

**TITLE 450. DEPARTMENT OF MENTAL HEALTH AND SUBSTANCE ABUSE
SERVICES**

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

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 450:1-9-5.3450:1-9-5.6.

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 patient by a licensed practitioner, or the patient at the direction of, or in the presence of, a practitioner.

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

"Approved narcotic drug" means a drug approved by the United States Food and Drug Administration for maintenance and/or detoxification of a person physiologically 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 patient, and are designed to provide sufficient information for problem formulation, intervention planning, case management needs, and formulation of appropriate substance abuse-related treatment and service planning.

"Buprenorphine" means a partial agonist, Schedule III narcotic approved for

use in opioid dependence treatment.

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

"Central registry" A document or database to which an OTP shall report patient 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 patient's attention, 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 a patient's withdrawal through the identification of objective and subjective symptoms and the severity of these symptoms.

"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" is:

- (A) Dispensing or administering an approved opioid agonist or partial agonist medication at stable dosage levels for a period in excess of 21 days to a patient for opioid dependence, and
- (B) Providing medical, clinical and educational services to the patient with opioid dependence.

"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 patient.

"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 patient.

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

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

"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. For the purposes of this chapter methadone diskettes will not be considered to be the same as tablet 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 before the patient may leave the clinic with the dose.

"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 an opioid patient and submitted to SAMHSA using form SMA-168.

"FDA" Federal Food and Drug Administration.

"Federal opioid treatment standards" means the established standards of SAMHSA, CSAT and the DEA that are used to determine whether an 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 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 patient identify and rank problems, establish agreed upon goals, and decide on the treatment process and resources to be utilized.

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

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

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

- (A) An Allopathic or Osteopathic Physician with a current license and board certification in psychiatry or board eligible in the state in which services are provided, or a current resident in psychiatry;
- (B) An Advanced Practice Registered Nurse licensed as a registered nurse with a current certification of recognition from the board of nursing in the state in which services are provided and certified in a psychiatric mental health specialty;
- (C) A Clinical Psychologist who is duly licensed to practice by the State Board of Examiners of Psychologists;
- (D) A Physician Assistant who is licensed in good standing in Oklahoma and has received specific training for and is experienced in performing mental health therapeutic, diagnostic, or counseling functions;
- (E) A practitioner with a license to practice in the state in which services are provided by one of the following licensing boards:
 - (i) Social Work (clinical specialty only);
 - (ii) Professional Counselor;
 - (iii) Marriage and Family Therapist;
 - (iv) Behavioral Practitioner; or
 - (v) Alcohol and Drug Counselor.

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

- (A) Psychology;
- (B) Social Work (clinical specialty only);
- (C) Professional Counselor;
- (D) Marriage and Family Therapist;
- (E) Behavioral Practitioner; or
- (F) Alcohol and Drug Counselor.

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

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

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

"Long-term detoxification treatment" 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 unit" means a satellite facility established as part of, but geographically separate from, an OTP from which appropriately licensed practitioners dispense or administer an opioid agonist or partial agonist treatment medication or collect samples for drug testing or analysis. No medical or clinical interventions related to OTP treatment can be conducted at this site.

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

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

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

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

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

in the treatment of opiate addiction or dependence.

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

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

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

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

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

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

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

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

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

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

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

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

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

"STD" means sexually transmitted disease.

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

communicable diseases.

"Tablet methadone" means methadone in a tablet form intended to be taken orally. For the purposes of this chapter diskettes will not be considered to be tablet methadone. Tablet methadone is not allowed for use by an OTP.

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

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

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

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

450:70-1-4. 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 or and buprenorphine including but not limited to therapy, rehabilitation services and substance use disorder treatment services including methadone and buprenorphine maintenance services, 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)].

SUBCHAPTER 3. FACILITY RECORD SYSTEM

PART 1. RECORD SYSTEM

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

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

~~(1) Entries in patient records shall be legible, signed with first name or initial, last name, and dated by the person making the entry;~~

~~(2) The patient shall be identified by name on each sheet in the patient record and on each screen of the electronic record.~~

- ~~(3) A signed consent for treatment shall be obtained and placed in the record before any person can be admitted into treatment at an OTP;~~
- ~~(4) A signed consent for follow-up shall be obtained and placed in the record before any contact after discharge can be made;~~
- ~~(6) A biopsychosocial assessment;~~
- ~~(7) Case management needs assessment;~~
- ~~(8) Service planning;~~
- ~~(9) Documentation of progress notes;~~
- ~~(10) A discharge biopsychosocial assessment;~~
- ~~(11) A continuing care plan;~~
- ~~(12) Consultation reports;~~
- ~~(13) Psychological or psychometric testing;~~
- ~~(14) Records and reports from other entities;~~
- ~~(15) Medication records;~~
- ~~(16) A discharge summary; and~~
- ~~(17) Referral and transfer.~~
- ~~(b) Compliance with 450:70-3-3 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.~~

PART 3. INTAKE AND ADMISSION ASSESSMENT

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 in a format requested by the ~~Commissioner or designee~~ Department and within twenty-four (24) hours of admission, change of medical status or discharge of any patient.
- (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.

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

- (a) The OTP shall document and assess all patients for appropriateness of admission taking into account the patient's needs as identified by, but not limited to:
 - (1) Acute intoxication ~~and~~ and/or withdrawal potential;
 - (2) Biomedical conditions and complications;
 - (3) Emotional, ~~and behavioral,~~ or cognitive conditions and complications;
 - (4) Readiness to change;
 - (5) Relapse, continued used, or continued problem potential; and
 - (6) ~~Recovery~~ 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 patients, outlining rehabilitation services. Minimum services include:

- (1) Individual therapy or rehabilitation services until the patient 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) ~~Vocational or educational services and referral and as indicated in this chapter; and~~ Individual Placement and Support services;
- (4) Case management services;
- (5) Peer recovery support services; and
- (4)(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.

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. Service plans completed by a licensure candidate must be co-signed by a fully licensed LBHP. ~~The individualized service plan shall include, but not be limited to:~~

- ~~(1) Presenting problems or diagnosis;~~
 - ~~(2) Strengths, needs, abilities, and preferences of the patient;~~
 - ~~(3) Goals for treatment with specific, measurable, attainable, realistic and time-limited;~~
 - ~~(4) Type and frequency of services to be provided;~~
 - ~~(5) Dated signature of primary service provider;~~
 - ~~(6) Description of patient's involvement in, and responses to, the service plan, and his or her signature and date;~~
 - ~~(7) Individualized discharge criteria or maintenance;~~
 - ~~(8) Projected length of treatment;~~
 - ~~(9) Measurable long and short term treatment goals;~~
 - ~~(10) Primary and supportive services to be utilized with the patient;~~
 - ~~(11) Type and frequency of therapeutic activities in which patient will participate;~~
 - ~~(12) Documentation of the patient's participation in the development of the plan;~~
- and

~~(13) Staff who will be responsible for the patient's treatment.~~

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

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

(d) Service plans shall be completed by the fourth (4) ~~therapy or rehabilitation service~~ 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; ~~or,~~

~~(6) Phase change.~~

(f) Each patient 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 patient's personal history, current needs for medical, social, and psychological services, and current needs for education, vocational rehabilitation, and employment services. 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) The OTP will provide adequate and appropriate therapy or rehabilitation services to each patient as clinically necessary. This therapy shall be provided by a program LBHP or Licensure Candidate. ~~Rehabilitation services must be provided by a LBHP, Licensure Candidate, CADC or CMII.~~ 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.

(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 patient's record ~~and that~~ shall include the following: chronologically describe the services provided by date and, for timed treatment sessions, time of service, the consumer's response to the services provided, and the consumer's progress in treatment.

- ~~(1) date;~~
- ~~(2) start and stop time for each timed treatment session;~~
- ~~(3) dated signature of the staff person providing the service;~~
- ~~(4) credentials of the staff person providing the service;~~
- ~~(5) when service is provided by a paraprofessional, signatures of the paraprofessional and a credentialed staff person;~~
- ~~(6) specific service plan needs, goals and/or objectives addressed;~~
- ~~(7) interventions used to address problem(s), goals and objectives;~~
- ~~(8) progress made toward goals and objectives, or lack of;~~
- ~~(9) patient response to the session or intervention;~~
- ~~(10) any new problem(s), goals and objectives identified during the session.~~

(b) Progress notes must be signed by the service provider and include the service provider's credentials.

~~(b)~~(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.

SUBCHAPTER 4. SERVICES SUPPORT AND ENHANCEMENT

PART 3. ORGANIZATIONAL AND FACILITY MANAGEMENT

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 patient is enrolled in another clinic;
- (3) The source and adequacy of financial assets necessary to operate the program;
- (4) If applicable, the compliance history of the applicant, including any issues reported to ODMHSAS by SAMHSA, DEA or any other regulatory agency;
- (5) Adequate planning and organizational structure demonstrated by full and complete answers submitted to all questions in the application materials;
- (6) A written statement that the applicant has read, understood and agreed to follow all federal and state regulations concerning operation of an OTP signed by the program sponsor and the medical director;
- (7) ~~Document~~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) ~~Demonstrate~~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; and

(9) Additional information and documentation for medication units in accordance with SAMHSA guidelines and as requested by ODMHSAS, if applicable; and

~~(9)~~(10) ~~Produce written~~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.

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

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

~~(b) These services shall be designed to:~~

- ~~(1) Reach and attract the facility's target population;~~
- ~~(2) Provide information on substance abuse and related issues to the public;~~
- ~~and~~
- ~~(3) Provide information to the public regarding the facility's services.~~

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

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

- ~~(1) Name of person(s) or organization(s) receiving the services;~~
- ~~(2) Name of person(s) providing the service;~~
- ~~(3) Number of persons attending;~~
- ~~(4) Location at which the services were provided;~~
- ~~(5) Date services were provided; and~~
- ~~(6) Description of the services provided.~~

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

~~(f) Compliance with 450:70-4-12 may be determined by:~~

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

- ~~(2) Documentation of community information, consultation, and outreach services, and~~
- ~~(3) Any other supporting facility documentation.~~

SUBCHAPTER 6. SUBSTANCE USE DISORDER TREATMENT SERVICES

PART 2. LEVELS OF TREATMENT

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

(a) Before providing medication assisted opioid recovery services through a medication unit, long term care facility or hospital, the program must receive the written approval of both SAMHSA and ODMHSAS, ~~and certified by ODMHSAS-~~certification, OBNDD approval, and national accreditation.

(b) Certification as an OTP will not be required for the maintenance or managed withdrawal of a patient who is admitted to a hospital or long term care facility for the treatment for medical conditions other than opioid addiction and who requires maintenance or withdrawal management during the stay in the hospital or long term care facility.

(c) Medication units, long term care facilities and hospitals shall be in compliance with the following:

- (1) Currently licensed by the 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.

PART 3. PHASES OF TREATMENT SERVICES

450:70-6-15. Service

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

(b) 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.

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

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

- (1) Advancement in phase and/or increased take-home privilege shall not occur without significant compliance with all current treatment plan goals.
 - (2) Advancement in phase and/or increased take-home privilege shall not occur if there are consistent or consecutive positive urine drug screens.
 - (3) Reduction in phase and/or decreased take-home privilege shall occur if there are consistent or consecutive positive urine drug screens and/or substantial non-compliance with the individualized service plan.
 - (4) For patients to be eligible for Phase IV or above they must be;
 - (A) be employed full time,
 - (B) be a full time student (at least twelve (12) semester hours),
 - (C) be retired, or
 - (D) have proof of disability.
 - (5) Prior to the patient advancing in Phase and/or receiving take-home medication, the patient shall demonstrate a level of stability as evidenced by:
 - (A) absence of alcohol and other drug abuse,
 - (B) regularity of program attendance,
 - (C) absence of significant behavior problems,
 - (D) absence of recent criminal activities, and
 - (E) employment, actively seeking employment or attending school if not retired, disabled, functioning as a homemaker, or otherwise producing evidence of economic stability.
 - (6) If an OTP is providing doses to a patient receiving residential level of care (ASAM Level 3) 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.
- (b) 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 a minimum ninety (90)-day period in which the patient attends the program for observation of medication assisted opioid treatment daily

or at least six (6) days a week. Phase I take-home dosage privileges are limited to a single dose each week including take home dosages required due to regularly scheduled clinic closures. All approved holidays allow an additional take-home dosage. The patient shall ingest all other doses under appropriate supervision at the clinic.

~~(1) During Phase I, the patient shall participate in a minimum of four (4) sessions of therapy or rehabilitation services per month, with at least one (1) session being individual therapy or rehabilitation service and/or case management.~~

(1) During Phase I, a minimum of four (4) treatment sessions per month shall be provided, including, but not exclusive to, therapy, rehabilitation, case management, Individual Placement and Support services, and peer recovery support services.

~~(2) During Phase I, the service plan shall be reviewed and updated a minimum of once monthly.~~

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

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

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

(2) For the first ninety (90) days of Phase II, a minimum of two (2) treatment sessions per month shall be provided, including, but not exclusive to, therapy, rehabilitation, case management, Individual Placement and Support services, and peer recovery support services.

(3) After the initial ninety (90) days in Phase II, the patient shall participate in at least one (1) session of individual therapy or rehabilitation treatment service per month.

~~(4) The service plan shall be reviewed and updated at least once every three (3) months during Phase II.~~

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

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

~~(2) The patient shall participate in at least one (1) session of individual therapy or rehabilitation service and/or case management per month during Phase III.~~

(2) A minimum of one (1) treatment session per month shall be provided, including, but not exclusive to, therapy, rehabilitation, case management, Individual Placement and Support services, and peer recovery support services.

~~(3) The service plan shall be reviewed and updated at least every six (6) months during Phase III or more frequently if circumstances warrant.~~

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

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

~~(2) The patient shall participate in at least one (1) session of individual therapy or rehabilitation service and/or case management per month during this phase.~~

(2) A minimum of one (1) treatment session per month shall be provided, including, but not exclusive to, therapy, rehabilitation, case management, Individual Placement and Support services, and peer recovery support services.

~~(3) The service plan shall be reviewed and updated at least every six (6) months during this phase.~~

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

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

~~(2) The patient shall participate in at least one (1) session of individual therapy or rehabilitation service or case management per month during this phase.~~

(2) A minimum of one (1) treatment session per month shall be provided, including, but not exclusive to, therapy, rehabilitation, case management, Individual Placement and Support services, and peer recovery support

services.

~~(3) The service plan shall be reviewed and updated at least every six (6) months during this phase.~~

(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.