RULE IMPACT STATEMENT

TITLE 450. DEPARTMENT OF MENTAL HEALTH AND SUBSTANCE ABUSE SERVICES
CHAPTER 70. STANDARDS AND CRITERIA FOR OPIOID TREATMENT PROGRAMS

PROPOSED RULES:
Chapter 70. Standards and Criteria for Opioid Treatment Programs

1. BRIEF DESCRIPTION OF THE PURPOSE OF THE RULE:
The proposed rules are intended to update terminology from "counseling" to "psychotherapy or therapy". Rules further clarify that "psychotherapy or therapy" must be provided by Licensed Behavioral Health Professionals or Licensure Candidates.

2. A DESCRIPTION OF THE CLASSES OF PERSONS WHO MOST LIKELY WILL BE AFFECTED BY THE PROPOSED RULE, INCLUDING CLASSES THAT WILL BEAR THE COST OF THE PROPOSED RULE, AND ANY INFORMATION ON COST IMPACTS RECEIVED BY THE AGENCY FROM ANY PRIVATE OR PUBLIC ENTITIES:
Organizations or individuals certified by, under contract with, or subject to certification by ODMHSAS, and the consumers and employees of each.

3. A DESCRIPTION OF THE CLASSES OF PERSONS WHO WILL BENEFIT FROM THE PROPOSED RULE:
Organizations or individuals certified by, under contract with, or subject to certification by ODMHSAS, and the consumers and employees of each.

4. A DESCRIPTION OF THE PROBABLE ECONOMIC IMPACT OF THE PROPOSED RULE UPON THE AFFECTED CLASSES OF PERSONS OR POLITICAL SUBDIVISIONS, INCLUDING A LISTING OF ALL FEE CHANGES AND, WHENEVER POSSIBLE, AND A SEPARATE JUSTIFICATION FOR EACH FEE CHANGE:
ODMHSAS does not anticipate an economic impact on any affected classes of persons or political subdivisions that meet minimum certification standards as currently required by this Chapter.

5. THE PROBABLY COSTS AND BENEFITS TO THE AGENCY AND TO ANY OTHER AGENCY OF THE IMPLEMENTATION AND ENFORCEMENT OF THE PROPOSED RULE, THE SOURCE OF REVENUE TO BE USED FOR IMPLEMENTATION AND ENFORCEMENT OF THE PROPOSED RULE, AND ANY ANTICIPATED EFFECT ON STATE REVENUES, INCLUDING A PROJECTED NET LOSS OR GAIN IN SUCH REVENUE IF IT CAN BE PROJECTED BY THE AGENCY:
The Department has determined that there is no probable cost to ODMHSAS or other agencies expected as a result of the proposed rules nor is there an anticipated effect on State revenues.

6. **A DETERMINATION OF WHETHER IMPLEMENTATION OF THE PROPOSED RULE WILL HAVE AN ECONOMIC IMPACT ON ANY POLITICAL SUBDIVISIONS OR REQUIRE THEIR COOPERATION IN IMPLEMENTING OR ENFORCING THE RULE:**
ODMHSAS does not anticipate these rules will have an economic impact upon any political subdivision, or require their cooperation to implement or enforce the proposed rule revision.

7. **A DETERMINATION OF WHETHER IMPLEMENTATION OF THE PROPOSED RULE WILL HAVE AN ADVERSE EFFECT ON SMALL BUSINESS AS PROVIDED BY THE OKLAHOMA SMALL BUSINESS REGULATORY FLEXIBILITY ACT:**
ODMHSAS has determined these rule revisions will not have an adverse economic impact on small businesses that meet minimum certification standards as currently required by this Chapter.

8. **AN EXPLANATION OF THE MEASURES THE AGENCY HAS TAKEN TO MINIMIZE COMPLIANCE COSTS AND A DETERMINATION OF WHETHER THERE ARE LESS COSTLY OR NON-REGULATORY METHODS OR LESS INTRUSIVE METHODS FOR ACHIEVING THE PURPOSE OF THE PROPOSED RULE:**
Throughout the year ODMHSAS staff evaluate internal processes and amend those processes and rules according to identified needs. ODMHSAS considers these revisions the least burdensome and intrusive method in streamlining these processes and accomplishing statutory compliance.

9. **A DETERMINATION OF THE EFFECT OF THE PROPOSED RULE ON THE PUBLIC HEALTH, SAFETY AND ENVIRONMENT AND, IF THE PROPOSED RULE IS DESIGNED TO REDUCE SIGNIFICANT RISKS TO THE PUBLIC HEALTH, SAFETY AND ENVIRONMENT, AN EXPLANATION OF THE NATURE OF THE RISK AND TO WHAT EXTENT THE PROPOSED RULE WILL REDUCE THE RISK.**
ODMHSAS anticipates the proposed revisions to rules will enhance the quality of services for clients receiving care in Community Mental Health Centers.

10. **A DETERMINATION OF ANY DETRIMENTAL EFFECT ON THE PUBLIC HEALTH, SAFETY AND ENVIRONMENT IF THE PROPOSED RULE IS NOT IMPLEMENTED.**
ODMHSAS does not anticipate any detrimental effects on the public health, safety, or environment if the proposed rule is not implemented.

**DATE PREPARED:**
January 29, 2018
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.

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

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

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

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

"Critical incident" means an occurrence or set of events inconsistent with the routine operation of an approved treatment facility, or the routine care of a patient. Critical incidents specifically include but are not necessarily limited to the following: adverse drug events; self-destructive behavior; deaths and injuries (including automobile accidents) to the patient, patient family, staff and visitors; medication errors; neglect or abuse of a patient; fire; unauthorized disclosure of information; damage to or theft of property belonging to a patient or an approved treatment facility; other unexpected occurrences; or events potentially subject to litigation. A critical incident may involve multiple individuals or results.

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

"Drug 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.

"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) Allopathic or Osteopathic Physicians 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) Practitioners with a license to practice in the state in which services are provided by one of the following licensing boards:
   (i) Psychology;
   (ii) Social Work (clinical specialty only);
   (iii) Professional Counselor;
   (iv) Marriage and Family Therapist;
   (v) Behavioral Practitioner; or
   (vi) Alcohol and Drug Counselor.
(C) Advanced Practice Nurse (certified in a psychiatric mental health specialty), licensed as a registered nurse with a current certification of recognition from the board of nursing in the state in which services are provided.
(D) A Physician Assistant who is licensed in good standing in the state and has received specific training for and is experienced in performing mental health therapeutic, diagnostic, or counseling functions.

"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.

"OBNDD" 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.

"Opie 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.

"Peak test" see Peak and Trough.

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

"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 counseling services at the program or any of its medication units. The program sponsor need not be a licensed physician but shall employ a licensed physician for the position of medical director.

"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 patients treatment plan.

"Transient consumer" means a methadone or buprenorphine patient from another geographic location requiring "courtesy dosing".

"Trough test" see Peak and Trough.

"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, opioid withdrawal or opioid maintenance using methadone or buprenorphine including but not limited to counseling/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 2. FACILITY INFRASTRUCTURE REQUIREMENTS

450:70-2-3. Tobacco-free campus
(a) The facility shall provide a tobacco-free campus for its employees, consumers and visitors. Possession and use of any tobacco product is prohibited on the grounds of the facility by employees, consumers, volunteers and visitors.
(b) Facility will visibly post signs on the property notifying consumers, employees and visitors that the visible possession and use of tobacco products is prohibited.
(c) Facility employees shall not share tobacco or tobacco replacement products with consumers.
(d) The facility shall offer assistance to employees who are tobacco users while he or she is employed by the facility. The assistance shall include, but is not limited to, the provision of information on the health impact of continued tobacco use; the integrated assessment of consumer's tobacco use into standard practice; referrals to tobacco cessation programs such as the Oklahoma Tobacco Helpline; the provision of or access to FDA-approved prescription and/or non-prescription medications for the treatment of nicotine dependence when available; the delivery of evidence-based behavioral interventions for tobacco use cessation by counseling/therapists and other clinicians; and provision of appropriate follow-up to facilitate cessation intervention and prevent relapse.
(e) The facility shall always inquire of the consumers' tobacco use status and be prepared to offer treatment upon request of the consumer.
(f) Compliance with this Section shall be determined by visual observation; posted signs; consumer and staff interviews; and a review of the facility's policy, procedures and other supporting documentation provided.

SUBCHAPTER 3. FACILITY RECORD SYSTEM

PART 3. INTAKE AND ADMISSION ASSESSMENT

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 counseling therapy or rehabilitation services until the patient is fully stabilized and as indicated in this chapter;
   2. Group and family counseling therapy or rehabilitation services for spouses, parents, or significant others and as indicated in this chapter;
   3. Vocational or educational counseling services and referral and as indicated in this chapter; and
   4. 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 5. BIOPSYCHSOCIAL ASSESSMENT

450:70-3-7. Biopsychsocial assessment
(a) All OTPs shall complete a biopsychsocial assessment which gathers sufficient information to assist the patient in developing an individualized treatment plan. The OTP may utilize the current edition of the Addiction Severity Index (ASI) or develop a biopsychsocial assessment which contains, but not be limited to, the following:
   1. Identification of the patient's strengths, needs, abilities, and preferences;
   2. Presenting problem and history of the presenting problem;
   3. Previous treatment history, including opioid substitution therapy:
      A. Mental health,
      B. Substance abuse, and
   4. Health history and current biomedical conditions and complications;
   5. Alcohol and drug use history;
   6. History of trauma;
   7. Family and social history, including family history of alcohol and drug use;
   8. Educational attainment, difficulties, and history;
   9. Cultural and religious orientation;
   10. Vocational, occupational and military history;
   11. Sexual history, including HIV, AIDS and STD at-risk behaviors;
   12. Marital or significant other relationship history;
   13. Recreational and leisure history;
   14. Legal history;
   15. Present living arrangement;
   16. Economic resources;
   17. Level of functioning;
   18. Current support system;
   19. Current medications, including the name of prescribing physician, name of medication, strength and dosage, and length of time the consumer has been on the medication;
   20. Patient's expectations in terms of service; and
   21. Assessment summary or diagnosis, and signature of the assessor and
date of the assessment.
(b) The assessment shall be completed by a LBHP or licensure candidate.
(c) The assessment shall be completed as soon as possible after admission and no
later than the third (3) counselingtherapy or rehabilitation service visit.
(d) In the event of a consumer re-admission after one (1) year of the last biopsychsocial
assessment, a new biopsychsocial assessment shall be completed. If readmission
occurs within one (1) year after the last biopsychsocial assessment, an update shall be
completed.
(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. 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, biopsychsocial 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) counselingtherapy 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 counselortherapist or rehabilitation service provider
assignment;  
(3) Change in frequency and types of services provided;  
(4) Critical incident reports;  
(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.

(h) The OTP will provide adequate and appropriate counseling or rehabilitation services to each patient as clinically necessary. This counseling shall be provided by a program counselor, qualified by education, training, or experience to assess the psychological and sociological background of patients, to contribute to the appropriate service plan for the patient and to monitor patient progress. Rehabilitation services must be provided by a LBHP, Licensure Candidate, CADC or CM II.

(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.

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**SUBCHAPTER 4. SERVICES SUPPORT AND ENHANCEMENT**

**PART 1. STAFF SUPPORT**

**450:70-4-2. Clinical supervision**

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

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

(1) Credentials required for the clinical supervisor;
(2) Specific frequency for case reviews with treatment and service providers;
(3) Methods and time frames for supervision of individual, group, and educational treatment services; and
(4) Written policy and procedures defining the program's plan for appropriate counselor/provider-to-patient ratio, and a plan for how exceptions may be handled.

(c) Ongoing clinical supervision should address:

(1) The appropriateness of services selected for the patient;
(2) Service effectiveness as reflected by the patient meeting his/her individual goals; and
(3) The provision of feedback that enhances the clinical skills of direct service staff and service providers.

(d) Compliance with 450:70-4-2 may be determined by:
   (1) A review of policies and procedures,
   (2) Clinical services manuals,
   (3) Clinical supervision manuals,
   (4) Documentation of clinical supervision,
   (5) Personnel records,
   (6) Treatment records,
   (7) Interviews with staff; and
   (8) Other facility documentation.

(e) Failure to comply with 450:70-4-2 will result in the initiation of procedures to deny, suspend and/or revoke certification.

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 counselors, 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 patients 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.

PART 3. ORGANIZATIONAL AND FACILITY MANAGEMENT
**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 counseling/therapy/rehabilitation service space, secure record storage, protect consumer confidentiality, and provide a safe, warm, welcoming, culturally and age appropriate environment.

(d) Hours of operation shall be during regularly scheduled times in which services are accessible to consumers and the general public, including those employed between the hours of 8:00 a.m. and 5:00 p.m., Monday through Friday. To accomplish this, the 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 counseling/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 employed and parenting patients' schedules, 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.

**450:70-4-7.4. 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 counseling/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 patients who are not assessed as appropriate to receive a single take home dose. The medical director shall be responsible for determining whether a patient can safely be dispensed opioid treatment drugs 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.

SUBCHAPTER 6. SUBSTANCE USE DISORDER TREATMENT SERVICES

PART 2. LEVELS OF TREATMENT

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 patient;
   (3) Require that a variety of ancillary services, such as mutual support groups, be available to the patient through the agency or through referral;
   (4) Require that the amount of counseling/therapy/rehabilitation services available to the patient be increased prior to discharge; and
   (5) Require that a patient be re-admitted to the agency or referred to another agency at the first indication of relapse unless it is an administrative withdrawal process.
   (6) There is no minimum time in treatment requirement for patients 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.

450:70-6-6. Administrative withdrawal
(a) The OTP shall have written policy and procedure stating an infraction of program rules by a patient may result in administrative medical withdrawal from methadone or buprenorphine and termination from treatment services. All patients will be notified of this policy. The program shall develop specific program requirements to address noncompliance with program rules resulting in termination. The violation or noncompliance with rules shall be limited to:
   (1) Threats of violence or actual bodily harm to staff or another patient, including abusive language or behavior;
   (2) Disruptive behavior, loitering;
   (3) Diversion of methadone, selling, distributing, using, or otherwise "dealing" in any illicit drug or chemical, including positive urine tests for non-prescribed medications and drugs;
   (4) Continued unexcused absences from counseling/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 patient experiencing administrative withdrawal shall be referred or transferred to an agency that is capable of, or more suitable for, meeting the patient’s needs. The referral or transfer is documented in the patient record and the following information is documented in the patient record:
   (1) The reason that the patient sought medical withdrawal or was placed on administrative withdrawal; and
   (2) The information and assistance provided to the patient in 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 treatment services.
(b) There shall be written policy stating a patient may be admitted to short-term managed withdrawal regardless of age. Patients under the age of eighteen (18) may be admitted with written parent or guardian approval.
(c) The program physician shall document in the patient record the reason for admitting the patient to short-term 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 comprehensive maintenance patients are required for short-term managed withdrawal patients.
(h) A primary counselor, LBHP, Licensure Candidate or CADC must be assigned by the program to monitor a patient’s progress toward the goal of short-term withdrawal management and possible drug-free treatment referral.
(i) Methadone is required to be administered daily by the OTP in reducing doses to reach a drug-free state over a period not to exceed thirty (30) days. Buprenorphine shall be administered as determined by the OTP medical director.
(j) All other requirements of comprehensive maintenance treatment apply.
(k) Compliance with 450:70-6-7 may be determined by:
   (1) A review of policies and procedures,
   (2) Treatment records,
   (3) Interviews with staff, and
   (4) Other facility documentation.

450:70-6-9. Interim maintenance treatment services
(a) The OTP shall have documentation before providing interim maintenance treatment services indicating the written approval of both SAMHSA and ODMHSAS.
(b) The OTP shall have written policy and procedure stating the program sponsor may place an individual who is eligible for admission to comprehensive maintenance services in interim maintenance services if the individual cannot be placed in comprehensive maintenance treatment services within a reasonable geographic distance and within fourteen (14) days of application for admission to comprehensive maintenance treatment services.
(c) The OTP shall identify the maximum length of stay in interim opioid services is one hundred and twenty (120) days.
(d) The OTP shall provide an initial and a minimum of two (2) additional drug screens shall be taken from interim patients during the one hundred and twenty (120) days of interim services.
(e) The OTP shall have written policies and procedures outlining all criteria for transfer from interim maintenance to comprehensive maintenance services.
(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 counselor LBHP, Licensure Candidate or CADC does not need to be assigned.
   (3) Interim maintenance is limited to two (2) one hundred and twenty (120) day episodes in any twelve (12) month period.
   (4) Educational, rehabilitative and counseling therapy services are not required.
   (5) An initial treatment plan and periodic updates are not required.
(i) Compliance with 450:70-6-9 may be determined by:
   (1) A review of policies and procedures,
   (2) Treatment records,
   (3) Interviews with staff, and
   (4) Other facility documentation

450:70-6-11. 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 counseling/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.

PART 3. PHASES OF TREATMENT SERVICES

450:70-6-15.3. Service—Clinical services
(a) The OTP shall have written policy and procedure stating the OTP shall provide adequate medical, counseling/therapy/rehabilitation services, vocational, educational, and other assessment and treatment services. These services must be available at the primary facility, except where the program sponsor has entered into a formal, documented agreement with a private or public agency, organization, practitioner, or institution to provide these services to patients enrolled in the OTP. The program sponsor, in any event, must be able to document that these services are fully and reasonably available to all patients.
(b) Services shall be designed to provide a variety of professional diagnostic and primary medication assisted opioid treatment services for patients, and their families and significant others, whose emotional and physical status allows them to function in their usual environment.
(c) 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 patients who either request such services or who have been determined through the assessment process to be in need of such services.
(d) The OTP shall have written policy and procedure stating patients accepted for opioid treatment shall attend prescribed counseling/therapy/rehabilitation services as mandated in the individualized service plan and this chapter.
(e) Time in treatment shall not be a requirement for patients receiving buprenorphine when granting take-home privileges.
(f) Compliance with 450:70-6-15.3 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 our (4) sessions of counseling/therapy or rehabilitation services per month with at least one (1) session being individual counseling/therapy or rehabilitation service and/or case management.

(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) counseling/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 counseling/therapy or rehabilitation service and/or case management.

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

4) The service plan shall be reviewed and updated at least 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 counseling/therapy or rehabilitation service and/or case management per month during Phase III.

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 counseling/therapy or rehabilitation service and/or case management per month during this phase.
   (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 counseling/therapy or rehabilitation service or case management per month during this phase.
   (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.

450:70-6-17.8. Service phases – Phase VI
(a) Patients who meet criteria for Phase VI, and who have been admitted to treatment for a minimum of one (1) year, and who are receiving thirty (30) days of take-home doses on July 1, 2007 shall be allowed to continue to be eligible to receive thirty (30) days of take-home doses of methadone after July 1, 2007.
   (1) If this patient is reduced in phase, the privilege of thirty (30) days take-home medication shall be withdrawn.
   (2) Once lost, the privilege to receive thirty (30) days of take-home medication shall not be available again.
   (3) If patient with the privilege to receive thirty (30) days of take-home medication changes clinics, it shall be the decision of the receiving clinic to either continue or ignore the continuation of the thirty (30) take-home medication privilege.
(b) Phase VI is designated for patients who voluntarily seek medically supervised withdrawal and abstinence from all drugs, including methadone as prescribed. A patient may enter this phase at any time in the treatment and rehabilitation process.

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

(2) During Phase VI, the counselor, LBHP, Licensure Candidate or CADC determines the frequency of counseling or rehabilitation service sessions with input from the patient. At the onset of Phase VI, the patient may require an increased level of counseling or rehabilitation service and other support services.

(3) The counselor, LBHP or Licensure Candidate and patient develop a continuing care plan prior to the successful completion of treatment.

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

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

(2) The medical director or program physician shall not allow the patient to attend the clinic less frequently than the most recent schedule allowed at the former program unless:
   (A) Copies of the patient's records are obtained to sufficiently document the patient's satisfactory adherence to all relevant federal and state regulations for the required time in treatment; and
   (B) the physician has completed an evaluation of the patient.

(3) At a minimum, staff from the admitting program shall document in the patient record and staff from the transferring program must provide the following information before the initial dose of methadone or buprenorphine is administered to a transfer patient:
   (A) The last date and amount of opioid treatment medication drug administered or dispensed at the former program;
   (B) The length of time in continuous treatment;
   (C) The most recent record of clinic attendance;
   (D) The name, address, and telephone number of the program contacted;
   (E) The date and time of the contact; and
   (F) The name of the program employee furnishing the information.

(d) 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.