding student interns).

PART 3. ORGANIZATIONAL AND FACILITY MANAGEMENT

450: 70-4-5. Service support and Enhancement

(a) Each OSTP shall have written policies and procedures describing operational methods, administration and organization adequate to ensure quality patient care, ability to operate in accordance with all approved accreditation elements and to meet the requirements of all pertinent Federal, State and local laws and regulations. In addition an OSTP will operate in accordance with all approved accreditation elements; including the Oklahoma Bureau of Narcotics and Dangerous Drugs (OBNDD), the Drug Enforcement Agency (DEA), and the Substance Abuse Mental Health Services Administration (SAMHSA).
(b) OSTPs will produce evidence of a current and valid certification from SAMHSA to be considered qualified to dispense opioid drugs in the treatment of opioid addiction. Prior to beginning the delivery of opioid substitution treatment services, an OSTP must apply for and receive temporary certification from ODMHSAS.
(c) An OSTP must produce evidence that the program has been determined under the Controlled Substances Act to be qualified and registered to dispense opioid agonist treatment medications to individuals for treatment of opioid addiction.
(d) In order to retain ODMHSAS certification an OSTP shall produce within twelve (12) months of opening, a current, valid accreditation by an accreditation body or other entity designated by SAMHSA such as Commission for the Accreditation of Residential Facilities (CARF), the Joint Commission for the Accreditation of Healthcare Organizations (JCAHO), or the Commission on Accreditation (COA) including a written description of the current accreditation status of the OSTP and must comply with any additional conditions for certification established by SAMHSA.
(e) An OSTP shall have an accurate and current description of organizational structure including;
(1) The names and contact information of all persons responsible for the OSTP,
(2) The current addresses of the OSTP and of each additional facility, medication unit or additional site under the control of the OSTP providing opioid agonist treatment, and
(3) The sources of any funding other than patient fees for the OSTP including the name and address of any governmental entity that provides such funding.
(f) Each OSTP shall formally designate a program sponsor and medical director.
(1) The program sponsor shall agree in writing on behalf of the OSTP to adhere

to all requirements set forth in this chapter and any regulations regarding the use of opioid agonist treatment medications in the treatment of opioid addiction which may be promulgated in the future.

(2) The medical director shall agree in writing to assume responsibility for administration of all medical services performed by the OSTP. In addition, the medical director shall be responsible for ensuring that the OSTP is in compliance with all applicable Federal, State, and local laws and regulations.

(g) The OSTP shall have a written organizational description, which is reviewed annually and minimally includes:

(1) The overall target population for whom services will be provided;

(2) The overall mission statement;

(3) The annual facility goals and objectives; and

(4) Documentation that these statements have been approved by the OSTP's governing authority.

(h) The OSTP shall have documentation demonstrating the documents listed in section (i), (1) through (4) above are available and communicated to staff.

(j) The OSTP shall have documentation demonstrating the documents listed in section (k), (1) through (4) above are available to the general public upon request.

(l) Each OSTP shall have in writing, by program component or service, the following:

(1) A description of the program;

(2) The philosophy of the program;

(3) Program goals and objectives;

(4) Identification of treatment professionals to provide these services; and

(5) Admission and exclusionary criteria to identify the type of consumers for whom the services are primarily intended.

(m) A written statement of the procedures and plans for attaining the facility goals and objectives. These procedures and plans should define specific tasks, set target dates and designate staff responsible for carrying out the procedures and plans.

(n) An OSTP shall notify the SMA within one (1) work day of any vacancy or replacement or other change in the status of the program sponsor or medical director.

(o) An OSTP, medication unit, or any part thereof including any related facility or individual shall allow inspections and surveys by duly authorized employees of ODMHSAS, SAMHSA, the accreditation body providing national accreditation, the DEA, and by authorized employees of any other relevant State or Federal governmental authority.

(p) OSTPs shall notify the SMA of plans to either close, or relocate the program not less than thirty (30) days prior to said closure, or relocation. Relocation shall be contingent upon ODMHSAS certification of any new treatment location.

(q) Each OSTP must notify the SMA in writing of clinic closure due to holidays, training prior to the date, and as soon after the event as possible in the case of emergencies.

(r) The OSTP shall have written policy and procedure establishing a standard fee for patients that shall be no more than $65.00 per week.

(s) Unless otherwise specified in this chapter, requirements, and exceptions, for each type of opioid treatment services shall apply, as required by 42 CFR, Chapter 1, Part 8.

(t) Each OSTP shall have written policy and procedure stating that programs in the same geographical area shall develop policy and procedure designed to work together

to maximize hours of operation and treatment accessibility.
(u) The OSTP shall have available specialized professional consultation or professional supervision.

450:70-4-6. New program approval

Determination of the need for new services shall be at the sole discretion of ODMHSAS as the designated state authority responsible for opioid substitution treatment through information provided by the proposed new agency including:
(1) Copies of all planned promotional materials, advertisements, and marketing strategies to publicize the proposed program;
(2) Policies and procedures that will be used to identify if a patient is enrolled in another clinic;
(3) The source and adequacy of financial assets necessary to operate the program;
(4) If applicable, the compliance history of the applicant, including any issues reported to ODMHSAS by SAMHSA, DEA or any other regulatory agency;
(5) Adequate planning and organizational structure demonstrated by full and complete answers submitted to all questions in the application materials;
(6) A written statement that the applicant has read, understood and agreed to follow all federal and state regulations concerning operation of an OSTP signed by the program sponsor and the medical director;
(7) Document the need for new services in the area as demonstrated by providing ODMHSAS with waiting lists, numbers of opioid related emergency room visits, opioid related arrest data, and federal drug use forecasting data;
(8) Demonstrate community acceptance with letters from local residents within one (1) mile of the proposed site(s). Written assurance must be provided to ODMHSAS of local community acceptance; and
(9) Demonstrate general community acceptance by providing ODMHSAS with copies of letters of support from local authorities.

450:70-4-7. Operations

(a) The program shall have policy and procedure to define operations for a minimum of forty (40) hours per week, (excluding holidays and emergencies) in outpatient settings and twenty-four (24) hours per day in inpatient and residential program settings.
(b) The OSTP shall have written policy and procedure for medication dispensing available six (6) days per week in outpatient settings; and seven (7) days per week in inpatient and residential settings with approval from SAMHSA.
(c) The facility shall be publicly accessible and accommodate office space, individual and group counseling space, secure record storage, protect consumer confidentiality, and provide a safe, warm, welcoming, culturally and age appropriate environment.
(d) Hours of operation shall be during regularly scheduled times in which services are accessible to consumers and the general public, including those employed between the hours of 8:00 a.m. and 5:00 p.m., Monday through Friday. To accomplish this, the OSTP shall have written policy and procedure providing at least two (2) hours per day either prior to 9:00 a.m. or after 5:00 p.m. for dispensing medication and counseling services.
(e) For facilities that do not provide twenty-four (24) hour services, the facility's hours of

operation shall be conspicuously displayed on the outside of the building. For facilities in multi-office buildings, the hours shall be posted either on the building directory or the facility's office door.

(f) Clinical services shall be organized with scheduled treatment sessions that accommodate employed and parenting patients' schedules, and offer treatment services during the day, evening, or weekends.

(g) The OSTP shall develop written policy and procedures to maintain security over all stocks of medication, the manner in which it is received, stored and distributed consistent with the regulations of the Drug Enforcement Administration, state and federal law.

(h) OSTPs must maintain written policies and procedures adequate to identify the theft or diversion of take-home medications to the illicit market, including labeling containers with the OSTP's name, address, and telephone number. Programs also must ensure that take-home supplies are packaged in a manner that is designed to reduce the risk of accidental ingestion, including child-resistant containers.

(i) An OSTP must maintain a written, active "Diversion Control Plan" or "DCP" as part of its quality assurance program that contains specific measures to reduce the possibility of diversion of controlled substances from legitimate treatment use and that assigns specific responsibility to the medical and administrative staff of the OSTP for carrying out the diversion control measures and functions described in the DCP. The DCP shall include:

(1) Written policy and procedure stating a requirement that treatment and administrative activities be continuously monitored to reduce the risk of diversion,

(2) Written policy and procedure for stopping identified diversion and for preventing future diversion,

(3) A written policy and procedure policy requiring employees who are formerly (within two (2) years) addicted to drugs including opioids or alcohol; to be considered risks to the security of drug stocks and shall not have access to the drug stocks or to the drug dispensing area, and

(4) Written policies and procedures for how staff members who diverts medication are held accountable for the medication diversion.

(j) The OSTP shall have written policy and procedure stating methadone shall not be provided to a patient who is known to be currently receiving methadone from another OSTP without prior approval from the Commissioner or designee. Patients who are known to be enrolled in more than one OSTP at a time will be forced to choose one clinic for treatment. That patient must then begin treatment as a new patient, including attending the clinic on a daily basis a minimum of six days per week, for a period of six months. The patient must also be reported to the SMA.

(k) The OSTP shall have written policy and procedure stating the OSTP shall provide counseling on preventing exposure to, and the transmission of, human immunodeficiency virus (HIV), hepatitis C (HCV) and tuberculosis for each patient admitted or readmitted to maintenance or detoxification treatment.

(l) The OSTP shall have written policy and procedure stating that methadone shall be dispensed orally only. Non-oral forms and tablet form methadone are prohibited from use.

(m) Each OSTP shall develop written policies and procedures giving preference to the use of liquid and diskette forms of methadone.
(n) OSTPs shall have written policies and procedures adequate to ensure that each opioid agonist treatment medication used by the program is administered and dispensed in accordance with its approved product labeling.
(o) Written policy and procedure shall reflect that dosing and administration decisions shall be made by a program physician familiar with the most up-to-date product labeling. These procedures must ensure that any significant deviations from the approved labeling, including deviations with regard to dose, frequency, or the conditions of use described in the approved labeling, are specifically documented in the patient's record.
(p) The OSTP shall have written policy and procedure stating the OSTP shall use only those opioid agonist treatment medications that are approved by the Food and Drug Administration for use in the treatment of opioid addiction. In addition, OSTPs who are fully compliant with the protocol of an investigational use of a drug and other conditions set forth in the application may administer a drug that has been authorized under an investigational new drug application through all applicable Federal law for investigational use in the treatment of opioid addiction.
(q) The OSTP shall maintain written policy and procedures for handling medical emergencies; and an emergency medical number shall be posted for use by staff.
(r) Crisis intervention and counseling services shall be available when indicated.

450:70-4-8. Drug testing

(a) The OSTP shall have written policy and procedure ensuring that an initial drug test is performed for each new patient, including permanent transfer patients, before the initial or maintenance dose is administered. At least monthly random tests are to be performed on each patient in comprehensive maintenance treatment for the initial year of treatment. A minimum of twelve (12) random drug tests annually with no less than one (1) per quarter are required thereafter. All drug testing shall be in accordance with all state and federal law and current drug screen standards.

(1) When a sample is collected from each patient for such test or analysis, it must be done in a manner to produce timely and reliable results.

(2) The program must have and follow written procedures for the screening of test samples for all drugs. The procedures shall describe in sufficient detail a plan for collection, storage, handling and analysis of test samples. The procedures shall further describe the program's response to test results that include at least the following:

(A) training for staff members of the importance and relevance of reliable and timely drug abuse test procedures and reports, the purpose of conducting drug tests, and the clinical significance of the results;

(B) A protocol for collection of test samples that minimizes the opportunity for falsification and incorporates the element of randomness;

(C) A protocol for storage of test samples in a secure place to ensure chain of custody and avoid substitution;

(D) A requirement for disclosure of test sample results to the patient and documentation in the patient record of program and patient response to the test results;

(E) Policy and procedure designed to reduce the negative and/or stigmatizing aspects of drug test collection;
(F) Policy stating that if a patient refuses to provide a test sample, upon request from a staff member, such refusal shall be considered the same as a positive result for illicit drugs. Such refusals shall be documented in the patient record; and
(G) There shall be no “grace period” allowed. Patients from which a UA is requested must submit a sample at that time or it will be considered a refusal.

(b) For patients in short-term detoxification treatment, the OSTP shall perform at least one initial drug test.

(c) For patients receiving long-term detoxification treatment, the program shall perform initial and monthly random tests on each patient as indicated in 450:70-4-8, (a). If the patient has more than one positive urine drug screen in any twelve (12) month period then upon the second positive UA the facility will initiate at least one (1) of the following two (2) items;

(1) Reduce the patient in Phase, or
(2) Initiate an individualized written relapse prevention plan consisting of;
(A) The patient continuing to receive opioid treatment as long as opioid treatment is medically necessary, acceptable to the patient and administrative withdrawal is not indicated,
(B) Address and identify other behavioral issues consistent with relapse in the patient’s treatment plan,
(C) Review the patient’s treatment plan and adjust, if necessary, at the first signs of the client’s relapse or impending relapse, and
(D) Ensure the client’s family members are provided opportunities to be involved in the client’s opioid treatment.

(d) The OSTP shall have written policy and procedure stating drug screens will, at a minimum, test for the following substances;

(1) Opioids,
(2) Methadone,
(3) Amphetamines,
(4) Cocaine,
(5) Benzodiazapines,
(6) Barbiturates,
(7) Marijuana.

(e) The OSTP shall have written policy and procedure stating drug testing shall include other drugs as may be indicated by the patient’s abuse patterns. In addition, if any other drug or drugs have been determined by a program to be abused in that program’s locality, or as otherwise indicated, each test or analysis must include any such drugs.

(f) The OSTP shall have written policy and procedure stating that following admission, the results of a single drug test shall not be the sole basis to determine significant treatment decisions.

(g) The OSTP shall have written policy and procedure stating that unsupervised take home use shall be determined by the medical director. In determining which patients may be permitted unsupervised use, the medical director shall consider the following

criteria in determining whether a patient is responsible in handling opioid drugs for unsupervised use. The same criteria shall be considered when receiving a patient from a transferring program verifying the amount of time the patient has spent satisfactorily adhering to the criteria found below. This information will be used to determine if the patient shall be allowed to continue the same frequency of clinic attendance permitted at the former program immediately before transferring to the new program. Criteria include but are not limited to:

(1) Absence of recent abuse of drugs (opioid or non-narcotic), including alcohol;
(2) Regular of clinic attendance;
(3) Absence of serious behavioral problems at the clinic;
(4) Absence of known recent criminal activity, e.g., drug dealing;
(5) Stability of the patient's home environment and social relationships;
(6) Length of time in comprehensive maintenance treatment;
(7) Assurance that take-home medication can be safely stored within the patient's home;
(8) Whether the rehabilitative benefit the patient derived from decreasing the frequency of clinic attendance outweighs the potential risks of diversion;
(9) The patients current phase in treatment.

(h) The OSTP shall have written policy and procedure stating approval for unsupervised use and the basis for such determinations consistent with all criteria shall document such determinations in the patient's medical record.

450:70-4-9. Information analysis and planning

(a) The OSTP shall have a defined and written plan for conducting an organizational needs assessment which specifies the methods and data to be collected, to include, but not limited to information from:

(1) Patients;
(2) Governing Authority;
(3) Staff;
(4) Stakeholders;
(5) Outcomes management processes; and
(6) Quality record review.

(b) The OSTP shall have a defined ongoing system to collect data and information on a quarterly basis to manage the organization.

(c) Information collected shall be analyzed to improve patient services and program performance.

(d) The OSTP shall prepare an end of year management report, which shall include, but not be limited to:

(1) an analysis of the needs assessment process; and
(2) performance improvement program findings.

(e) The management report shall be communicated and made available to, among others:

(1) the governing authority;
(2) facility staff; and
(3) ODMHSAS, as requested.

450:70-4-10. Performance improvement program

(a) The OSTP shall have an ongoing performance improvement program designed to objectively and systematically monitor, evaluate and improve the quality of consumer care.

(b) The performance improvement program shall address the fiscal management of the OSTP.

(c) Each OSTP shall identify a performance improvement officer.

(d) The OSTP shall document performance improvement activities. These activities shall include, but not be limited to:

(1) Outcomes management specific to each program;

(2) A quarterly quality record review including medical records;

(3) An annual review and revision as appropriate of all program policies and Procedures;

(4) The performance improvement activities shall support increased access to and retention in treatment. The activities shall include a walk through of the intake and admission process. Steps of the walk through include, but are not limited to:

(A) Select two staff from the facility, including one member of management, to play the roles of "patient" and "family member";

(B) All staff shall be notified prior to doing the walk-through exercise;

(C) Complete the intake and admission process as defined by OSTP policy as a typical patient and family member would experience; and

(D) At each step, ask the staff what changes would make it better for the patient and what changes would make it better for the staff. Write all ideas of the staff and participant in the exercise;

(5) Documentation of the walk through process includes, but is not limited to:

(A) Note your observations and feelings of participants in this exercise;

(B) List the process barriers and the improvements that could be made to address these barriers;

(C)Address the needs from both the patient and staff perspectives; and

(D) Identify a potential area for change and describe what implementation looked like, how would you know the change would be successful, what changes could be tested to improve the current process;

(6) Staff privileging; and

(7) Review of critical and unusual incidents, sentinel events, patient grievances and complaints.

(e) The OSTP shall monitor the implementation of the performance improvement plan on an ongoing basis and shall make adjustments as needed.

(f) Performance improvement findings shall be communicated and made available to, among others:

(1) the governing authority,

(2) facility staff,

(3) patients,

(4) stakeholders, and

(5) ODMHSAS, as requested.

450:70-4-11. Critical incidents

(a) The OSTP shall have written policy and procedures for the reporting of every critical incident. Documentation of critical incidents shall minimally include:

(1) The facility, name and signature of the person(s) reporting the incident;

(2) The name(s) of the patient(s), staff member(s) or property involved;

(3) The time, date and physical location of the incident;

(4) The time and date the incident was reported and the name of the staff person within the facility to whom it was reported;

(5) A description of the incident;

(6) Resolution or action taken, description of the action taken, date action was taken, and signature of appropriate staff member(s); and

(7) Severity of each injury, if applicable. Severity shall be indicated as follows:

(A) No off-site medical care required or first aid care administered on-site;

(B) Medical care by a physician or nurse or follow-up attention required; or

(C) Hospitalization or immediate off-site medical attention was required.

(b) Critical incidents shall be reported to ODMHSAS as follows:

(1) Critical incidents requiring medical care by a physician or nurse or follow-up attention and incidents requiring hospitalization or immediate off-site medical attention shall be delivered via fax or mail to ODMHSAS Provider Certification within twenty-four (24) hours of the incident being documented.

(2) Critical incidents involving allegations constituting a sentinel event or patient abuse shall be reported to ODMHSAS immediately via telephone or fax, but not more than twenty-four (24) hours of the incident. If reported by telephone, the report shall be followed with a written report within twenty-four (24) hours.

450:70-4-12. Community information, consultation, outreach, and street outreach

(a) Each OSTP shall, as a regular part of patient-based planning and services provision, provide the community with information, consultation and outreach services to aid in reaching and attracting their specified target population(s). These outreach efforts shall be conducted by staff members or approved program volunteers.

(b) These services shall be designed to:

(1) Reach and attract the facility's target population;

(2) Provide information on substance abuse and related issues to the public; and

(3) Provide information to the public regarding the facility's services.

(c) These services include, but are not limited to, presentations or outreach efforts to community groups, organizations, and individuals.

(d) Written documentation of all community information, consultation, and outreach services shall be maintained, and shall include the following:

(1) Name of person(s) or organization(s) receiving the services;

(2) Name of person(s) providing the service;

(3) Number of persons attending;

(4) Location at which the services were provided;

(5) Date services were provided; and

(6) Description of the services provided.

(e) Facilities providing street outreach services shall have written policy and procedures describing the processes for systematically reaching into a community for the purpose of identifying persons in need of services, alerting persons and their families to the availability of services, locating needed services, and enabling persons to enter and accept the treatment services system.

SUBCHAPTER 5. CONSUMER RIGHTS

450:70-5-1. Consumer rights

All treatment facilities shall comply with applicable rules in Title 450, Chapter 15. Consumer Rights. Those programs which are providing services within a correctional facility should detail the following due to circumstance:

(1) The provider shall document provisions of 450:15-3-2 (a), (b), and (d).

(2) The provider shall provide written grievance policy and procedure including time frames for the grievance process.

(3) The provider shall describe the procedure used when the grievance is against a staff. This policy may refer to DOC mandated policy and procedure.

(4) The provider shall describe the facility's responsibility for evaluation, review, and resolution should the allegation be substantiated.

450:70-5-2. Consumer's grievance policy

Each treatment facility shall comply with applicable rules in Title 450, Chapter 15. Consumer Rights.

450:70-5-3. ODMHSAS advocate general

The ODMHSAS Advocate General, in any investigation regarding consumer rights, shall have access to consumers, facility records and facility staff as set forth in Title 450, Chapter 15.

SUBCHAPTER 6. SUBSTANCE ABUSE TREATMENT SERVICES

PART 1. CASE MANAGEMENT

450:70-6-1. Case management, adults

(a) Case management is an essential element during the treatment process which enhances the patient's potential for successful recovery. Case management services are designed to address areas of a patient's life that, if not addressed, often contribute to relapse. Case management services facilitate the patient's potential for a successful re-integration into community living. Case management services may be provided by either the primary service provider or a Certified Behavioral Health Case Manager.

(b) Case management services shall be made available to all patients involved with an OSTP and shall include the following:

(1) Screening to determine the priority of needs to be addressed through case management services; which shall include the completion of an assessment. and evidence that the following were evaluated:

(A) Patient's job skills and potential;

(B) Patient's strengths and resources;
(C) Patient's present living situation and support system;
(D) Patient's needs or problems which interfere with the ability to successfully function in the community;
(E) Patient's use of substances and stage of change; and
(F) Patient's medical and health status.

(2) Case management services and monitoring shall address issues and problem identified in the consumer evaluation and shall also:

(A) Incorporate needed referral sources to address the patient's identified needs;
(B) Be developed jointly between the Certified Behavioral Health Case Manager or primary service provider, and the patient; and
(C) Address the provision and frequency of case management services specified in the treatment plan.

(c) Case management referrals for adults include, but are not limited to:

(1) Medical, dental, and other health care services;
(2) Psychiatric and psychological services;
(3) Violence and domestic violence services;
(4) Family, and significant other, counseling services;
(5) Educational services, including vocational rehabilitation services;
(6) Employment services;
(7) Social services, including supplemental income, food and public housing;
(8) Legal services;
(9) Recovery self-help fellowships;
(10) Parenting and child development education; and
(11) Continuing substance abuse treatment at a lesser level of care.

450:70-6-2. Case management services, locale and frequency

Case management services shall be provided within community settings; or any other appropriate settings, based on the individual needs of the patient. Contact with patients shall be made as specified in the treatment plan.

450:70-6-3. Case management services, staff credentials

Individuals providing case management services shall be certified as a behavioral health case manager pursuant to Oklahoma Administrative Code, Title 450, Chapter 50, or be the primary service provider.

PART 2. LEVELS OF TREATMENT

450:70-6-4. Levels of Care

OSTPs shall document the provision of one (1) or more of the following levels of care in policy and procedure. All facilities shall include the requirements found in Facility Record System. Any OSTP certified by ODMHSAS providing any of the following levels of care shall also provide short and long term withdrawal treatment.

450:70-6-5. Withdrawal treatment

(a) Any OSTP providing medication assisted treatment shall provide withdrawal treatment including both short and long term withdrawal treatment as defined in 450:70-6-7 and 450:70-6-8.

(b) The OSTP shall have written policy and procedure defining the protocols developed, implemented, and complied with for withdrawal treatment. Protocols shall:

(1) Promote successful withdrawal treatment;

(2) Require that dose reduction occur at a rate well tolerated by the patient;

(3) Require that a variety of ancillary services, such as mutual support groups, be available to the patient through the agency or through referral;

(4) Require that the amount of counseling available to the patient be increased prior to discharge; and

(5) Require that a patient be re-admitted to the agency or referred to another agency at the first indication of relapse unless it is an administrative withdrawal process.

(c) The OSTP shall have written policy and procedure stating patients involved in maintenance treatment will enter withdrawal treatment;

(1) Only when initiated as administrative withdrawal or when requested by the patient and approved by the OSTP medical director; and

(2) When planned and supervised by the medical director or a program physician;

(d) The OSTP shall have written policy and procedure stating that before a patient begins withdrawal treatment, the patient must be:

(1) Informed by the agency medical director, a program physician or a staff member that:

(A) The patient has the right to leave opioid treatment at any time,

(B) The risks of withdrawal treatment, and

(C) Signs and symptoms of relapse.

(2) The patient will receive a schedule for medical withdrawal treatment developed by the medical director or a program physician with input from the patient.

(e) The OSTP shall have written policy and procedure stating that if a patient who is receiving withdrawal treatment for reasons other than administrative withdrawal, appears to a staff member to relapse, the patient is permitted to reenter maintenance treatment, if otherwise eligible;

(f) The OSTP shall have written policy and procedure stating that if a patient who has completed withdrawal treatment within the past thirty (30) days appears to a staff member to relapse, the patient may be re-admitted to treatment without physical examination or assessment unless requested by the medical director.

(g) The OSTP shall have written policy and procedure stating periodic consideration shall be given to withdrawing from continued opioid treatment, when appropriate to the patient's progress and goals.

(1) Consideration for withdrawal from continued opioid treatment shall be discussed at least once annually with the patient.

(2) Such consideration and decisions shall be determined by the patient, medical director, and the program staff as part of an individualized treatment planning process and treatment progress.

450:70-6-6. Administrative withdrawal

(a) The OSTP shall have written policy and procedure stating an infraction of program rules by a patient may result in administrative medical withdrawal from methadone and termination from treatment. All patients will be notified of this policy. The program shall develop specific program requirements to address noncompliance with program rules resulting in termination. The violation or noncompliance with rules shall be limited to;

(1) Threats of violence or actual bodily harm to staff or another patient, including abusive language or behavior;

(2) Disruptive behavior, loitering;

(3) Diversion of methadone, selling, distributing, using, or otherwise "dealing" in any illicit drug or chemical, including positive urine tests for non-prescribed medications and drugs;

(4) Continued unexcused absences from counseling and other support services;

(5) Involvement in criminal activities;

(6) Any other serious rule violations; and

(7) Non-payment of fees.

(b) The OSTP shall have written policy and procedure stating administrative medical withdrawal shall be scheduled in such a way as to minimize the psychological and physical effects of such withdrawal.

(1) Administrative medical withdrawal shall be completed in a manner appropriate to the client's level of medication and the circumstances justifying such action;

(2) Programs may facilitate a transfer to another program or referral to a medical facility in lieu of administrative medical withdrawal; and

(3) Administrative withdrawal resulting from non payment of fees cannot be accomplished in less than fifteen (15) days.

(c) The OSTP shall have written policy and procedure stating a patient experiencing administrative withdrawal shall be referred or transferred to an agency that is capable of, or more suitable for, meeting the patient's needs. The referral or transfer is documented in the patient record and the following information is documented in the patient record:

(1) The reason that the patient sought medical withdrawal or was placed on administrative withdrawal; and

(2) The information and assistance provided to the patient in withdrawal treatment, medical withdrawal or administrative withdrawal.

450:70-6-7. Short term withdrawal (detoxification)

(a) The OSTP shall have written policy and procedure regarding short term withdrawal (detoxification) treatment.

(b) There shall be written policy stating a patient may be admitted to short-term withdrawal (detoxification) regardless of age. Patients under the age of eighteen (18) may be admitted with written parent or guardian approval.

(c) The program physician shall document in the patient record the reason for admitting the patient to short-term withdrawal (detoxification).

(d) Take-home medication is not allowed during short-term withdrawal (detoxification).
(e) A history of one year opiate dependence is not required for admission to short-term withdrawal (detoxification).
(f) No test or analysis is required except for the initial drug screening test, and a tuberculin skin test.
(g) The initial treatment plan and periodic treatment plan evaluation required for comprehensive maintenance patients are required for short-term withdrawal (detoxification) patients.
(h) A primary counselor must be assigned by the program to monitor a patient's progress toward the goal of short-term withdrawal (detoxification) and possible drug-free treatment referral.
(i) The narcotic drug is required to be administered daily by the OSTP in reducing doses to reach a drug-free state over a period not to exceed thirty (30) days.
(j) All other requirements of comprehensive maintenance treatment apply.

450:70-6-8. Long term withdrawal (detoxification)
(a) There shall be written policy stating a patient may be admitted to long-term withdrawal detoxification regardless of age. Patients under the age of eighteen (18) with written parent or guardian approval.
(b) The narcotic drug is required to be administered daily in reducing doses to reach a drug-free state over a period not to exceed one hundred and eighty (180) days.
(c) The patient is required to be under observation while ingesting the drug at least six (6) days a week.
(d) Initial and random monthly drug screening tests must be performed on each patient.
(e) Initial and monthly treatment plans are required.
(f) All other requirements of comprehensive maintenance treatment apply.

450:70-6-9. Interim maintenance treatment
(a) The OSTP shall have documentation before providing interim maintenance treatment services indicating the written approval of both SAMHSA and ODMHSAS.
(b) The OSTP shall have written policy and procedure stating the program sponsor may place an individual who is eligible for admission to comprehensive maintenance treatment in interim maintenance treatment if the individual cannot be placed in comprehensive maintenance treatment within a reasonable geographic distance and within fourteen (14) days of application for admission to comprehensive maintenance treatment.
(c) The OSTP shall have written policy and procedure identifying the maximum length of stay in interim opioid treatment is one hundred and twenty (120) days.
(d) The OSTP shall have written policy and procedure stating an initial and a minimum of two (2) additional drug screens shall be taken from interim patients during the one hundred and twenty (120) days of interim treatment.
(e) The OSTP shall have written policies and procedures outlining all criteria for transfer from interim maintenance to comprehensive maintenance treatment.
(f) The OSTP shall have policy and procedure ensuring interim maintenance treatment shall be provided in a manner consistent with all applicable Federal and State laws and regulations.

(g) The interim maintenance treatment program shall meet and/or possess all applicable Federal and State certifications, licensures, laws and regulations.
(h) The OSTP shall have written policy and procedure stating all rules and requirements for comprehensive maintenance treatment apply to interim maintenance treatment with the exception of:

(1) Opioid agonist treatment medication is required to be administered daily and under observation. Unsupervised or take home dosing is not allowed.
(2) A primary counselor does not need to be assigned.
(3) Interim maintenance treatment is limited to two (2) one hundred and twenty (120) day episodes in any twelve (12) month period.
(4) Educational, rehabilitative and counseling services are not required.
(5) An initial treatment plan and periodic updates are not required.

450:70-6-10. Medication units, long term care facilities and hospitals

(a) Before providing opioid treatment services through a medication unit, long term care facility or hospital, the program must receive the written approval of both SAMHSA and ODMHSAS.
(b) Certification as an OSTP will not be required for the maintenance or detoxification treatment of a patient who is admitted to a hospital or long term care facility for the treatment for medical conditions other than opioid addiction and who requires maintenance or detoxification treatment during the stay in the hospital or long term care facility.
(c) Medication units, long term care facilities and hospitals shall be in compliance with the following:

(1) Currently licensed by the U. S. Drug Enforcement Agency; approved by the Substance Abuse and Mental Health Service Administration.
(2) Written policy and procedure stating the medical director shall make all recommendations for medication dosages according to best medical practice guidelines and all applicable rules contained in this chapter.
(3) Written policy and procedure stating all female consumers shall have a pregnancy test on admission and at least annually thereafter, unless otherwise indicated.
(4) Written policy and procedure to address the provision of all services in compliance with Federal Drug Administration Guidelines for opioid treatment programs in accordance with 42 CFR, Part 8.

450:70-6-11. Programs using opioid antagonist or long acting opioid agonist

(a) The OSTP shall have written policy and procedure stating a certified substance abuse facility providing a program using an experimental opioid blockade or a long acting agonist in the treatment of opioid substance abuse shall have documentation of approval by the Federal Drug Administration; and comply with all other federal and state statutes and regulations governing such programs.
(b) The OSTP shall have written policy and procedure stating the program shall provide at least two (2) hours of services per day before 8:00 A.M. or after 5:00 P.M. for dispensing and counseling.
(c) Compliance may be determined by a review of facility policy and procedures, and

documentation of FDA approval.
(d) The OTP shall have written policy and procedure stating that unless otherwise indicated all relevant sections of this chapter apply.

450:70-6-12. HIV education, testing and counseling services

All OSTPs shall provide and document the provision of HIV education, testing, and counseling services for drug dependent persons. Every OSTP shall:

(1) Provide educational sessions regarding HIV to such persons, and also make the sessions available to spouses or other sexual partners of the drug dependent person;
(2) Refer all drug dependent persons for HIV infection testing and counseling;
(3) Provide HIV testing and counseling by the facility staff, or with an organization for the testing or counseling services and maintain all test results in the confidential manner prescribed by applicable state or federal statutes or regulations; and
(4) Provide services described in items (1) through (3) at least once during each episode of treatment.

450:70-6-13. Treatment Professional

Only a treatment professional, as defined in 450:70-1-1, shall provide alcohol and drug treatment services in any level of care.

450:70-6-14. Co-occurring Disorder Capability

All program components described in this chapter shall work toward becoming co-occurring disorder capable, and engage in a performance improvement process to enhance co-occurring capability, according to the State Integrated Services Initiative consensus document. Co-occurring capability involves the development of specific policies and procedures to welcome, screen and process of assessment, treatment planning, treatment programming, interagency care coordination, psychopharmacologic management, and discharge planning to ensure that attention to assisting the patient with managing his or her co-occurring mental illness is appropriately organized as a component of the substance abuse treatment intervention.

PART 3. Phases of treatment

450:70-6-15. Treatment

(a) Each OSTP shall use opioid agonists in conjunction with other treatment modalities such as, but not limited to, individual, family and group therapy; vocational training and placement; and other modalities enhancing positive life style changes in the consumer.
(b) The OSTP shall have written policy and procedure stating the medical director shall ensure the consumer's daily opioid dosage shall conform with all State and Federal guidelines and this chapter.
(c) The OSTP shall have written policy and procedure stating each patient accepted for treatment as a patient at an OSTP shall be assessed no less than annually by the medical director or an appropriately trained program physician as part of a process to determine the most appropriate combination of services and treatment.
(d) The OSTP shall have written policy and procedure stating the OSTP shall provide

adequate medical, counseling, vocational, educational, and other assessment and treatment services. These services must be available at the primary facility, except where the program sponsor has entered into a formal, documented agreement with a private or public agency, organization, practitioner, or institution to provide these services to patients enrolled in the OSTP. The program sponsor, in any event, must be able to document that these services are fully and reasonably available to all patients.
(e) Services shall be designed to provide a variety of professional diagnostic and primary alcohol and other drug abuse treatment services for consumers, and their families and significant others, whose emotional and physical status allows them to function in their usual environment.
(f) The OSTP shall have written policy and procedure stating there will be referral to adequate and reasonably accessible community resources, vocational rehabilitation, education, and employment services for patients who either request such services or who have been determined through the assessment process to be in need of such services.
(g) The OSTP shall have written policy and procedure stating patients accepted for opioid substitution treatment shall attend prescribed counseling as mandated in the individualized treatment plan and this chapter.
(h) The OSTP shall have written policy and procedure stating that each patient accepted for treatment at an OSTP shall be assessed initially and periodically by qualified personnel to determine the most appropriate combination of services and treatment. The treatment plan also must identify the frequency and intensity of services to be provided. The plan must be reviewed and updated to reflect that patient's personal history, current needs for medical, social, and psychological services, and current needs for education, vocational rehabilitation, and employment services.
(i) The OSTP shall have written policy and procedure stating the OSTP will provide adequate substance abuse counseling to each patient as clinically necessary. This counseling shall be provided by a program counselor, qualified by education, training, or experience to assess the psychological and sociological background of patients, to contribute to the appropriate treatment plan for the patient and to monitor patient progress.
(j) The OSTP shall have written policy and procedure stating if a patient misses appointments for two weeks or more without notifying the clinic, the episode of care is considered terminated and is to be so noted in the patient’s record. An exception determination would be in circumstances where the patient can provide documented proof of exceptional circumstances. The documentation must be maintained in the patient’s record. If the patient does return for care and is accepted into the program, the patient is considered a new patient and is to be so noted in the patient’s record.

450:70-6-16. Women and pregnant women
(a) The OSTP shall have written policy and procedure stating the OSTP address the special needs of patients who are pregnant. Prenatal care and other gender specific services or pregnant patients must be provided either by the OSTP or by referral to appropriate healthcare providers.
(b) An OSTP shall ensure that policies and procedures are developed, implemented, and complied with for the treatment of female patients, to include:

(1) Documentation that staff members are educated in the unique needs of female patients,
(2) A requirement that each female patient be informed about or referred to a same sex support group at the agency or in the community, and
(3) An OSTP shall ensure that a policy and procedure is developed, implemented, and complied with for the treatment of pregnant patients, to include:

(A) Priority is given to pregnant individuals seeking opioid treatment;
(B) The reasons for a pregnant individual's denial of admission to an agency are documented;
(C) A pregnant patient is offered prenatal care either at the agency or through referral to a medical practitioner;
(D) The agency shall establish a written agreement with a medical practitioner who is providing prenatal care to a pregnant patient, to include a procedure for exchanging opioid treatment and prenatal care information;
(E) A staff member shall educate a pregnant patient who does not obtain prenatal care services for prenatal care;
(F) A staff member shall obtain a written refusal of prenatal care services from a pregnant patient who refuses prenatal care services offered by the agency or a referral for prenatal care;
(G) A pregnant patient receiving comprehensive maintenance treatment before pregnancy shall be maintained at the pre-pregnancy dose of opioid agonist medication, if effective;
(H) Dosage requirements shall be followed for a pregnant patient's initial and subsequent doses of opioid agonist treatment medication;
(I) A pregnant patient shall be monitored by an agency medical practitioner to determine if pregnancy induced changes in the elimination or metabolization of opioid agonist treatment medication may necessitate an increased or split dose;
(J) A pregnant patient discharged from the agency shall be referred to a medical practitioner and that a staff member document the name, address, and telephone number of the medical practitioner in the patient record; and
(K) While eventual withdrawal from the use of all drugs, including methadone, may be an appropriate treatment goal, some clients may remain in opioid treatment for relatively long periods of time.

450:70-6-17. Treatment phases

(a) The OSTP shall have written policy and procedure describing practices in accordance with the principle that take-home doses of methadone are a privilege given only to those individuals who will benefit from them and who have demonstrated responsibility in taking methadone as prescribed including:

(1) The requirement of time in treatment as outlined elsewhere in this rule shall be considered as a minimum reference point after which a patient may be considered for take-home privileges. The time reference in this chapter does not

mean that a patient in treatment for a particular time has a specific right to take-home medication.

(2) Programs must educate the patient regarding safe transportation and storage of methadone as well as emergency procedures in case of accidental ingestion.

(3) Before take-home privileges are allowed, the patient must have a lock box for transportation of methadone and home storage.

(4) The program shall have policies that address the responsibilities of patients granted take-home medications. The policies shall include methods of assuring patient's appropriate use and storage of medication.

(5) The program shall have policies in place addressing the disposal of take-home bottles to include bottles returned with labels intact and consequences of unreturned bottles.

(6) Regardless of time in treatment, the medical director, using reasonable judgment, may deny or rescind the take-home medication privileges of a patient.

(7) All take-home privileges shall be made according to the rules of this section regarding the patients' current phase of treatment.

(b) The OSTP shall have written policy and procedure stating the medical director may, based on reasonable judgment, grant emergency take-home doses of methadone based on emergency circumstances related to medical, criminal justice, family or employment. The circumstances and basis for the action must be documented in the patient record and should address the concerns outlined in this section.

(1) Take-home doses for instate emergencies is limited to a maximum of three (3) doses and out-of-state is limited to a maximum of six (6) doses.

(2) The medical director may, based on reasonable judgment, grant vacation take-home doses of methadone for up to two (2) weeks per calendar year. The circumstances and basis for the action must be documented in the patient record and should address the concerns outlined in this section.

(3) All exceptions with take-home medication must be authorized through the exception request process.

(c) The OSTP shall have written policy and procedure describing structured phases of treatment and rehabilitation to support patient progress and to establish requirements regarding patient attendance and service participation. The requirements listed below for each phase indicate minimum requirements and the frequency and extent of treatment and rehabilitation services may be increased, based on individual patient need and unless otherwise indicated in this chapter.

(1) Phase I consists of a minimum ninety (90)-day period in which the patient attends the program for observation of opioid treatment daily or at least six (6) days a week. Phase I take-home dosage privileges are limited to a single dose each week including take home dosages required due to regularly scheduled clinic closures. All approved holidays allow an additional take-home dosage. The patient shall ingest all other doses under appropriate supervision at the clinic.

(A) During Phase I, the patient shall participate in a minimum of our (4) sessions of counseling per month with at least one (1) session being

individual counseling and/or case management.

(B) During Phase I, the treatment plan shall be reviewed and updated at least monthly.

(C) Prior to the patient moving to Phase II and/or receiving take-home medication, the patient shall demonstrate a level of stability as evidenced by absence of alcohol and other drug abuse, regularity of program attendance, absence of significant behavior problems, absence of recent criminal activities, and employment, actively seeking employment or attending school if not retired, disabled, functioning as a homemaker, or otherwise economically stable.

(D) Advancement in phase and/or increased take-home privilege shall not occur without significant compliance with all current treatment plan goals.

(E) Advancement in phase and/or increased take-home privilege shall not occur if there are consistent or consecutive positive urine drug screens.

(2) Phase II is designated for patients who have been admitted more than ninety (90) days, and who have successfully met all Phase I criteria.

(A) During Phase II, the program may issue no more than two (2) take-home doses of methadone at a time including take-home dosages required due to regular and/or holiday scheduled clinic closures. With the exception of any take-home doses, the patient shall ingest all other doses under appropriate supervision at the clinic.

(B) The patient shall participate in at least two (2) counseling sessions per month during the first ninety (90) days of Phase II, with at least one (1) of the sessions being individual counseling and/or case management.

(C) After the initial ninety (90) days in Phase II, the patient shall participate in at least one (1) session of individual counseling per month.

(D) The treatment plan shall be reviewed and updated at least once every three (3) months during Phase II.

(E) Advancement in phase and/or increased take-home privilege shall not occur without significant compliance with all current treatment plan goals.

(F) Advancement in phase and/or increased take-home privilege shall not occur if there are consistent or current positive urine drug screens.

(G) Reduction in phase and/or decreased take-home privilege shall occur if there are consistent or consecutive positive urine drug screens and/or substantial non-compliance with the individualized treatment plan.

(3) Phase III is designated for patients who have been admitted more than six (6) months and who have successfully completed Phase II criteria.

(A) During Phase III, the program may issue no more than four (4) take-home doses of methadone plus closed and holiday days.

(B) The patient shall participate in at least one (1) session of individual counseling and/or case management per month during Phase III.

(C) The treatment plan shall be reviewed and updated at least every six (6) months during Phase III or more frequently if circumstances warrant.

(D) Advancement in phase and/or increased take-home privilege shall not occur without significant compliance with all current treatment plan goals.

(E) Advancement in phase and/or increased take-home privilege shall not

occur if there are consistent or current positive urine drug screens.

(F) Reduction in phase and/or decreased take-home privilege shall occur if there are consistent or consecutive positive urine drug screens and/or substantial non-compliance with the individualized treatment plan.

(4) Phase IV is designated for patients who have been admitted more than nine (9) months and who have successfully met progressive Phase III criteria.

(A) During Phase IV, the program may issue one(1) week take-home doses plus closed and holiday days.

(B) The patient shall participate in at least one (1) session of individual counseling and/or case management per month during this phase.

(C) The treatment plan shall be reviewed and updated at least every six (6) months during this phase.

(D) Advancement in phase and/or increased take-home privilege shall not occur without significant compliance with all current treatment plan goals.

(E) Advancement in phase and/or increased take-home privilege shall not occur if there are consistent or current positive urine drug screens.

(F) Reduction in phase and/or decreased take-home privilege shall occur if there are consistent or consecutive positive urine drug screens and/or substantial non-compliance with the individualized treatment plan.

(G) For patients to be eligible for Phase IV or above they must be;

(i) be employed full time,

(ii) be a full time student (at least twelve (12) semester hours),

(iii) be retired, or

(iv) have proof of disability.

(5) Phase V is designated for patients who have been admitted for more than one (1) year.

(A) During Phase V, the program may issue two (2) weeks maximum take-home doses.

(B) The patient shall participate in at least one (1) session of individual counseling or case management per month during this phase.

(C) The treatment plan shall be reviewed and updated at least every six (6) months during this phase.

(D) Advancement in phase and/or increased take-home privilege shall not occur without significant compliance with all current treatment plan goals. occur if there are consistent or current positive urine drug screens.

(E) Reduction in phase and/or decreased take-home privilege shall occur if there are consistent or consecutive positive urine drug screens and/or substantial non-compliance with the individualized treatment plan.

(F) Patients who meet criteria for Phase VI, and who have been admitted to treatment for a minimum of one (1) year, and who are receiving thirty (30) days of take-home doses on July 1, 2007 shall be allowed to continue to be eligible to receive thirty (30) days of take-home doses after July 1, 2007.

(i) If this patient is reduced in phase, the privilege of thirty (30) days take-home medication shall be withdrawn.

(ii) Once lost, the privilege to receive thirty (30) days of take-home

medication shall not be available again.

(iii) If patient with the privilege to receive thirty (30) days of take-home medication changes clinics, it shall be the decision of the receiving clinic to either continue or ignore the continuation of the thirty (30) take-home medication privilege.

(6) Phase VI is designated for patients who voluntarily seek medically supervised withdrawal and abstinence from all drugs, including methadone as prescribed. A patient may enter this phase at any time in the treatment and rehabilitation process.

(A) During Phase VI, the medical director determines take-home doses based on stability.

(B) During Phase VI, the counselor determines the frequency of counseling sessions with input from the patient. At the onset of Phase VI, the patient may require an increased level of counseling and other support services.

(C) The counselor and patient develop a continuing care plan prior to the successful completion of treatment.

(d) The OSTP shall have written policy and procedure stating these guidelines when a patient is transferring to another clinic or level of care.

(1) The admitting program shall obtain from the patient an authorization for disclosure of confidential information, for the purpose of obtaining accurate and current information concerning the patient's treatment at the former program.

(2) The medical director or program physician shall not allow the patient to attend the clinic less frequently than the most recent schedule allowed at the former program unless:

(A) Copies of the patient’s records are obtained to sufficiently document the patient’s satisfactory adherence to all relevant federal and state regulations for the required time in treatment; and

(B) the physician has completed an evaluation of the patient.

(3) At a minimum, staff from the admitting program shall document in the patient record and staff from the transferring program must provide the following information before the initial dose of narcotic drug is administered to a transfer patient:

(A) The last date and amount of narcotic drug administered or dispensed at the former program;

(B) The length of time in continuous treatment;

(C) The most recent record of clinic attendance;

(D) The name, address, and telephone number of the program contacted;

(E) The date and time of the contact; and

(F) The name of the program employee furnishing the information.