



# OKLAHOMA

## Mental Health & Substance Abuse

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### TITLE 450

## CHAPTER 70. STANDARDS AND CRITERIA FOR OPIOID TREATMENT PROGRAMS

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## SUBCHAPTER 1. GENERAL PROVISIONS

### **450:70-1-1. Purpose**

This chapter sets forth rules regulating program requirements, activities, and services standards and criteria used in the certification of facilities and organizations providing medication assisted opioid 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. Rules outlining general certification qualifications applicable to facilities and organizations certified under this Chapter are found in OAC 450:1-9-5 through OAC 450:1-9-5.6.

### **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.

**"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 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 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. 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.

**"OBND"** 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 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.

**"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.

**"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.

**"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 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.

#### **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 certified substance use disorder treatment facilities and organizations providing medication assisted opioid treatment programs, including opioid withdrawal or opioid maintenance using methadone and buprenorphine, short term withdrawal management, long term withdrawal management or interim maintenance-services 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 [REVOKED]**

**SUBCHAPTER 2. FACILITY INFRASTRUCTURE REQUIREMENTS  
[REVOKED]**

**450:70-2-1. Physical facility environment and safety [REVOKED]**

**450:70-2-2. Hygiene and sanitation [REVOKED]**

**450:70-2-3. Tobacco-free campus [REVOKED]**

**SUBCHAPTER 3. FACILITY RECORD SYSTEM**

**PART 1. RECORD SYSTEM**

**450:70-3-1. Purpose [REVOKED]**

**450:70-3-2. Patient record system [REVOKED]**

**450:70-3-3. Patient records, basic requirement [REVOKED]**

**450:70-3-3.1. Transfer of persons served**

(a) The OTP shall refer persons served to other resources when the individual has treatment or service needs the facility does not provide.

(1) The OTP shall maintain a directory of currently available local resources.

(2) The transferring program must supply patient clinical 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.

(A) 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 person served, 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 person served, and the program may delete confidential information about another person served or family member of the person served who has not consented to the release.

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

(C) If the program denies the request, in whole or in part, the program shall furnish the person served 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 record of the person served.
- (b) The OTP shall have written policy and procedure stating these guidelines when a person served is transferring from one clinic or level of care to another:
- (1) The admitting program shall obtain from the person served an authorization for disclosure of confidential information, for the purpose of obtaining accurate and current information concerning the individual's treatment at the former program.
  - (2) The medical director or program physician at the admitting program shall not allow the person served to attend the clinic less frequently than the most recent schedule allowed at the former program unless:
    - (A) Copies of the clinical records are obtained to sufficiently document the satisfactory adherence of the person served to all relevant federal and state regulations for the required time in treatment; and
    - (B) The program physician has completed an evaluation of the person served.
  - (3) At a minimum, staff from the admitting program shall document in the clinical record and staff from the transferring program must provide the following information before the initial dose of methadone or buprenorphine is administered to a person served who is transferring:
    - (A) The last date and amount of opioid treatment medication 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.
- (c) Compliance with 450:70-3-3.1 may be determined by:
- (1) A review of policies and procedures,
  - (2) Treatment records,
  - (3) Performance improvement guidelines,
  - (4) Interviews with staff, and
  - (5) Other facility documentation.

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

**PART 3. INTAKE AND ADMISSION ASSESSMENT**

**450:70-3-5. Assessment and record content - 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) 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.
- (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.



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

(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) 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) 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.

(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)(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.

(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.

#### **450:70-3-5.2. Assessment and record content - Symptoms**

(a) Any person served seeking admission while under the influence, or undergoing withdrawal of alcohol or drugs other than opioids shall be assessed prior to admission for medical needs. The written criteria to be used for medical needs assessment shall be approved by the OTP medical director and meet state and federal requirements regarding standards of care.

(b) Using a standardized and accepted instrument (such as the COWS Scale) no person served shall be admitted to medication assisted opioid recovery services unless symptoms of opioid dependency listed below are present with at least two symptoms coming from numbers one (1) through seven (7);

- (1) Elevated resting pulse rate;
- (2) Increased sweating;
- (3) Tremors;
- (4) Variation in pupil size;
- (5) Increased yawning;
- (6) Runny nose and/or tearing;
- (7) Presence of "gooseflesh";
- (8) Increased restlessness;
- (9) Bone and/or joint pain;

- (10) Increased anxiety or irritability; or
- (11) Gastrointestinal distress.
- (c) Compliance with 450:70-3-5.2 may be determined by:
  - (1) A review of policies and procedures,
  - (2) Treatment records, and
  - (3) Other facility documentation.

**450:70-3-5.3. Assessment and record content – Dispensed and prescribed pharmaceuticals**

- (a) The OTP shall have written policy and procedure stating the clinical record shall contain adequate documentation of any prescription medication, including methadone or buprenorphine, that a person served may be taking, including the name of the medication, 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 person served is to be taking the medication. 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.
- (b) Compliance with 450:70-3-5.3 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 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.

**450:70-3-5.5. Assessment and record content – Care of minors**

- (a) Written approval from a parent or guardian for a person served under the age of eighteen (18) admitted to maintenance treatment shall be obtained if required by law. If a minor is eligible to self-consent to treatment pursuant to state law, written approval from a parent or guardian is not required.
- (b) Compliance with 450:70-3-5.5 may be determined by:
  - (1) A review of policies and procedures,
  - (2) treatment records, and
  - (3) Other facility documentation.

**450:70-3-5.6 Assessment and record content – Central registry**

(a) The OTP shall have written policy and procedure outlining the requirement for the reporting of persons receiving medication assisted opioid treatment to the ODMHSAS. This report to the Central Registry shall be made electronically as requested by the Department and within twenty-four (24) hours of admission, change of medical status or discharge of any person served.

(b) Compliance with 450:70-3-5.6 may be determined by:

- (1) A review of policies and procedures,
- (2) Treatment records, and
- (3) Other facility documentation.

**450:70-3-5.7. Assessment and record content –Consent and admission information**

(a) The OTP shall have written policy and procedure stating the admission requirements for opioid treatment programs.

(b) All applicants for medication assisted opioid treatment shall sign a written consent for opioid treatment in the primary language of the applicant.

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

- (1) Date of initial contact requesting services;
- (2) Identification information, including the name, home address, and telephone number of the person served;
- (3) Referral source;
- (4) Mental status examination and findings;
- (5) History and physical information;
- (6) Family to be notified in case of emergency; and

(d) Compliance with 450:70-3-5.7 may be determined by:

- (1) A review of policies and procedures,
- (2) Treatment records, and
- (3) Other facility documentation.

**450:70-3-5.8. Assessment and record content – ASAM**

(a) The OTP shall document and assess all persons served for appropriateness of admission taking into account the needs of the person served as identified by, but not limited to:

- (1) Acute intoxication and/or withdrawal potential;
- (2) Biomedical conditions and complications;
- (3) Emotional, behavioral, or cognitive conditions and complications;
- (4) Readiness to change;
- (5) Relapse, continued used, or continued problem potential; and
- (6) Recovery/living environment.

(b) Compliance with 450:70-3-5.8 may be determined by:

- (1) A review of policies and procedures,
- (2) Treatment records, and
- (3) Other facility documentation.

**450:70-3-5.9. Assessment and record content – Supportive service array**

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

- (1) Individual therapy or rehabilitation services until the person served is fully stabilized and as indicated in this Chapter;
- (2) Group and family therapy or rehabilitation services for spouses, parents, or significant others and as indicated in this chapter;
- (3) Individual Placement and Support Services;
- (4) Case management services;
- (5) Peer recovery support services; and
- (6) Referral for additional services as outlined by the individualized treatment plan.

(b) Compliance with 450:70-3-5.9 may be determined by:

- (1) A review of policies and procedures,
- (2) Treatment records, and
- (3) Other facility documentation.

**450:70-3-5.10. Assessment and record content – Service notification**

(a) The OTP shall have written policy and procedure requiring the person served to be informed of all services that are available through the agency; and of all policies and procedures that may impact the treatment of the person served.

(b) There shall be written verification such notification was made, signed by the person served.

(c) The OTP shall have written policy and procedure requiring the person served be informed of the following upon admission:

- (1) The progression of opioid dependence and the patient's assessed stage of opioid use disorder of the person served;
- (2) The goal and benefits of medication assisted opioid-recovery services;
- (3) The signs and symptoms of overdose and when to seek emergency assistance;
- (4) The characteristics of opioid agonist and partial 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 person served 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 person served to file a grievance with the ODMHSAS

Consumer Advocate office agency for any reason, including involuntary discharge.

(d) Compliance with 450:70-3-5.10 may be determined by:

- (1) A review of policies and procedures,
- (2) Treatment records, and
- (3) Other facility documentation.

**450:70-3-5.11. Assessment and record content – Chronic pain**

(a) The OTP shall have written policy and procedure requiring the OTP to see that an individual who requires administration of opioid agonist treatment and partial agonist medication only for relief of chronic pain is:

- (1) Identified during the physical examination or assessment;
- (2) Not admitted for opioid agonist or partial agonist medication treatment; and
- (3) Referred to appropriate medical services.

(b) Compliance with 450:70-3-5.11 may be determined by:

- (1) A review of policies and procedures,
- (2) Treatment records, and
- (3) Other facility documentation.

**450:70-3-5.12. Assessment and record content – Co-occurring disorder**

(a) The OTP 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 person served may have a mental disorder, the person served is referred for assessment and treatment of the mental disorder.

(b) All required consents, for communication and collaboration with the behavioral health professional to monitor and evaluate interactions between the opioid agonist or partial agonist treatment medication and any medications used to treat the mental disorder of the person served are required to be completed and in the chart.

(c) Compliance with 450:70-3-5.12 may be determined by:

- (1) A review of policies and procedures,
- (2) Treatment records, and
- (3) Other facility documentation.

**450:70-3-5.13 Assessment and record content – Medical**

(a) The OTP shall have written policy and procedure requiring the OTP to ensure that, if, during the assessment or physical examination, a determination is made that a person served may have a medical condition requiring intervention, the person served is referred for assessment and treatment of the medical condition.

(b) The OTP will have all required consents, for communication and collaboration with the health professional to monitor and evaluate interactions between the opioid agonist or partial agonist treatment medication and medications used to treat the medical condition of the person served.

(c) Compliance with 450:70-3-5.13 may be determined by:

- (1) A review of policies and procedures,

- (2) Treatment records, and
- (3) Other facility documentation.

**450:70-3-5.14. Assessment and record content – Medical service refusal**

(a) The OTP shall have written policy and procedure allowing the medical director to refuse the admission and/or medication assisted opioid recovery services to any person served 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.

(b) Compliance with 450:70-3-5.14 may be determined by:

- (1) A review of policies and procedures,
- (2) Treatment records, and
- (3) Other facility documentation.

**450:70-3-5.15 Assessment and record content – Identification [REVOKED]**

**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 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.

**450:70-3-5.17. Assessment and record content – Service refusal**

(a) The OTP shall ensure that a refusal of a particular service by a person served does not preclude the person served from accessing other needed mental health

or substance use disorder treatment services. Should the service provider determine the needs of the person served cannot be met within the facility, clinical documentation of assessments and referrals for the person served shall contain, at a minimum:

- (1) Date of initial contact requesting services;
  - (2) Identification information, including the name, home address and telephone number of the person served;
  - (3) Referral source;
  - (4) Mental status examination and results;
  - (5) History and physical;
  - (6) Family to be notified in case of emergency;
  - (7) A continuing care plan;
  - (8) What agency was contacted; and
  - (9) Where and why the individual was referred.
- (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.

#### **450:70-3-6. 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.
- (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.
- (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. COMPREHENSIVE ASSESSMENT**

**450:70-3-7. Comprehensive assessment**

(a) All OTPs shall complete a comprehensive assessment which gathers sufficient information to assist the person served in developing an individualized 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 complete a comprehensive assessment which contains 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;
- (4) Alcohol and drug use history;
- (5) History of trauma;
- (6) Family and social history, including family history of alcohol and drug use;
- (7) Educational attainment, difficulties, and history;
- (8) Cultural and religious orientation;
- (9) Vocational, occupational and military history;
- (10) Sexual history, including HIV, AIDS and STD at-risk behaviors;
- (11) Marital or significant other relationship history;
- (12) Recreational and leisure history;
- (13) Legal history;
- (14) Present living arrangement;
- (15) Economic resources;
- (16) Level of functioning;
- (17) Current support system;
- (18) Expectations of the person served in terms of service; and
- (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 fourteen (14) calendar days following admission.

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

**PART 7. SERVICE PLANNING****450:70-3-8. Individualized service planning**

(a) Upon completion of the admission evaluation, an individualized service plan shall be developed by a LBHP or licensure candidate in collaboration with the person served.



(b) The service plan shall be based on the patient's presenting problems or diagnosis, intake assessment, biopsychosocial assessment, and expectations of recovery of the person served.

(c) Frequency of services shall be determined by mutual agreement between the facility treatment team and the person served.

(d) Service plans shall be completed by the fourth visit after admission.

(e) The service plan review should occur according to the time frame required by the agency but, no less often than every six (6) months; 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 therapist or rehabilitation service provider assignment;

(3) Change in frequency and types of services provided;

(4) Critical incident reports; or

(5) Sentinel events.

(f) Each person served accepted for treatment shall be assessed initially and periodically by qualified personnel to determine the most appropriate combination of services and treatment. The service plan also must identify the frequency and intensity of services to be provided.

(g) The plan must be reviewed and updated to reflect that personal history, current needs for medical, social, and psychological services, and current needs for education, vocational rehabilitation, and employment services of the person served. Service plan updates shall be completed by an LBHP or licensure candidate. Service plan updates completed by a licensure candidate must be co-signed and dated by a fully licensed LBHP.

(h) Service plans, both comprehensive and update, must include dated signatures of the person served (if age fourteen [14] or older), the parent/guardian (if required by law), and the LBHP or Licensure Candidate. If a minor is eligible to self-consent to treatment pursuant to state law, a parent/guardian signature is not required. Licensure candidate signatures must be co-signed by a fully-licensed LBHP in good standing. Signatures must be obtained after the service plan is completed.

(i) Compliance with 450:70-3-8 may be determined by:

(1) A review of policies and procedures,

(2) Treatment records, and

(3) Other facility documentation.

## **PART 9. PROGRESS NOTES**

### **450:70-3-9. Progress notes**

(a) Unless defined otherwise by level of care, medication assisted opioid treatment services and any issues related to treatment shall be reflected by written documentation in the clinical record that shall chronologically describe the services provided by date and, for timed treatment sessions, time of service, and the consumer's progress in treatment.

- (b) Progress notes must be signed by the service provider and include the service provider's credentials.
- (c) Compliance with 450:70-3-8 may be determined by:
  - (1) A review of policies and procedures,
  - (2) Treatment records, and
  - (3) Other facility documentation.

## **PART 11. DISCHARGE**

### **450:70-3-10. Discharge assessment**

(a) All consumers shall be assessed for biopsychosocial appropriateness of discharge from each level of care using ASAM criteria that includes a list of symptoms for all six dimensions and each of the levels of care, to determine a clinically appropriate placement in the least restrictive level of care. This organized process involves a professional determination for appropriate placement to a specific level of care based on the consumer's severity of symptoms and current situations.

- (1) Acute intoxication and/or withdrawal potential;
- (2) Biomedical conditions and complications;
- (3) Emotional, behavioral or cognitive conditions and complications;
- (4) Readiness to change;
- (5) Relapse, continued use or continued problem potential; and
- (6) Recovery/living environment.

- (b) Compliance with 450:70-3-10 may be determined by:
- (1) A review of policies and procedures, and
  - (2) Discharge assessments in clinical records.

### **450:70-3-10.1 Discharge summary/continuing care plan [REVOKED]**

## **SUBCHAPTER 4. SERVICES SUPPORT AND ENHANCEMENT**

### **PART 1. STAFF SUPPORT**

#### **450:70-4-1. Purpose [REVOKED]**

#### **450:70-4-2. Clinical supervision [REVOKED]**

#### **450:70-4-3. Staff privileging [REVOKED]**

#### **450:70-4-4. Staffing – Dosing coverage**

(a) The OTP 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 FDA-approved opioid agonist or partial agonist medications. It is recommended that physicians have, or be in the process of obtaining, specialty certification and/or

licensure related to opioid treatment.

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

- (1) a review of policies and procedures,
- (2) staff schedules,
- (3) treatment records, and
- (4) other facility documentation.

**450:70-4-4.1. Staffing – Transportation, dispensing and responsibility**

(a) The OTP 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 approved opioid agonist or partial agonist medications.

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

(2) Acceptance of delivery of scheduled medications must be made only by a licensed practitioner employed at the OTP or other authorized individuals designated in writing who must sign for all scheduled medications. Staff who are currently or previously experience a significant opioid use disorder are not allowed to perform this function.

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

(4) The OTP 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 OTP 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.

(b) Transportation of opioid medications by OTP staff shall also:

(1) Be limited to persons served by the OTP in a residential treatment facility, hospital, long-term care facility, or jail, or consumers receiving treatment through a mobile medication unit in accordance with 450:70-6-10.1; and

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

(c) Compliance with 450:70-4-4.1 may be determined by:

- (1) A review of policies and procedures,
- (2) Personnel records,
- (3) Privileging documents,
- (4) Training records,
- (5) Interviews with staff, and
- (6) Other facility documentation.

**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) 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.

#### **450:70-4-4.3. Staffing – Training**

(a) The OTP shall have written policy and procedure requiring each person engaged in the medication assisted recovery services for a significant opioid use disorder 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 service options. All physicians, nurses, and other licensed professional care providers, including therapists and rehabilitation service providers, must comply with the credentialing requirements of their respective professions. Hiring preference should be given to staff with substance use disorder and/or opioid use disorder treatment specific licenses and certifications.

(1) All direct service and medical staff shall receive training relevant to service delivery in a medication assisted opioid treatment setting. There shall be seven (7) clock hours of such training during each year.

(2) All direct service staff shall receive initial training and ongoing training updates for all personnel employed by the treatment facility covers at a minimum:

- (A) Rights of the persons served;
- (B) Person and family centered services;
- (C) The prevention of violence in the workplace;
- (D) Confidentiality requirements;
- (E) Cultural competency; and
- (F) Expectations regarding professional conduct.

(3) All physicians working in an OTP should have, or be in the process of obtaining, specialty certification and/or licensure related to medication assisted opioid and/or substance use disorder treatment.

(b) Compliance with 450:70-4-4.3 may be determined by:

- (1) A review of policies and procedures,
- (2) Credentialing and privileging documents,
- (3) Training records,
- (4) Interviews with staff, and

(5) 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) 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.

(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**

**450:70-4-5. Service support and enhancement**

(a) Each OTP shall have written policies and procedures describing operational methods, administration and organization adequate to ensure quality 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 OTP will operate in accordance with all approved accreditation elements; including the OBNDD, DEA and SAMHSA.

(b) OTPs will produce evidence of a current and valid certification from SAMHSA to be considered qualified to dispense opioid medications in the treatment of significant opioid use disorders and dependence. Prior to beginning the delivery of medication-assisted opioid recovery services, an OTP must apply for and receive a permit for temporary operations from ODMHSAS.

(c) An OTP 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 significant opioid use disorders and opioid dependence.

(d) In order to retain ODMHSAS certification an OTP shall produce within twelve (12) months of opening, a current, valid accreditation by an accreditation body or other entity designated by SAMHSA such as CARF, JC, or COA including a written description of the current accreditation status of the OTP and must comply with any additional conditions for certification established by SAMHSA.

(e) Compliance with 450:70-4-5 may be determined by:

- (1) A review of policies and procedures,
- (2) Current certifications, accreditations, registrations, and licenses, and

- (3) Other facility documentation.

#### **450:70-4-5.1. Organizational - Staffing**

- (a) An OTP shall have an accurate and current description of organizational structure including;
  - (1) The names and contact information of all persons responsible for the OTP.
  - (2) The current addresses of the OTP and of each additional facility, medication unit or additional site under the control of the OTP providing opioid agonist treatment services, and
  - (3) The sources of any funding other than fees from persons served for the OTP including the name and address of any governmental entity that provides such funding.
- (b) Each OTP shall formally designate a program sponsor and medical director.
  - (1) The program sponsor shall agree in writing on behalf of the OTP to adhere to all requirements set forth in this chapter and any regulations regarding the use of opioid agonist or partial agonist treatment medications in the treatment of significant opioid use disorders 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 OTP. In addition, the medical director shall be responsible for ensuring that the OTP is in compliance with all applicable Federal, State, and local laws and regulations.
- (c) Compliance with 450:70-4-5.1 may be determined by:
  - (1) A review of policies and procedures, and
  - (2) Other facility documentation.

#### **450:70-4-5.2. Organizational - Structure and documentation [REVOKED]**

#### **450:70-4-5.3. Organizational - Notification of ODMHSAS**

- (a) An OTP shall notify the SOTA within one (1) work day of any vacancy or replacement or other change in the status of the program sponsor or medical director.
- (b) An OTP, 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.
- (c) OTPs shall notify the SOTA 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.
- (d) Each OTP must notify the SOTA 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.
- (e) Compliance with 450:70-4-5.3 may be determined by:
  - (1) A review of policies and procedures,
  - (2) Interviews with staff, and

(3) Other facility documentation.

**450:70-4-5.4. Organizational - Fee structure and exceptions**

(a) The OTP shall have written policy and procedure establishing a standard fee for persons served receiving methadone as part of a medication assisted treatment program that shall be inclusive of all regular and normal, clinical, administrative and medical services and procedures and be no more than \$65.00 per week, unless an exception is approved by ODMHSAS.

(b) 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.

(c) The fee for persons served receiving buprenorphine as part of a medication assisted treatment program shall be set by the OTP medical director.

(d) Compliance with 450:70-4-5.4 may be determined by:

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

**450:70-4-5.5. Organizational - Cooperative agreements**

(a) Each OTP 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.

(b) Compliance with 450:70-4-5.5 may be determined by:

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

**450:70-4-5.6. Organizational - Consultation**

(a) The OTP shall have available specialized professional consultation or professional supervision.

(b) Compliance with 450:70-4-6 may be determined by:

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

**450:70-4-6. New program approval**

(a) Determination of the need for new services shall be at the sole discretion of ODMHSAS as the designated state authority responsible for medication assisted opioid recovery services 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 person served 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 OTP signed by the program sponsor and the medical director;
  - (7) Documentation of 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) Demonstration of the general community acceptance by providing ODMHSAS with copies of letters of support from local authorities and local residents living near the site;
  - (9) Additional information and documentation for medication units in accordance with SAMHSA guidelines and as requested by ODMHSAS, if applicable; and
  - (10) Written documentation that ODMHSAS has received and accepted all the requirements listed above.
- (b) Compliance with 450:70-4-7 may be determined by:
- (1) A review of policies and procedures,
  - (2) On-site verification of hours posted,
  - (3) Interviews with staff, and
  - (4) Other facility documentation.

#### **450:70-4-7. Operations - Hours**

- (a) The OTP shall have policy and procedure to define operations for a minimum of forty (40) hours per week, (excluding holidays and emergency closure) in outpatient settings and twenty-four (24) hours per day in inpatient and residential program settings.
- (b) The OTP shall have written policy and procedure for medication dispensing available at least 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 therapy/rehabilitation service space, secure record storage, and protect consumer confidentiality.
- (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 OTP 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 therapy/rehabilitation 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 schedules of persons served who are employed and parenting, and offer treatment services during the day, evening, or weekends.

(g) Compliance with 450:70-4-7 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.

#### **450:70-4-7.1. 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 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.

(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 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.

(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.

(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.

(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 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 450:70-4-7.3 may be determined by:

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

**450:70-4-7.4. Operations – Emergencies and exception for weekend dosing**

(a) The OTP shall maintain written policy and procedures for handling medical emergencies; and an emergency medical number shall be posted for use by staff.

(b) Crisis intervention and therapy/rehabilitation services shall be available when indicated.

(c) If the OTP is closed on Sunday or for holidays, there shall be written policy and procedure describing the process for providing services to and dosing for those persons served who are not assessed as appropriate to receive a single take home dose. The medical director shall be responsible for determining whether a person served can safely be dispensed medications for unsupervised use. The basis for the decision shall be, at a minimum, the nine criteria listed in 450:70-4-8 (g), (1) through (9).

(d) Compliance with 450:70-4-7.4 may be determined by:

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

**450:70-4-8. Drug testing**

(a) Each OTP shall have written policy and procedure ensuring that an initial drug test is performed for each person served, including permanent transfers, before the initial or maintenance dose is administered. All drug testing shall be in accordance with all state and federal law and current drug screen standards. Unless federal opioid treatment standards at 42 CFR § 8.12 state otherwise, OTPs must provide drug tests that have received FDA marketing authorization for commonly used and misused substances that may impact safety, recovery, or otherwise complicate treatment. A minimum of eight (8) random drug tests shall be performed each year for each person served, with the exception of persons served with extenuating circumstances which are documented in the clinical record.

(b) Each OTP shall conduct drug testing in accordance with the following:

- (1) When a sample is collected from each person served for such test or analysis, it must be done in a manner to produce timely and reliable results.
- (2) The OTP 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 person served and documentation in the clinical record of program and patient response to the test results of the program and person served;

(E) Policy and procedure designed to reduce the negative and/or stigmatizing aspects of drug test collection;

(F) Policy stating that if a person served 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 clinical record; and

(G) There shall be no “grace period” allowed. Persons served from which a UA is requested must submit a sample at that time or it will be considered a refusal.

(c) Compliance with 450:70-4-7.8 may be determined by:

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

#### **450:70-4-8.1. Drug testing –Withdrawal Management [REVOKED]**

#### **450:70-4-8.2. Drug testing – Required substance identification**

(a) The OTP shall have written policy and procedure stating drug screens will follow federal guidelines and will, at a minimum, test for the following substances;

- (1) Opioids;
- (2) Methadone;
- (3) Amphetamines;
- (4) Cocaine;
- (5) Benzodiazepines; and
- (6) Barbiturates.

(b) The OTP shall have written policy and procedure stating drug testing shall include other drugs as may be indicated by the abuse patterns of the person served. 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.

(c) The OTP 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.

(d) Compliance with 450:70-4-8.2 may be determined by:

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

#### **450:70-4-8.3. 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 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;
- (3) Absence of serious behavioral problems at the clinic;
- (4) Absence of known recent criminal activity, e.g., drug dealing;
- (5) Whether the take-home medication can be safely transported and stored;
- (6) Length of time in comprehensive maintenance treatment;
- (7) Whether the rehabilitative benefit the person served derived from decreasing the frequency of clinic attendance outweighs the potential risks of diversion; and
- (8) 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) 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.

#### **450:70-4-8.4. Take-home doses, general requirements**

(a) The OTP shall have written policy and procedure describing practices in accordance with the principle that take-home doses of methadone and

buprenorphine are a privilege given only to those persons served who will benefit from them and who have demonstrated responsibility in taking methadone or buprenorphine as prescribed including:

- (1) Programs must educate the person served regarding safe transportation and storage of methadone, as well as emergency procedures in case of accidental ingestion.
  - (2) Before take-home privileges are allowed, the person served must have a lock box for transportation of methadone and home storage.
  - (3) The program shall address the responsibilities of persons served granted take-home medications. The policies shall include methods of assuring appropriate use and storage of medication by persons served.
  - (4) The program shall address the disposal of take-home bottles for methadone to include;
    - (A) Requiring take-home bottles to be returned to the OTP and to require labels to be intact and the consequences for not returning bottles described.
    - (B) Allowing disposal of take-home bottles to include procedures to insure the ability of the OTP to check for diversion by requiring persons served to submit used take-home bottles in "call backs."
- (b) Compliance with 450:70-4-8.4 may be determined by:
- (1) A review of policies and procedures,
  - (2) Treatment records, and
  - (3) 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.
- (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.

**450:70-4-9. Information analysis and planning [REVOKED]**

**450:70-4-10. Performance improvement program [REVOKED]**

**450:70-4-11. Critical incidents [REVOKED]**

**450:70-4-12. Community information, consultation, outreach, and street outreach [REVOKED]**

## **SUBCHAPTER 5. CONSUMER RIGHTS**

### **450:70-5-1. Consumer rights**

(a) All OTPs shall comply with applicable rules in Title 450, Chapter 15. Consumer Rights.

(b) Compliance with 70-5-2 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.

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

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

(b) Compliance with 70-5-2 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.

### **450:70-5-3. ODMHSAS advocate general**

(a) 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.

(b) Compliance with 70-5-3 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.

## **SUBCHAPTER 6. SUBSTANCE USE DISORDER TREATMENT SERVICES**

### **PART 1. CASE MANAGEMENT**

#### **450:70-6-1. Case management, services**

(a) Case management services shall be provided in accordance with Chapter 50

of this Title and shall include planned referral, linkage, monitoring and support, and advocacy assistance provided in partnership with a person served to support that individual in self-sufficiency and community tenure. Activities include:

- (1) Completion of strengths based assessment for the purpose of individual plan of care development;
- (2) Development of case management care plan which can be reflected as a part of the comprehensive service plan;
- (3) Referral, linkage and advocacy to assist with gaining access to appropriate community resources;
- (4) Contacts with other individuals and organizations that influence the recipient's relationship with the community, i.e., family members, law enforcement personnel, landlords, etc.;
- (5) Monitoring and support related to the individual plan of care to reassess goals and objectives and assess progress and or barriers to progress;
- (6) Follow-up contact with the persons served regarding missed appointments (including physician/medication, therapy, rehabilitation, or other supportive service appointments as delineated on the service plan); and
- (7) Crisis diversion (unanticipated, unscheduled situation requiring supportive assistance, face-to-face or telephone, to resolve immediate problems before they become overwhelming and severely impair the individual's ability to function or maintain in the community) to prevent progression to a higher level of care.

(b) Individuals providing case management services shall be an LBHP, Licensure Candidate, CADC or certified as a behavioral health case manager pursuant to Chapter 50 of this Title.

(c) Compliance with this Section may be determined by a review of clinical records, policy and procedures, and facility personnel records.

#### **450:70-6-2. Case management services, locale and frequency [REVOKED]**

#### **450:70-6-3. Case management services, staff credentials [REVOKED]**

### **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.

(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. Withdrawal Management**

(a) Any OTP providing medication assisted recovery services shall provide both short- and long-term withdrawal management as defined in 450:70-6-7 and



450:70-6-8.

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

- (1) Promote successful withdrawal management;
- (2) Require that dose reduction occur at a rate well tolerated by the person served;
- (3) Require that a variety of ancillary services, such as mutual support groups, be available to the person served through the agency or through referral;
- (4) Require that the amount of therapy/rehabilitation services available to the person served be increased prior to discharge; and
- (5) Require that a person served be re-admitted to the agency or referred to another agency at the first indication of relapse unless it is an administrative withdrawal process.
- (6) There is no minimum time in treatment requirement for persons served receiving buprenorphine when granting take-home privileges.

(c) Compliance with 450:70-6-5 may be determined by:

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

**450:70-6-5.1. 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 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 patient.

(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.

**450:70-6-5.2. Withdrawal management– Reentering maintenance treatment**

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

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

(c) The OTP shall ensure there shall be periodic consideration given to withdrawing from continued opioid treatment services, when appropriate to the progress and goals of the person served.

(1) Consideration for withdrawal from continued medication assisted opioid recovery services shall be discussed at least once annually with the person served.

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

(d) Compliance with 70-5-2 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.

**450:70-6-6. Administrative withdrawal**

(a) The OTP shall have written policy and procedure stating an infraction of program rules by a person served may result in administrative medical withdrawal from methadone or buprenorphine and termination from treatment services. All persons served 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 person served, 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 therapy/rehabilitation services and other support services;

(5) Involvement in criminal activities;

(6) Any other serious rule violations; and

(7) Non-payment of fees.

(b) The OTP shall ensure 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 OTP shall have written policy and procedure stating a person served experiencing administrative withdrawal shall be referred or transferred to an agency that is capable of, or more suitable for, meeting the needs of the served person. The referral or transfer is documented in the clinical record and the following information is documented in the clinical record:
- (1) The reason that the person served sought medical withdrawal or was placed on administrative withdrawal; and
  - (2) The information and assistance provided to the person served in managed withdrawal, medical withdrawal or administrative withdrawal.
- (d) Compliance with 450:70-6-6 may be determined by:
- (1) A review of policies and procedures,
  - (3) Treatment records,
  - (4) Critical incident reports,
  - (5) Interviews with staff, and
  - (6) Other facility documentation.

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

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

#### **450:70-6-8. Long-term managed withdrawal**

- (a) There shall be written policy stating a person served may be admitted to long-term managed withdrawal regardless of age. Written approval from a parent or guardian for a person served under the age of eighteen (18) shall be obtained if required by law. If a minor is eligible to self-consent to treatment pursuant to state law, written approval from a parent or guardian is not required.
- (b) Methadone 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. Buprenorphine shall be administered as determined by the OTP medical director.
- (c) The person served is required to be under observation while ingesting the drug at least six (6) days a week. This is not required for buprenorphine.
- (d) Initial and random monthly drug screening tests must be performed on each person served.
- (e) Initial service plans and monthly service plan reviews are required.
- (f) All other requirements of comprehensive maintenance treatment apply.
- (g) A history of one year of opioid dependence and an attempt at another form of treatment is not required for admission to long-term withdrawal management.
- (h) Compliance with 450:70-6-8 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 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 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 to persons 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 maintenance services 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 (180) 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.

(6) 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, OBND approval, and national accreditation. A mobile medication unit must have an associated OTP physical location for purposes of ODMHSAS certification.

(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) 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. Long-term care facilities, hospitals, and correctional facilities**

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.

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

(a) The OTP 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 or partial agonist in the treatment of an opioid use disorder 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 OTP 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 therapy/rehabilitation services.

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

(d) Compliance with 70-6-11 may be determined by:

(1) A review of facility policy and procedures, and

(2) Documentation of FDA approval.

(3) Other facility documentation.

#### **450:70-6-12. HIV 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.

#### **450:70-6-13. Treatment Professional [REVOKED]**

#### **450:70-6-14. Co-occurring Disorder Capability [REVOKED]**

### **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 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.

#### **450:70-6-15.1. Dosing**

(a) The OTP shall have written policy and procedure stating the medical director shall ensure the daily medication dosage of persons served shall conform with all State and Federal guidelines, best medical practice and this Chapter.

(b) Compliance with 450:70-6-15.1 may be determined by:

- (1) A review of policies and procedures,
- (2) Treatment records, and
- (3) Other facility documentation.

#### **450:70-6-15.2. Medical Director visits**

(a) The OTP shall have written policy and procedure stating each person served accepted for treatment as a patient at an OTP 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.

(b) Compliance with 450:70-6-15.2 may be determined by:

- (1) A review of policies and procedures,
- (2) Treatment records, and
- (3) Other facility documentation.

#### **450:70-6-15.3. Service– Clinical services [REVOKED]**

#### **450:70-6-15.4. Service – Termination of treatment**

(a) The OTP shall have written policy and procedure stating if a person served 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 clinical



record. An exception determination would be in circumstances where the person served can provide documented proof of exceptional circumstances. The documentation must be maintained in the clinical record. If the person served does return for care and is accepted into the program, the person served is considered a new person served and is to be so noted in the clinical record.

(b) Compliance with 450:70-6-15.4 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 of persons 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 metabolism 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. Service phases – Take home doses [REVOKED]**

##### **450:70-6-17.1. Service phases – Take home doses, exceptions [REVOKED]**

##### **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 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. 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.

(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.

(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.

##### **450:70-6-17.3. Service phases – Phase I**

(a) Phase I consists of the first ninety (90) days of treatment. During Phase I, a minimum of four (4) treatment sessions per month shall be provided. Available services shall include, but not be limited to, therapy, rehabilitation, case management, Individual Placement and Support services, and peer recovery support services.

(b) Compliance with 450:70-6-17.3 may be determined by:

- (1) A review of policies and procedures,
- (2) Treatment records, and
- (3) Other facility documentation.

**450:70-6-17.4. Service phases – Phase II**

(a) Phase II consists of the second ninety (90) days of treatment. During Phase II, a minimum of two (2) treatment sessions per month shall be provided. Available services shall include, but not be limited to, therapy, rehabilitation, case management, Individual Placement and Support services, and peer recovery support services.

(b) Compliance with 450:70-6-17.4 may be determined by:

- (1) A review of policies and procedures,
- (2) Treatment records, and
- (3) Other facility documentation.

**450:70-6-17.5. Service phases – Phase III**

(a) Phase III consists of the third ninety (90) days of treatment. During Phase III, a minimum of one (1) treatment session per month shall be provided. Available services shall include, but not limited to, therapy, rehabilitation, case management, Individual Placement and Support services, and peer recovery support services.

(b) Compliance with 450:70-6-17.5 may be determined by:

- (1) A review of policies and procedures,
- (2) Treatment records, and
- (3) Other facility documentation.

**450:70-6-17.6. Service phases – Phase IV**

(a) Phase IV consists of the last ninety (90) days of the first year of treatment. During Phase IV, a minimum of one (1) treatment session per month shall be provided. Available services shall include, but not limited to, therapy, rehabilitation, case management, Individual Placement and Support services, and peer recovery support services.

(b) Compliance with 450:70-6-17.6 may be determined by:

- (1) A review of policies and procedures,
- (2) Treatment records, and
- (3) Other facility documentation.

**450:70-6-17.7. Service phases – Phase V**

(a) Phase V begins after one (1) year of continuous treatment. During Phase V, a minimum of one (1) treatment session per month shall be provided. Available services shall include, but not be limited to, therapy, rehabilitation, case management, Individual Placement and Support services, and peer recovery support services.

(b) Compliance with 450:70-6-17.7 may be determined by:

- (1) A review of policies and procedures,
- (2) Treatment records, and
- (3) Other facility documentation.

**450:70-6-17.8. Service phases – Phase VI**

- (a) Phase VI begins after two (2) years of continuous treatment.
  - (1) During Phase VI, the LBHP, Licensure Candidate or CADC determines the frequency of treatment sessions with input from the person served. At the onset of Phase VI, the person served may require an increased level of therapy or rehabilitation service and other support services.
  - (2) The LBHP or Licensure Candidate and person served develop a continuing care plan prior to the successful completion of treatment.
- (b) Compliance with 450:70-6-17.8 may be determined by:
  - (1) A review of policies and procedures,
  - (2) Treatment records, and
  - (3) Other facility documentation.

#### **PART 4. PEER RECOVERY SUPPORT SERVICES**

##### **450:70-6-18. Peer recovery support services**

- (a) Peer recovery support services are an optional service within certified Opioid Treatment Programs. Peer recovery support services may be offered to individuals sixteen (16) and older with substance use disorders, including co-occurring disorders.
- (b) Peer recovery support services shall:
  - (1) Be based on an individualized, recovery-focused service philosophy that allows individuals the opportunity to learn to manage their own recovery and advocacy process;
  - (2) Recognize the unique value of services being provided by persons with lived experience who are able to demonstrate their own hopefulness and recovery; and
  - (3) Enhance the development of natural supports, coping skills, and other skills necessary to function as independently as possible in the community, including, but not limited to assisting re-entry into the community after a hospitalization or other institutional settings.
- (c) Peer Recovery Support Services shall be provided only by staff certified as a Peer Recovery Support Specialist (PRSS) in accordance with OAC 450:53.
- (d) The facility shall retain records to verify compliance with training and certification requirements of each provider of this service.
- (e) Facilities offering these services shall have provisions in place for direct supervision and other supports for staff providing this service.
- (f) Facilities offering peer recovery support services shall have written policies and procedures specific to the provision of these services.
- (g) Compliance with this Section shall be determined by a review of the following: clinical records, policy and procedures, and facility personnel records.