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 450:1-9-5.3.

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" 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.

"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" 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 extra ordinary circumstance.

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

"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) <u>An Allopathic or Osteopathic Physicians Physician</u> 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;
- (B)(E) A Practitioners practitioner with a license to practice in the state in which services are provided by one of the following licensing boards:

(i) Psychology;

(ii)(i) Social Work (clinical specialty only);

(iii)(ii) Professional Counselor;

(iv)(iii) Marriage and Family Therapist;

(v)(iv) Behavioral Practitioner; or

(vi)(v) 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.

"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.

"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 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 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.

SUBCHAPTER 2. FACILITY INFRASTRUCTURE REQUIRMENTS [REVOKED]

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

(a) All facilities providing medication assisted opioid treatment service shall have written policies and procedures intended to ensure the safety and protection of all

persons within the facility's physical environment (property and buildings, leased or owned).

- (b) These policies and procedures shall include, but are not limited to:
 - (1) Meeting all fire and safety regulations, code and statutory requirements of federal, state, or local government.
 - (2) All OTPs shall have an annual fire and safety inspection approving continued occupancy from the State Fire Marshal, or local authorities; and shall maintain a copy of said inspection and attendant correspondence regarding the clearing of any deficiency.
 - (3) An emergency preparedness plan to provide effective utilization of resources to best meet the physical needs of patients, visitors, and staff during any disaster (including, but not limited to; fire, flood, tornado, explosion, prolonged loss of heat, light, water, and/or air conditioning).
 - (A) This plan shall include procedures facilitating the transfer of patients in the event the OTP is unable to open.
 - (B) This plan shall be evaluated annually, and revised as needed.
 - (4) A designated Safety Officer.
 - (5) Staff training and orientation regarding the location and use of all fire extinguishers and first aid supplies and equipment and an emergency preparedness plan.
 - (6) Emergency evacuation routes and shelter areas shall be prominently posted in all areas.
 - (7) There shall be emergency power to supply lighting to pre-selected areas of the facility.
 - (8) The maintenance of facility grounds to provide a safe environment for consumers (specific to age group[s] served), staff and visitors.
 - (9) Storage of dangerous substances (toxic or flammable substances) in locked, safe areas or cabinets.
 - (10) A written plan for the protection and preservation of consumer records in the event of a disaster.
- (c) Compliance with 450:70-2-1 may be determined by a review of:
 - (1) Facility policy and procedures,
 - (2) Fire and safety inspection reports and correspondence,
 - (3) Disaster plans,
 - (4) Any other supporting facility documentation, and
 - (5) Interviews with staff and consumers.

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

- (a) OTPs shall provide:
 - (1) Lavatories and toilet facilities in a minimum ratio of one per twenty persons on site.
 - (2) Sewerage discharge into a municipal sewerage system or collected, treated and disposed of in an independent sewerage system.
 - (3) Solid waste disposal through public systems or in a manner approved by the local agency having jurisdiction and the Oklahoma State Department of Health or Department of Environmental Quality, as necessary.

- (4) Water obtained from an approved public water supply or tested at least quarterly and treated as necessary, thereby maintaining a determination as an approved water supply by the authority having jurisdiction and the Oklahoma Department of Health or Department of Environmental Quality, as indicated by the building permit.
- (5) The facility shall have proof of regular inspections and treatment by a licensed pest control operator.
- (6) House-keeping services so that a hygienic environment is maintained in the facility.
- (b) Compliance with 450:70-2-2 may be determined by:
 - (1) A review of utility/garbage bills,
 - (2) Water testing results,
 - (3) Pest inspections and
 - (4) Other related documents.

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

- (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 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 1. RECORD SYSTEM

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

(a) Each OTP shall maintain an organized system for the content, confidentiality, storage retention and disposition of patient records.

- (b) The OTP shall have written policies and procedures concerning patient records which define required documentation within the patient record.
- (c) Patient records shall be maintained in a locked and secure manner.
- (d) The OTP shall maintain identification and filing systems which enable prompt record location and accessibility by service providers.
- (e) Patient records shall be maintained in the facility where the individual is being treated or served. In the case of temporary office space or satellites, records may be maintained in the main (permanent) office and transported in secured lock boxes to and from temporary offices or satellites, when necessary. Patient records may be permanently maintained at the OTPs administrative offices; however, a working copy of the patient record for the purposes of documentation and review of services provided must be maintained at the site in which the patient is receiving treatment.
- (f) The OTP shall have policies which govern the storage, retention, and disposition of patient records, including electronic records. These policies shall be compatible with protection of patient's rights against confidential information disclosure at a later date, and compliant with applicable state and federal law.
- (g) Compliance with 450:70-3-2 may be determined by:
 - (1) A review of policies and procedures,
 - (2) Treatment records,
 - (3) Performance improvement guidelines,
 - (4) Interviews with staff, and
 - (5) Other facility documentation.

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

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

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 timelimited:
 - (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) 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;
 - (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.
- (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 11. DISCHARGE

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

(a) The discharge summary shall at a minimum include:

- (1) Presenting problem(s) at intake;
- (2) Initial condition and condition of patient at discharge;
- (3) Medication summary, if the patient is taking medications;
- (4) Treatment and services provided, and a summary of treatment outcomes;
- (5) Specific referrals for continuing services and needed resources;
- (6) The patient's response to the services received or an explanation explaining no response; and
- (7) The signature of the staff member completing the summary, and the date.
- (8) In the event of the death of a patient, a summary statement including this information shall be documented in the record.
- (b) A discharge summary shall be entered in each patient's record within fifteen (15) days of discharge.
- (c) Compliance with 450:70-3-10 may be determined by:
 - (1) A review of policies and procedures, and
 - (2) Discharge assessments in treatment records.

SUBCHAPTER 4. SERVICES SUPPORT AND ENHANCEMENT

PART 3. ORGANIZATIONAL AND FACILITY MANAGEMENT

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

- (a) The OTP shall have written policy and procedure stating drug screens will follow federal guidelines and will, at a minimum, test for the following substances;:
 - (1) Opioids,
 - (2) Methadone;
 - (3) Amphetamines,:
 - (4) Cocaine,;
 - (5) Benzodiazepines; and
 - (6) Barbiturates,
 - (7) Marijuana.
- (b) The OTP shall have written policy and procedure stating drug testing shall include other drugs as may be indicated by the patient's abuse patterns. In addition, if any other drug or drugs have been determined by a program to be abused in that program's locality, or as otherwise indicated, each test or analysis must include any such drugs.
- (c) The OTP shall have written policy and procedure stating that following admission, the results of a single drug test shall not be the sole basis to determine significant treatment decisions.
- (d) Compliance with 450:70-4-8.2 may be determined by:
 - (1) A review of policies and procedures.
 - (2) Treatment records,
 - (3) Interviews with staff, and
 - (4) Other facility documentation.

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

(a) The OTP shall have a defined and written plan for conducting an organizational

needs assessment which specifies the methods and data to be collected, to include, but not limited to information from:

- (1) Patients:
- (2) Governing Authority;
- (3) Staff:
- (4) Stakeholders;
- (5) Outcomes management processes; and
- (6) Quality record review.
- (b) The OTP shall have a defined ongoing system to collect data and information on a quarterly basis to manage the organization.
- (c) Information collected shall be analyzed to improve patient services and program performance.
- (d) The OTP shall prepare an end of year management report, which shall include, but not be limited to:
 - (1) an analysis of the needs assessment process; and
 - (2) performance improvement program findings.
- (e) The management report shall be communicated and made available to, among others:
 - (1) the governing authority;
 - (2) facility staff; and
 - (3) ODMHSAS, as requested.
- (f) Compliance with 450:70-4-9 may be determined by:
 - (1) A review of program evaluation plans,
 - (2) Written annual program evaluations,
 - (3) Special or interim program evaluations,
 - (4) Program goals and objectives, and
 - (5) Other supporting documentation provided.

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

- (a) The OTP shall have an ongoing performance improvement program designed to objectively and systematically monitor, evaluate and improve the quality of consumer care.
- (b) The performance improvement program shall address the fiscal management of the OTP.
- (c) Each OTP shall identify a performance improvement officer.
- (d) The OTP shall document performance improvement activities. These activities shall include, but not be limited to:
 - (1) Outcomes management specific to each program;
 - (2) A quarterly quality record review including medical records;
 - (3) An annual review and revision as appropriate of all program policies and Procedures;
 - (4) The performance improvement activities shall support increased access to and retention in treatment. Improve the current process;
 - (5) Staff privileging; and
 - (6) Review of critical and unusual incidents, sentinel events, patient grievances and complaints.

- (e) The OTP shall monitor the implementation of the performance improvement plan on an ongoing basis and shall make adjustments as needed.
- (f) Performance improvement findings shall be communicated and made available to, among others:
 - (1) the governing authority,
 - (2) facility staff,
 - (3) patients,
 - (4) stakeholders, and
 - (5) ODMHSAS, as requested.
- (g) Compliance with 450:70-4-10 shall be determined by:
 - (1) A review of the written program evaluation plan,
 - (2) Written program evaluations (annual and/or special or interim,
 - (3) Program goals and objectives (and other supporting documentation provided), and
 - (4) Other facility documentation.

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

- (a) The OTP shall have written policy and procedures for the reporting of every critical incident. Documentation of critical incidents shall minimally include:
 - (1) The facility, name and signature of the person(s) reporting the incident;
 - (2) The name(s) of the patient(s), staff member(s) or property involved;
 - (3) The time, date and physical location of the incident;
 - (4) The time and date the incident was reported and the name of the staff person within the facility to whom it was reported;
 - (5) A description of the incident;
 - (6) Resolution or action taken, description of the action taken, date action was taken, and signature of appropriate staff member(s); and
 - (7) Severity of each injury, if applicable. Severity shall be indicated as follows:
 - (A) No off-site medical care required or first aid care administered on-site;
 - (B) Medical care by a physician or nurse or follow-up attention required; or
 - (C) Hospitalization or immediate off-site medical attention was required.
- (b) Critical incidents shall be reported to ODMHSAS as follows:
 - (1) Critical incidents requiring medical care by a physician or nurse or followup attention and incidents requiring hospitalization or immediate off-site medical attention shall be delivered via fax or mail to ODMHSAS Provider Certification within twenty-four (24) hours of the incident being documented.
 - (2) Critical incidents involving allegations constituting a sentinel event or patient abuse shall be reported to ODMHSAS immediately via telephone or fax, but not more than twenty-four (24) hours of the incident. If reported by telephone, the report shall be followed with a written report within twenty-four (24) hours.
- (c) Compliance with 450:70-4-11 shall be determined by:
 - (1) A review of facility policies and procedures,
 - (2) Critical incident reports at the facility, and those submitted to ODMHSAS,
 - (3) Performance improvement program documents and reports,
 - (4) Staff interviews, and
 - (5) Any other relevant documentation of the facility or ODMHSAS.

SUBCHAPTER 6. SUBSTANCE USE DISORDER TREATMENT SERVICES

PART 3. PHASES OF TREATMENT SERVICES

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.
 - (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 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.