CHAPTER 70. STANDARDS AND CRITERIA FOR OPIOID TREATMENT PROGRAMS

SUBCHAPTER 1. GENERAL PROVISIONS

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 or partial agonist treatment medications.

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

"Administrative withdrawal" means medically supervised withdrawal involving the gradual tapering of dose of medication over time, coinciding with the 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 dependent upon opioid drugs.

"ASAM criteria" means the most current edition of the American Society of Addiction Medicine's published criteria for admission to treatment, continued services, and discharge.

"Biopsychsocial assessment" means in-person interviews conducted by a LBHP or Licensure Candidate designed to elicit historical and current information regarding the behavior and experiences of a person served, 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 dependence treatment.

"CARF" means the Commission on the Accreditation of Rehabilitation Facilities.

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

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

"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 person served, and results in significant distress and dysfunction.

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

"Clinical record" or **"treatment record"** means the collection of written information about the evaluation or treatment of a person served that includes the intake data, evaluation, service plan, description of services provided, medications as prescribed, continuing care plan, and discharge information.

"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.

"COA" means the Commission on Accreditation.

"Comprehensive maintenance treatment" means dispensing or administering an approved opioid agonist or partial agonist medication at stable dosage levels for a period in excess of 21 days for opioid use disorder; and providing medical, clinical and educational services to the person served with opioid use disorder.

"Continuing care plan" or **"discharge summary"** means a written plan of recommendations and specific referrals for implementation of continuing care services, including medications, developed with the knowledge and cooperation of the person served.

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

"Critical incident" means an occurrence or set of events inconsistent with the routine operation of a facility, service setting, or otherwise routine care of a person served. Critical incidents specifically include but are not necessarily limited to the following: adverse drug events; self-destructive behavior; deaths and injuries to persons served, staff and visitors; medication errors; persons receiving residential treatment that are absent without leave (AWOL); neglect or abuse of a person served; fire; unauthorized disclosure of information; damage to or theft of property belonging to persons served or the facility; other unexpected occurrences; or events potentially subject to litigation. A critical incident may involve multiple individuals or results.

"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.

"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.

"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 or partial 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~~medications will be transferred or otherwise shared with others to whom the medication was not prescribed or dispensed.

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

"Exception request process" means a process recording the justification of the need to make a change in treatment protocol for person receiving medication assisted treatment for opioid use disorder and submitted to SAMHSA using form SMA-168.

"FDA"means the 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 OTP is qualified to engage in medication assisted opioid treatment.

"HIPAA" means Health Insurance Portability and Accountability Act

"Holiday" means those days recognized by the State of Oklahoma as holidays.

"Individual Placement and Support" or **"IPS"** means an evidence based specific type of employment and education service to help people with mental illness, substance use disorders or co-occurring disorders, find and keep competitive employment.

"Individualized service planning" means the ongoing process by which a clinician and the person served 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 person served is awaiting transfer to a program that provides comprehensive maintenance treatment.

"JC" or **"TJC"** means the Joint Commission.

"Licensed Behavioral Health Professional" or **"LBHP"** means:

(A) An Allopathic or Osteopathic Physician with a current license and board certification in psychiatry or board eligible in the state in which services are provided, or a current resident in psychiatry;

(B) An Advanced Practice Registered Nurse licensed as a registered nurse with a current certification of recognition from the board of nursing in the state in which services are provided and certified in a psychiatric mental health specialty;

(C) A Clinical Psychologist who is duly licensed to practice by the State Board of Examiners of Psychologists;

(D) A Physician Assistant who is licensed in good standing in Oklahoma and has received specific training for and is experienced in performing mental health therapeutic, diagnostic, or counseling functions;

(E) A practitioner with a license to practice in the state in which services are provided by one of the following licensing boards:

(i) Social Work (clinical specialty only);

(ii) Professional Counselor;

(iii) Marriage and Family Therapist;

(iv) Behavioral Practitioner; or

(v) Alcohol and Drug Counselor.

"Licensure candidate" means practitioners actively and regularly receiving board approved supervision, and extended supervision by a fully licensed clinician if board's supervision requirement is met but the individual is not yet licensed, to become licensed by one of the following licensing boards:

(A) Psychology;

(B) Social Work (clinical specialty only);

(C) Professional Counselor;

(D) Marriage and Family Therapist;

(E) Behavioral Practitioner; or

(F) Alcohol and Drug Counselor.

"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 or buprenorphine treatment services are rendered. This term includes~~

~~skilled, intermediate, and custodial care facilities which operate within the terms of licensure.~~

"Long-term care facility" means a facility that provides rehabilitative, restorative, and/or ongoing services to those in need of assistance with activities of daily living. Long-term care facilities include extended acute care facilities; rehabilitation centers; skilled nursing facilities; permanent supportive housing; assisted living facilities; and chronic care hospitals.

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

~~**"Medical director"** means a physician, licensed to practice medicine in Oklahoma, who assumes responsibility for the administration of all medical services performed by an OTP, 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 dependence on an opioid drug.~~

"Medical director" means a physician, licensed to practice medicine in Oklahoma, who assumes responsibility for all medical and behavioral health services provided by the program, including their administration.

"Medical withdrawal" means a condition created by administering an opioid agonist or partial 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 for Opioid Use Disorder" or **"MOUD"** means medications, including opioid agonist medications, approved by the Food and Drug Administration under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), for use in the treatment of opioid use disorder.

"Medication unit" means a satellite facility established as part of, but geographically separate from, an OTP from which appropriately licensed practitioners dispense or administer an opioid agonist or partial agonist treatment medication or collect samples for drug testing or analysis. ~~No medical or clinical interventions related to OTP treatment can be conducted at this site.~~Medication units include mobile and brick and mortar facilities.

"Non-oral methadone" means an injectable form of methadone not allowed for use by an OTP.

"Nurse practitioner" means a registered nurse who is prepared through advanced education and clinical training, to provide a wide range of health care services.

"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.

"OBNDD" means the Oklahoma Bureau of Narcotics and Dangerous Drug Control.

"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 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 or partial 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" 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 drug" means any of a class of drugs also called narcotics, having a dependence-forming or dependence-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 opioid agonist or partial 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 dependence. 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 Treatment Program (OTP)"means an organization which has been certified by ODMHSAS to provide therapeutic services and FDA-approved medications for opioid use disorder, referred to in statute as an Opioid Substitution Treatment Program.

"Opioid Use Disorder treatment" means the dispensing of MOUD, along with the provision of a range of medical and behavioral health services, as clinically necessary and based on an individualized assessment and a mutually agreed-upon care plan,

to an individual to alleviate the combination of adverse medical, psychological, or physical effects associated with an Opioid Use Disorder.

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

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

"Person served" means an individual, adult, adolescent, or child, who has applied for, is receiving or has received evaluation or treatment services from a facility operated or certified by ODMHSAS or with which ODMHSAS contracts and includes all persons referred to in OAC Title 450 as client(s), consumer(s), patient(s) or resident(s) or a combination thereof.

"Physician assistant" means a licensed or certified mid-level medical practitioner who works under the supervision of a licensed physician (MD) or osteopathic physician (DO).

"Program physician"means a licensed physician who provides medical treatment and counsel to the persons served by an OTP while under the supervision of the medical director.

"Program sponsor"means a person named in the application for an OTP permit who is responsible for the operation of the OTP and who assumes responsibility for all its employees, including any practitioners, staff, or other persons providing medical, rehabilitative, or therapy 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.

"Psychotherapy" or **"Therapy"** means a goal directed process using generally accepted clinical approaches provided face-to-face by a Licensed Behavioral Health Professional (LBHP) or Licensure Candidate with consumers in individual, group, or family settings to promote positive, emotional, or behavioral change.

"Rehabilitation Services" means face-to-face individual or group services provided by qualified staff to develop skill necessary to perform activities of daily living and successful integration into community life. Rehabilitation services must be provided by a Licensed Behavioral Health Professional (LBHP), Licensure Candidate, Certified Alcohol and Drug Counselor (CADC) or Certified Behavioral Health Case Manager II (CM II).

"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 physical or psychological injury to a person served, staff member, or visitor, 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. These events signal the need for immediate investigation and response. Sentinel events include, but are not limited to, suicide, homicide, assault and other forms of violence, including domestic violence or sexual assault, and adverse drug events resulting in serious injury or death. Sentinel events include occurrences that take place at the facility and/or during the delivery of services, as well as suicide and unintentional drug overdose deaths that occur at any time while a person receiving outpatient services is an active client, within seventy-two (72) hours of contact after mobile/outpatient crisis intervention services are provided, and within seventy-two (72) hours of discharge from inpatient and residential settings, including sites certified under Chapter 23 of this Title.

"Service Provider" means a person who is allowed to provide services for those with substance use disorders within the regulation and scope of their certification level or license.

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

"State Opioid Treatment Authority" or **"SOTA"**means 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 dependence with an opioid drug. For Oklahoma it is the Oklahoma Department of Mental Health and Substance Abuse Services.

"Split dosing" means dispensing of a single dose of MOUD as separate portions to be taken within a 24-hour period. Split dosing is indicated among, but not limited to, those patients who: possess a genetic variant which increases methadone metabolism; concurrently take other medications or drink alcohol that also induce hepatic enzymes leading to more rapid metabolism of methadone; who are pregnant; or for whom methadone or buprenorphine are being used to treat a concurrent pain indication in addition to the diagnosis of OUD. This leads to more stable, steady-state medication levels.

"STD" means sexually transmitted disease.

"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. Tablet methadone is not allowed for use by an OTP.

"Take-home dose" or **"take-home medication"** means one or more doses of an opioid agonist or partial agonist treatment medication dispensed to a person served for use off the premises.

"Therapeutic hour(s)" means the amount of time in which the person served was engaged with a service provider in identifying, addressing, and/or resolving those issues that have been identified in that individual's treatment plan.

"Urine drug screen" 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 person served has achieved a drug free state.~~

"Withdrawal management" means the dispensing of a MOUD in decreasing doses to an individual to alleviate adverse physical effects incident to withdrawal from the continuous or sustained use of an opioid and as a method of bringing the individual to an opioid-free state within such period. Long-term withdrawal management refers to the process of medication tapering that exceeds thirty (30) days.

SUBCHAPTER 3. FACILITY RECORD SYSTEM

PART 3. INTAKE AND ADMISSION ASSESSMENT

450:70-3-5. Assessment and record content - ~~Medical~~Initial medical examination

(a) All OTPs shall assess each individual for appropriateness for admission, ensuring the individual is placed in the least restrictive level of care.

~~(b) Each OTP shall ensure that persons served are admitted to treatment by a program physician, who determines that such treatment is appropriate for the specific person served by applying current and established DSM diagnostic and ASAM criteria.~~

~~(c) The OTP shall have written policy and procedure stating the program shall require each person served to undergo a complete, fully documented history and physical examination by the medical director, a program physician or physician with a valid Oklahoma license before admission to the medication assisted opioid treatment program. For the purposes of this chapter, a Physician Assistant or Nurse Practitioner, with appropriate Oklahoma license/certification and working under the direction and supervision of the OTP medical director may perform services allowed by Oklahoma certification or licensure such as those listed here, unless otherwise specified. A full medical examination, including the results of serology and other tests, must be completed within fourteen (14) days following admission.~~

(b) OTPs shall require each person served to undergo an initial medical examination. The initial medical examination shall be comprised of two parts:

(1) A screening examination to ensure that the person served meets criteria for admission and that there are no contraindications to treatment with MOUD; and

(2) A full history and examination, to determine the individual's broader health status, with lab testing as determined to be required by an appropriately licensed practitioner. An individual's refusal to undergo lab testing for co-occurring physical health conditions should not preclude them from access to treatment, provided such refusal does not have potential to negatively impact treatment with medications.

(c) If there are no contraindications, an individual may commence treatment with MOUD after the screening examination has been completed. Both the screening examination and full examination must be completed by an appropriately licensed practitioner. If the licensed practitioner is not an OTP practitioner, the screening examination must be completed no more than seven (7) days prior to OTP admission. Where the examination is performed outside of the OTP, the written results and narrative of the examination, as well as available lab testing results, must be transmitted, consistent with applicable privacy laws, to the OTP, and verified by an OTP practitioner.

(d) A full in-person physical examination, including the results of serology and other tests that are considered to be clinically appropriate, must be completed within fourteen (14) calendar days following an individual’s admission to the OTP. The full exam can be completed by a non-OTP practitioner, if the exam is verified by a licensed OTP practitioner as being true and accurate and transmitted in accordance with applicable privacy laws.

(e) Serology testing and other testing as deemed medically appropriate by the licensed OTP practitioner based on the screening or full history and examination, drawn not more than thirty (30) days prior to admission to the OTP, may form part of the full history and examination.

(f) The screening and full examination may be completed via telehealth for those individuals being admitted for treatment at the OTP with either buprenorphine or methadone, if a practitioner or primary care provider determines that an adequate evaluation can be accomplished via telehealth. When using telehealth, the following caveats apply:

(1) In evaluating patients for treatment with schedule II medications (such as Methadone), audio-visual telehealth platforms must be used, except when not available to the patient. When not available, it is acceptable to use audio-only devices, but only when the patient is in the presence of a licensed practitioner who is registered to prescribe (including dispense) controlled medications. The OTP practitioner shall review the examination results and order treatment medications as indicated.

(2) In evaluating patients for treatment with schedule III medications (such as Buprenorphine) or medications not classified as a controlled medication (such as Naltrexone), audio-visual or audio only platforms may be used. The OTP practitioner shall review the examination results and order treatment medications as indicated.

~~(d)~~(g) Compliance with 450:70-3-5 may be determined by:

(1) A review of policies and procedures,

(2) Treatment records, and

(3) Other facility documentation.

450:70-3-5.16. Assessment and record content - Initial dosing

(a) OTPs 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 person served 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~~

~~clinical record that forty (40) milligrams did not suppress opiate abstinence symptoms.~~

~~(3) Any increase above forty (40) milligrams shall be based on the physician's medical judgment and documented in the chart.~~

(2) For each new person served enrolled in an OTP, the initial dose of methadone shall be individually determined and shall include consideration of the type(s) of opioid(s) involved in the individual's opioid use disorder, other medications or substances being taken, medical history, and severity of opioid withdrawal.

(3) The total dose for the first day should not exceed fifty (50) milligrams unless the OTP practitioner, licensed under the appropriate State law and registered under the appropriate State and Federal laws to administer or dispense MOUD, finds sufficient medical rationale, including but not limited to if the individual is transferring from another OTP on a higher dose that has been verified, and documents in the clinical record that a higher dose was clinically indicated.

(4) Buprenorphine may be administered in tablet or sublingual form.

(5) Initial and later treatment dosing shall be determined by the medical director and according to best medical practice.

(b) Compliance with 450:70-3-5.16 may be determined by:

(1) A review of policies and procedures,

(2) Treatment records, and

(3) Other facility documentation.

450:70-3-5.1. Assessment and record content - History

~~(a) Persons served who have had a complete history and physical including laboratory tests within the past three months may be admitted to the OTP 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.~~

~~(b)~~(a) The OTP shall have written policy and procedure stating any FDA-approved medications for use in treating a significant opioid use disorder when used by an OTP for persons with a history of physiologic dependence, shall only be used in treating persons with a history of symptoms of opioid use disorder as stated in Title 43A, ~~Section 3-601 A. 1.~~Section 3-601(A) and as verified by the medical director or a program physician through medical examination; or persons with a history of dependence as stated in Title 43A, ~~Section 3-601 A. 1.~~Section 3-601(A) and written documentation from an agency at which another type of substance use disorder 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 treatment regimen. ~~When buprenorphine is used to provide medication assisted treatment in this setting, a one year history of opioid use disorder or dependence shall be required.~~

~~(c)~~(b) The OTP shall have written policy and procedure stating that if clinically appropriate, the program physician may waive the requirement as stated in Title 43A, ~~Section 3-601 A. 1.~~Section 3-601(A)(2) for:

(1) A person served within six (6) months of release from a correctional institution;

(2) A person served with a pregnancy verified by the program physician; or

(3) A person served having previously received medication-assisted recovery services for an opioid use disorder and within two (2) years of discharge from an OTP.

~~(d)~~(c) Compliance with 450:70-3-5.1 may be determined by:

(1) A review of policies and procedures,

(2) Treatment records, and

(3) Other facility documentation.

450:70-3-5.4. Assessment and record content - Level of care

~~(a) The OTP shall have written policy and procedure stating that persons served with two (2) or more unsuccessful managed withdrawal 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 OTP shall not admit a person served for more than two (2) withdrawal management episodes in one (1) year.~~

(a) The OTP shall have written policy and maintain current procedures that ensure that those persons served who choose to taper from treatment medication are provided the opportunity to do so with informed consent and at a mutually agreed upon rate that minimizes taper-related risks. Such consent must be documented in the clinical record by the treating practitioner.

(b) Compliance with these standards and criteria may be determined by a review of the following:

(1) Policy and Procedures,

(2) Review of all facility records, and

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

450:70-3-6. Assessment - Process requirements

(a) A periodic physical examination shall occur no less than one time each year and be conducted by an OTP practitioner. The periodic physical examination shall be documented in the clinical record and include:

(1) A review of MOUD dosing;

(2) Treatment response;

(3) Other substance use disorder treatment needs; and

(4) Other relevant physical and psychiatric treatment needs and goals.

~~(a)~~(b) Written policies and procedures governing the intake and assessment process shall specify the following:

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

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

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

(4) Any prospective data regarding the person served to be recorded during the intake process;

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

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

~~(b)~~(c) Compliance with 450:70-3-5.16 may be determined by:

(1) A review of policies and procedures,

(2) Treatment records, and

(3) Other facility documentation.

PART 5. ~~BIOPSYCHSOCIAL~~COMPREHENSIVE ASSESSMENT

450:70-3-7. ~~Biopsychsocial~~Comprehensive assessment

(a) All OTPs shall complete a ~~biopsychsocial~~comprehensive assessment which gathers sufficient information to assist the person served in developing an individualized ~~treatment~~service plan and shall include screening for imminent risk of harm to self or others. The OTP may utilize the current edition of the Addiction Severity Index (ASI) or ~~develop~~complete a ~~biopsychsocial~~comprehensive assessment which contains~~, but not be limited to,~~ the following:

(1) Identification of the strengths, needs, abilities, and preferences of the person served;

(2) Presenting problem and history of the presenting problem;

(3) Previous mental health and substance use disorder treatment history, including opioid substitution therapy~~:~~;

~~(A) Mental health,~~

~~(B) Substance abuse, and~~

~~(4) Health history and current biomedical conditions and complications;~~

~~(5)~~(4) Alcohol and drug use history;

~~(6)~~(5) History of trauma;

~~(7)~~(6) Family and social history, including family history of alcohol and drug use;

~~(8)~~(7) Educational attainment, difficulties, and history;

~~(9)~~(8) Cultural and religious orientation;

~~(10)~~(9) Vocational, occupational and military history;

~~(11)~~(10) Sexual history, including HIV, AIDS and STD at-risk behaviors;

~~(12)~~(11) Marital or significant other relationship history;

~~(13)~~(12) Recreational and leisure history;

~~(14)~~(13) Legal history;

~~(15)~~(14) Present living arrangement;

~~(16)~~(15) Economic resources;

~~(17)~~(16) Level of functioning;

~~(18)~~(17) Current support system;

~~(19) Current medications, including the name of prescribing physician, name of medication, strength and dosage, and length of time the consumer has been on the medication;~~

~~(20)~~(18) Expectations of the person served in terms of service; and

~~(21)~~(19) Assessment summary or diagnosis, and signature of the assessor and date of the assessment.

(b) The assessment shall be completed by a LBHP or licensure candidate.

(c) The assessment shall be completed as soon as possible after admission and no later than ~~the third (3) therapy or rehabilitation service visit~~fourteen (14) calendar days following admission.

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

(e) Compliance with 450:70-3-7 may be determined by:

(1) A review of policies and procedures,

(2) Treatment records, and

(3) Other facility documentation.

SUBCHAPTER 4. SERVICES SUPPORT AND ENHANCEMENT

PART 1. STAFF SUPPORT

450:70-4-4.2. Staffing - Medical Director coverage

(a) The OTP 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) active persons served in an OTP.

~~(b) With the exception of short-term, ad hoc absences, a designee cannot substitute for the medical director. For short-term, ad hoc absences such as those due to illness or planned time off, a physician or physician assistant may temporarily serve as a substitute for the medical director.~~

(b) The medical director may delegate specific responsibilities to authorized program physicians, appropriately licensed non-physician practitioners with prescriptive authority functioning under the medical director's supervision, or appropriately licensed and/or credentialed non-physician healthcare professionals providing services in the OTP, in compliance with applicable Federal and State laws. Such delegations will not eliminate the medical director's responsibility for all medical and behavioral health services provided by the OTP.

(c) Compliance with 450:70-4-4.2 may be determined by:

(1) A review of policies and procedures,
(2) Staff schedules,
(3) Privileging documents,
(4) Employee contracts,
(5) Interviews with staff, and
(6) Other facility documentation.

450:70-4-4.4. Staffing - Qualifications

(a) The OTP shall have written policy and procedure requiring FDA-approved medications for opioid use disorder be administered or dispensed only by a practitioner licensed and registered under the appropriate State and Federal laws to administer or dispense such medications, or by an agent of such practitioner if the agent is supervised by and under the order of the licensed practitioner, if the agent is authorized by Federal and State law to administer or dispense medications for opioid use disorder.

(b) The facility shall maintain documentation verifying the qualifications for the service providers.

~~(c) Staff shall be at least twenty-one (21) years old (excluding student interns).~~

~~(d)~~(c) Compliance with 450:70-4-4.4 may be determined by:

(1) A review of policies and procedures,
(2) Credentialing and privileging documents,
(3) Interviews with staff, and
(4) Other facility documentation.

~~(e)~~(d) Failure to comply with 450:70-4-4.4 will result in the initiation of procedures to deny, suspend and/or revoke certification.

PART 3. ORGANIZATIONAL AND FACILITY MANAGEMENT

450:70-4-7.1. Operations - Medication security

(a) The OTP 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 DEA, state and federal law.

~~(b) OTPs 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 OTP'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.~~

(b) OTPs must maintain current procedures adequate to identify the theft or diversion of take-home medications, including labeling containers with the OTP's name, address, and telephone number. Programs also must ensure that each individual take-home dose is packaged in a manner that is designed to reduce the risk of accidental ingestion, including child-proof containers (see Poison Prevention Packaging Act, Pub. L. 91-601 (15 U.S.C. 1471 et seq.)).

(c) Programs must provide education to each person served on: Safely transporting medication from the OTP to their place of residence; and the safe storage of take-home doses at the individual's place of residence, including child and household safety precautions. The provision of this education should be documented in the clinical record.

~~(c)~~(d) An OTP 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~~dispensed MOUD from legitimate treatment use and that assigns specific responsibility to the medical and administrative staff of the OTP 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, and
(3) Written policies and procedures for how staff members who diverts medication are held accountable for the medication diversion.

~~(d)~~(e) Compliance with 450:70-4-7.1 may be determined by:

(1) A review of policies and procedures,

(2) Personnel records,
(3) On-site verification,
(4) Interviews with staff, and
(5) Other facility documentation.

450:70-4-7.2. Operations - Dual enrollments

(a) The OTP shall have written policy and procedure stating FDA-approved medications shall not be provided to a person served who is known to be currently receiving medications from another OTP. ~~Persons Served who are known to be enrolled in more than one OTP at a time shall be required to choose one OTP for treatment. The person served must also be reported to the SOTA.~~

(b) A person served enrolled in an OTP shall not be permitted to obtain treatment in any other OTP except in circumstances involving an inability to access care at the person's OTP of record. Such circumstances include, but are not limited to, travel for work or family events, temporary relocation, or an OTP's temporary closure. If the medical director or program practitioner of the OTP in which the person served is enrolled determines that such circumstances exist, the individual may seek treatment at another OTP, provided the justification for the particular circumstances are noted in the clinical record both at the OTP in which the individual is enrolled and at the OTP that will provide the MOUD.

~~(b)~~(c) Compliance with 450:70-4-7.2 may be determined by:

(1) A review of policies and procedures,
(2) Treatment records,
(3) Interviews with staff, and
(4) Other facility documentation.

450:70-4-7.3. Operations - Dosing considerations

(a) The OTP shall have written policy and procedure stating that methadone shall be dispensed orally and in liquid form only. Non-oral forms and tablet form methadone are prohibited from use. Tablet and sublingual forms of buprenorphine are allowed.

(b) Each OTP shall develop written policies and procedures giving preference to the use of liquid and diskette forms of methadone. Diskettes shall be dissolved in liquid prior to being dispensed, or dissolved in liquid by the patient in full and clear view of OTP staff.

(c) OTPs shall have written policies and procedures adequate to ensure that each opioid agonist and partial agonist treatment medication used by the program is administered and dispensed in accordance with its approved product labeling.

(d) 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~~of each MOUD is completed in accordance with its FDA-approved 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 clinical record.

(e) The OTP shall have written policy and procedure stating the OTP shall use only those opioid agonist treatment medications that are approved by the Food and Drug Administration for use in the treatment of significant opioid use disorders and opioid dependence.

(f) The OTP shall be fully compliant with the protocol of any 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 significant opioid use disorders and opioid dependence.

(g) Compliance with 450:70-4-7.3may be determined by:

(1) A review of policies and procedures,
(2) Treatment records,
(3) Interviews with staff, and
(4) Other facility documentation.

450:70-4-8.3. Take-home doses, general criteria

(a) The OTP shall have written policy and procedure stating that unsupervised take-home use shall be determined by the medical director. In determining which persons served may be permitted unsupervised take-home use, the medical director shall consider the following criteria in determining whether a person served is responsible in handling opioid medications. The same criteria shall be considered when receiving a person served from a transferring program verifying the amount of time the person served has spent satisfactorily adhering to the criteria found below. This information will be used to determine if the person served 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 unapproved use of drugs (opioid or non-narcotic), including alcohol~~active substance use disorders, other physical or behavioral health conditions that increase the risk of patient harm as it relates to the potential for overdose, or the ability to function safely;
(2) ~~Regular clinic attendance~~Regularity of attendance for supervised medication administration;
(3) Absence of serious behavioral problems at the clinic;
(4) Absence of known recent ~~criminal~~diversion activity, e.g., drug dealing;
~~(5) Stability of the home environment and social relationships of the person served;~~

(5) Whether the take-home medication can be safely transported and stored; and
~~(6) Length of time in comprehensive maintenance treatment;~~
~~(7) Assurance that take-home medication can be safely stored within the home of the person served;~~
~~(8)~~(6) Whether the rehabilitative benefit the person served derived from decreasing the frequency of clinic attendance outweighs the potential risks of diversion~~; and~~.
~~(9) The current phase in treatment of the person served.~~

(b) Such determinations and the basis for such determinations consistent with the criteria above shall be documented in the clinical record.

(c) The medical director, using reasonable judgment, may deny or rescind the take-home medication privileges of a person served.

~~(d) No unsupervised or take-home doses shall be dispensed to persons served in short-term withdrawal management or interim maintenance treatment.~~

~~(c)~~(d) Compliance with 450:70-4-8.3 may be determined by:
(1) A review of policies and procedures,
(2) Treatment records,
(3) Interviews with staff,
(4) Incident reports, and
(5) Other facility documentation.

450:70-4-8.5. Take-home doses, limits

(a) With the exception of FDA-approved buprenorphine and buprenorphine combination products for opioid use disorder, take-home doses shall be limited, in accordance with 42 CFR § 8.12. Unless requirements at 42 CFR § 8.12 state otherwise, take-home doses shall be limited as follows:
(1) Any person served in comprehensive treatment may receive their individualized take-home doses as ordered for days the OTP is closed for business, including one weekend day and State and Federal holidays, regardless of length of time in treatment.
(2) During the first fourteen (14) days of treatment, the take-home supply (beyond that of (1) in this subsection) is limited to seven (7) days.
(3) Beginning at fifteen (15) days of treatment, the take-home supply (beyond that of (1) in this subsection) is limited to fourteen (14) days.
(4) Beginning at thirty-one (31) days of treatment, the take-home supply (beyond that of (1) in this subsection) is limited to twenty-eight (28) days.

(b) The number of take-home doses allowed shall be at the OTP practitioner's discretion but shall be based on the criteria listed in OAC 450:70-4-8.3.

~~(b)~~(c) Compliance with 450:70-4-8.5 may be determined by:
(1) A review of policies and procedures,
(2) Treatment records, and
(3) Other facility documentation.

SUBCHAPTER 6. SUBSTANCE USE DISORDER TREATMENT SERVICES

PART 2. LEVELS OF TREATMENT

450:70-6-4. Levels of Care

(a) OTPs shall document the provision of the following levels of care in policy and procedure, with the exception of medication units, unless that level of service is provided. ~~All facilities shall include the requirements found in Facility Record System. All OTPs certified by ODMHSAS providing any of the following levels of care shall also provide short and long term withdrawal treatment services.~~

(b) Compliance with 70-6-4 may be determined by a review of the following:
(1) Policy and Procedures,
(2) Review of treatment records, and
(3) Any other supporting facility documentation.

450:70-6-5.1. Withdrawal management - Maintenance to withdrawal management

(a) The OTP shall have written policy and procedure stating persons served involved in maintenance management will enter withdrawal ~~treatment~~management:
(1) Only when initiated as administrative withdrawal or when requested by the person served and approved by the OTP medical director; and
(2) When planned and supervised by the medical director or a program physician.

(b) The OTP shall have written policy and procedure stating that before a person served begins managed withdrawal, the person served must be:

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

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

(B) The risks of managed withdrawal and

(C) Signs and symptoms of relapse.

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

(c) Compliance with 70-6-5.1 may be determined by a review of the following:

(1) Policy and Procedures,

(2) Review of treatment records, and

(3) Any other supporting facility documentation.

450:70-6-7. Short-term managed withdrawal

(a) The OTP shall have written policy and procedure regarding short-term managed withdrawal ~~treatment~~ services.

(b) There shall be written policy stating a person served may be admitted to short-term managed withdrawal regardless of age. Persons served under the age of eighteen (18) may be admitted with written parent or guardian approval. If a minor is eligible to self-consent to treatment pursuant to state law, written approval from a parent or guardian is not required.

(c) The program physician shall document in the clinical record the reason for admitting the person served to short-term managed withdrawal.

(d) Take-home medication is not allowed during short-term managed withdrawal.

(e) A history of one year or more opioid dependence and an attempt at another form of treatment is not required for admission to short-term managed withdrawal.

(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 persons served in comprehensive maintenance are required for persons served in short-term managed withdrawal.

(h) A primary LBHP, Licensure Candidate or CADC must be assigned by the program to monitor progress toward the goal of short-term withdrawal management and possible drug-free treatment referral.

(i) Methadone is required to be administered daily by the OTP in reducing doses to reach a drug-free state over a period not to exceed thirty (30) days. Buprenorphine shall be administered as determined by the OTP medical director.

(j) All other requirements of comprehensive maintenance treatment apply.

(k) Compliance with 450:70-6-7 may be determined by:

(1) A review of policies and procedures,

(2) Treatment records,

(3) Interviews with staff, and

(4) Other facility documentation.

450:70-6-9. Interim maintenance treatment services

~~(a) The OTP shall have documentation before providing interim maintenance treatment services indicating the written approval of both SAMHSA and ODMHSAS.~~

(a) The program shall notify ODMHSAS when a person served begins and leaves interim treatment, and before the date of transfer to comprehensive services, and shall document such notifications.

(b) The OTP shall have written policy and procedure stating the program sponsor may place an individual who is eligible for admission to comprehensive maintenance services in interim maintenance services if the individual cannot be placed in comprehensive maintenance treatment services within a reasonable geographic distance and within fourteen (14) days of ~~application for admission to comprehensive maintenance treatment services~~the time the individual requests treatment for OUD.

(c) The OTP shall identify the maximum length of stay in interim opioid services is one hundred and eighty (180) days.

(d) The OTP shall provide a minimum of two (2) drug screens topersons served in interim maintenance during the one hundred and eighty (180) days of interim services.

(e) The OTP shall have written policies and procedures outlining all criteria for transfer from interim maintenance to comprehensive maintenance services. These transfer criteria shall be in writing and shall include, at a minimum, a preference for pregnant women in admitting persons served to interim maintenance and in transferring persons served from interim maintenance to comprehensive maintenance treatment. Individuals enrolled in interim treatment shall not be discharged without the approval of an OTP practitioner, who shall consider on-going and patient-centered treatment needs, which are to be documented in the clinical record, while awaiting transfer to a comprehensive treatment program.

(f) The OTP shall have policy and procedure ensuring interim maintenanceservices shall be provided in a manner consistent with all applicable Federal and State laws and regulations.

(g) The interim maintenance services program shall meet and/or possess all applicable Federal and State certifications, licensures, laws and regulations.

(h) The OTP shall have written policy and procedure stating all rules and requirements for comprehensive maintenance services apply to interim maintenance services with the exception of:

(1) Opioid agonist medication is required to be administered daily and under observation. Unsupervised or take home dosing is not allowed.

(2) A primary LBHP, Licensure Candidate or CADC does not need to be assigned, but crisis services should be available.

(3) Interim maintenance is limited to one hundred and eighty (80) days in any twelve (12) month period.

(4) By day one hundred and twenty (120), a plan for continuing treatment beyond one hundred and eighty (180) days shall be developed and documented in the clinical record.

(5) Educational, rehabilitative and therapy services are not required. However, information pertaining to locally available, community-based resources for ancillary services shall be made available to persons served in interim maintenance.

(5) An initial treatment plan and periodic updates are not required.

(i) Compliance with 450:70-6-9 may be determined by:

(1) A review of policies and procedures,

(2) Treatment records,

(3) Interviews with staff, and

(4) Other facility documentation

450:70-6-10. Medication units

(a) Before providing medication assisted opioid use disorder services through a stand-alone medication unit, the program must receive the written approval of both SAMHSA and ODMHSAS, and ODMHSAS certification, OBNDD approval, and national accreditation. A mobile medication unit must have an associated OTP physical location for purposes of ODMHSAS certification.

~~(b) Certification as an OTP will not be required for the maintenance or managed withdrawal of a person served 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 withdrawal management during the stay in the hospital or long term care facility.~~

(b) Any services that are provided in an OTP may be provided in the medication unit, assuming compliance with all applicable Federal, State, and local law, and the use of units that provide appropriate privacy and have adequate space.

(c) Medication units shall be in compliance with the following:

(1) Currently licensed by the DEA; and approved by SAMHSA.

(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)~~(3) 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.

(d) Compliance with 450:70-6-10 may be determined by:

(1) A review of policies and procedures,

(2) Certifications and licenses, and

(3) Other facility documentation.

450:70-6-10.1. ~~Mobile medication units~~Long-term care facilities, hospitals, and correctional facilities

~~(a) Before providing medication assisted opioid used disorder services through a mobile medication unit, the program must provide notification to SAMHSA, ODMHSAS Provider Certification, OBNDD, and the program's national accreditation entity. The mobile medication unit must have an associated OTP physical location for purposes of ODMHSAS certification.~~

~~(b) Mobile medication units shall have the following:~~

~~(1) 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.~~

~~(2) 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.~~

~~(c) Mobile medication units may provide the following services, in accordance with applicable state and federal requirements and applicable rules contained in this Chapter:~~

~~(1) Administering and dispensing medications for opioid use disorder treatment;~~

~~(2) Collecting samples for drug testing or analysis;~~

~~(3) Dispensing of take-home medications; and~~

~~(4) Initiating methadone or buprenorphine after an appropriate medical assessment has been performed.~~

~~(d) Mobile medication units that provide appropriate privacy and adequate space may additionally provide the following services:~~

~~(1) Intake/initial biopsychsocial and appropriate medical assessments (with a full physical examination to be conducted within fourteen [14] days of admission); and~~

~~(2) Clinical services, such as therapy, provided in-person or when permissible through use of telehealth services.~~

~~(e) Any required assessment or treatment services not provided by the mobile medication unit must be provided by the OTP in accordance with all requirements in this Chapter.~~

~~(f) Compliance with 450:70-6-10.1 may be determined by:~~

~~(1) A review of policies and procedures,~~

~~(2) Certifications and licenses, and~~

~~(3) Other facility documentation.~~

Certification as an OTP is not required for the initiation or continuity of medication treatment or withdrawal management of an individual who is admitted to a hospital, long-term care facility, or correctional facility that is registered with the Drug Enforcement Administration as a hospital/clinic, for the treatment of medical conditions other than OUD, and who requires treatment of OUD with methadone during their stay, when such treatment is permitted under applicable Federal law.

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

(a) Every OTP shall provide or refer for Human Immunodeficiency Virus (HIV), Sexually Transmitted Diseases (STD), and Acquired Immunodeficiency Syndrome (AIDS) education, testing, and counseling services for drug dependent persons in accordance with 43A O.S. § 3-425.1 and 42 CFR § 8.12. Every OTP shall:

(1) Provide or refer for educational sessions regarding HIV/STD/AIDS and viral hepatitis to persons served and the significant other(s) of persons served;

(2) Provide or refer all drug dependent persons, and their identified significant others, for HIV/STD/AIDS and viral hepatitis testing and counseling;

(3) Provide counseling on preventing exposure to, and the transmission of, HIV, viral hepatitis, and STDs and either directly provide services and treatments or actively link to treatment each person admitted or readmitted to treatment who has received positive test results for these conditions from initial and/or periodic medical examinations;

(4) Provide documentation of services or referral to services described in (1) through (3) above, including refusal of these services; and

(5) Maintain all test results in the confidential manner prescribed by applicable state or federal statutes or regulations.

(b) Compliance with 450:70-6-12 shall be determined by a review of written policies and procedures, clinical records, and other supporting facility records and documentation.

PART 3. TREATMENT SERVICES

450:70-6-15. Clinical Services

(a) Each OTP shall use opioid agonists or partial agonists in conjunction with other treatment services including, but not limited to, individual, family and group therapy; case management; Individual Placement and Support services; peer recovery support services; and other services ~~enhancing positive life style changes in the consumer~~that support recovery.

(b) The OTP shall provide adequate and appropriate services to each person served as clinically necessary, including medical services, therapy/rehabilitation services, crisis intervention services, vocational/educational services, and other screening, 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 individuals enrolled in the OTP. The program sponsor, in any event, must be able to document that these services are fully and reasonably available to all persons served.

(c) Services shall be provided by appropriately credentialed staff in accordance with state requirements, including Chapter 50 and Chapter 53 of this Title. Therapy shall be provided by a program LBHP or Licensure Candidate. Rehabilitation services must be provided by a LBHP, Licensure Candidate, CADC or Certified Case Manager II. Case Management services must be provided by a LBHP, Licensure Candidate, CADC, or Certified Case Manager I or II. Peer recovery support services must be provided by a Certified Peer Recovery Support Specialist. Individual Placement and Support (IPS) services must be provided by a provider trained and credentialed in IPS.

(d) The OTP 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 consumers who either request such services or who have been determined through the assessment process to be in need of such services.

(e) The OTP shall have written policy and procedure stating consumers shall attend clinical services as prescribed in the individualized service plan and this Chapter.

(f) Compliance with 450:70-6-15 may be determined by:

(1) A review of policies and procedures,

(2) Treatment records, and

(3) Other facility documentation.

450:70-6-16. Treatment for persons served who are pregnant

(a) The OTP shall have written policy and procedure stating the OTP address the special needs of persons served who are pregnant and ensure appropriate evidence-based treatment protocols. Prenatal care and reproductive health services for persons served who are pregnant or post-partum must be provided either by the OTP or by referral to appropriate healthcare providers.

(b) An OTP shall ensure that policies and procedures are developed, implemented, and complied with for the treatment of persons served who are pregnant, to include:

(1) Documentation that staff members are educated in the unique needs ofpersons served who are pregnant;
(2) Priority for pregnant individuals seeking medication assisted opioid treatment medications for opioid use disorder;
(3) Documentation of the reasons for a pregnant individual's denial of admission to an agency;
(4) Availability of prenatal care for persons served who are pregnant either at the agency or through referral to a medical practitioner;
(5) Written agreement(s) with a medical practitioner who is providing prenatal care to a person served who is pregnant, to include procedures for exchanging medication assisted opioid treatment and prenatal care information regarding medications utilized for opioid use disorder and prenatal care;
(6) Education from agency staff to a person served who is pregnant who does not obtain prenatal care services for prenatal care;
(7) Procedures to obtain a written refusal of prenatal care services from a person served who is pregnant who refuses prenatal care services offered by the agency or a referral for prenatal care;
(8) Procedures to ensure a person served who is pregnant receiving comprehensive maintenance treatment before pregnancy shall be maintained at the pre-pregnancy dose of opioid agonist or partial agonist medication, if effective;
(9) Monitoring by an agency medical practitioner of a person served who is pregnant to determine if pregnancy induced changes in the elimination or metabolization of opioid agonist or partial agonist treatment medication may necessitate an increased or split dose; and
(10) Referral of a person served who is pregnant who is discharged from the agency to a medical practitioner and that a staff member document the name, address, and telephone number of the medical practitioner in the clinical record.

(c) Compliance with 70-6-11 may be determined by:
(1) A review of policies and procedures,
(2) Treatment records,
(3) Interviews with staff, and
(4) Other facility documentation.

450:70-6-17.2. Service phases - General

(a) The OTP shall have written policy and procedure describing structured phases of treatment and rehabilitation to support progress of persons served and to establish requirements regarding 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. The OTP shall utilize ASAM criteria to determine the appropriate level of care during each phase of treatment.

(b) Refusal of persons served to participate in treatment services as prescribed in 450:70-6-17.3 through 450:70-6-17.8 shall not preclude them from receiving medications from the OTP. The OTP shall document refusal of treatment services in the clinical record.

~~(b)~~(c) If an OTP is providing doses to a person served receiving residential level of care substance use disorder services, the required minimum services listed for each phase may be delivered by the residential level of care substance use disorder provider. The OTP shall document the provision of these services and the provider delivering such services in the service plan.

~~(c)~~(d) Compliance with 450:70-6-17.2 may be determined by:
(1) A review of policies and procedures,
(2) Treatment records, and
(3) Other facility documentation.