580-9-44-.29 <u>Level I-O: Opioid Maintenance Therapy</u>.

(1) Rule Compliance. Each Level I-O Opioid Maintenance Therapy Program shall comply with all applicable rules and the rules specified in this chapter:

(a) Program Description. The entity shall develop, maintain and implement a written program description that defines its Level I-O Opioid Maintenance Therapy Program.

1. Location. The entity shall specifically identify and describe the setting in which the Level I-O Program is provided. Services may be provided in any facility that meets all applicable federal, state and local certification, licensure, building, life-safety, fire, health and zoning regulations, including the DMH facility certification standards.

2. Admission Criteria. The entity shall develop, maintain and document implementation of written criteria for admission to its Level I-O Program, in compliance with the requirements of Rule 580-9-44-.13(9) and the following specifications:

(i) The entity's admission criteria shall specify the target population for its Level I-O Program, which shall include, at a minimum:

(I) Individuals who are currently physiologically dependent upon an opiate drug and who became physiologically dependent at least one (1) year prior to seeking admission to Opioid Maintenance Therapy.

(II) Other individuals, as authorized by the entity's medical director, who have a history of Opioid use and are susceptible to relapse to Opioid addiction leading to high risk behaviors with potentially life-threatening consequences, but who do not present with a one (1) year history of addiction, including:

I. Pregnant women.

II. Individuals who have been released from a penal institution within six (6) months of the current admission

request, if the client was eligible for admission prior to incarceration.

III. Individuals who have had a previous admission to Opioid maintenance therapy of at least six (6) months duration that occurred within two (2) years of the current admission request.

IV. Individuals who are HIV positive.

(ii) The entity shall provide written documentation in each individual clinical record that each client admitted to a Level I-O Program for Opioid Maintenance or Withdrawal Therapy meets the criteria for Opioid Dependence Disorder, as according to the specific diagnostic criteria given in the most recent edition of the Diagnostic and Statistical Manual of Mental Disorders of the American Psychiatric Association.

(iii) The entity shall provide written documentation in each individual case record that each client admitted to a Level I-O Program meets the dimensional criteria for admission to this level of care as defined in the most recent edition of the ASAM PPC-2R.

(iv) Medical necessity of each admission to a Level I-O Program shall be established by the program's medical director or a physician authorized by the program's medical director and documented in the clinical record.

(v) Adolescent Specific Criteria. An entity shall not admit an individual under age eighteen (18) to a Level I-O Program for Opioid Maintenance Therapy unless the entity can document that:

(I) The client has had two (2) unsuccessful attempts at drug-free treatment within a twelve (12) month period of time; or

(II) The client has had two (2) unsuccessful attempts at short-term detoxification.

(III) The entity has obtained written authorization of the admission from the State Opioid Treatment Authority (SOTA).

I. The entity shall develop, maintain and document implementation of written policies and procedures which govern the process utilized to request and obtain written authorization from the SOTA prior to admission of an individual under age eighteen 18 to a Level I-O Program.

3. Core Services. Each Level I-O Program shall demonstrate the capacity to provide a basic regimen of treatment services appropriate to the client's developmental and cognitive levels and other assessed needs.

(i) At a minimum, the entity shall demonstrate and document its capacity to provide the following core services:

(I) Placement assessment.

(II) Medication management.

(III) Medication administration.

(IV) Alcohol and/or drug screening/testing.

(V) Individual counseling.

(VI) Group counseling.

(VII) Family counseling.

(VIII) Psychoeducation.

(IX) Case management:

I. Case planning.

II. Linkage.

III. Advocacy.

IV. Monitoring.

(ii) Medical Services. The entity shall have medical protocols established for I-O Level of Care by a licensed physician or staff or under contract with the entity as the medical director. The medical protocol shall be in compliance with the program standards, ethics and licensure requirements of the medical profession.

(iii) Mental Health Services. The entity shall develop, maintain and document implementation of policies and procedures to ensure that clients with mental health needs are identified through assessment services and have access to appropriate care concurrently with Opioid Maintenance or Withdrawal Therapy.

(iv) Family Support. The entity shall initiate and document in the client record:

(I) Continuous efforts to involve the client's family and other natural supports in the treatment process.

(II) Family and other natural supports' participation in the client's treatment process.

4. Therapeutic Component Implementation.

(i) Each Level I-O Program shall provide written documentation of compliance with all applicable local, state and federal regulations, including Federal Regulation 42 CFR Part 8, DEA, Certificate of Need, etc. in addition to all applicable sections of the rules set forth, herein.

(ii) Each Level I-O Program shall establish a written schedule of operating hours and services that shall:

(I) Provide for dosing and counseling services seven (7) days each week.

(II) Establish hours of operation that are flexible to accommodate the majority of client school, work and family responsibility schedules.

(III) Provide access to clinical services personnel twenty-four (24) hours a day, seven (7) days a week.

I. The physical plant is of adequate size to accommodate the proposed number of clients, required program activities, and provide a safe, therapeutic environment that supports enhancement of each client's well-being and affords protection of privacy and confidentiality.

(iii) Counseling Services: The entity shall document the provision of scheduled counseling and recovery support services and activities that shall, at a minimum, include:

(I) Interventions that address:

I. Emotional and psychological needs.

II. Health education.

III. Medication administration and monitoring.

5. Assessment: The entity shall comply with all standards set forth in Rule 580-9-44-.13(7) of these rules and in addition, shall comply with the requirements of this section:

(i) Before an entity admits an individual to a Level I-O Program, the program's medical director, or a physician or physician extender properly authorized by the medical director, shall conduct and document the findings of a medical evaluation.

(ii) A pregnancy test shall be completed, and the results documented, for each female of childbearing potential prior to the initiation of Opioid Maintenance Therapy, or any medically assisted withdrawal or detoxification procedures.

(iii) A comprehensive medical examination that includes the following components, at a minimum, shall be completed and documented in the clinical record, within fourteen (14) days of each admission:

(I) A complete medical history.

(II) A tuberculosis (TB) skin test or chest x-ray if the skin was ever previously positive.

(III) Screening tests for STDs.

(IV) Other laboratory tests as clinically indicated by the client's history and physical examination.

(iv) An annual medical examination shall be conducted and documented in the clinical record by the program's medical director, or a physician or physician extender authorized by the program's medical director.

6. Client Orientation:

(i) All clients shall be oriented to the Opioid Therapy process prior to administration of any medication.

(ii) The entity shall provide written documentation that each client, upon admission and throughout the treatment process, receives oral and written information that explains in a manner understood by the client:

(I) Signs and symptoms of overdose and when to seek emergency assistance.

(II) A description of the medications to be administered by the program, including potential:

I. Benefits.

II. Risks.

III. Side effects.

IV. Drug interactions.

(III) Common myths about Opiate Maintenance Therapy and medications used in the treatment and withdrawal process.

(IV) The nature of addictive disorders.

(V) The goals and benefits of medication assisted treatment and the process of recovery.

(VI) Noncompliance and discharge procedures, including administrative withdrawal from medication.

(VII) Toxicology testing procedures.

(VIII) Medication dispensing procedures.

7. Drug Testing: The entity shall develop, describe in writing and document implementation of an organized process to monitor drug use by program participants, which shall, at a minimum, comply with the standards provided in Rule 580-9-44-.13(25), and include the following specifications:

(i) The results of a drug test shall be utilized as a guide to review and modify treatment approaches and not as the sole criterion to discharge a client from treatment.

(ii) Baseline toxicology tests shall be completed on the day of Diagnostic Interview Examination that shall, at a minimum, screen for:

(I) Opiates.

(II) Methadone.

(III) Benzodiazepines.

(IV) Barbiturates.

(V) Cocaine.

(VI) Amphetamines.

(VII) Tetrahydrocannabinol.

(VIII) Alcohol.

(IX) Any other drug known to be frequently abused in the locality of the Opiate Maintenance Therapy Program.

(iii) Random drug tests shall be conducted at least once per month throughout the duration of each client's participation in Opioid Maintenance Therapy. A minimum of twelve (12) drug tests shall be conducted per year.

(iv) The entity shall document the provision of a minimum of two (2) drug tests per month for each client during the first ninety (90) days in Opioid Maintenance Therapy and for those, otherwise, in Phase 1 of the program.

(v) The entity shall document the utilization of drug testing cutoff concentrations as follows:

(I) Marijuana: 100 ng/ml

(II) Cocaine: 300 ng/ml

(III) Opiate: 300 ng/ml

(IV) Amphetamine/methamphetamine: 1000 ng/ml

(V) Benzodiazepine: 200 ng/ml

(VI) Methadone: 300 ng/ml

(VII) Barbiturates: 200 ng/ml

(VIII) Alcohol: .03 gm/dl

(IX) In cases where Opiate Maintenance drugs other than methadone are being used, the clinic should contact the State Opioid Treatment Authority to determine the acceptable immunoassay cut-off concentrations.

(vi) The entity shall provide documentation that all drug tests are conducted by a laboratory certified by an independent, federally approved accreditation entity.

(vii) The results of all drug tests shall be filed in the clinical record.

8. Procedure for Addressing Positive Toxicology Reports. The entity shall develop, maintain and document implementation of written policies and procedures that establish protocols for addressing positive toxicology results for illicit drugs and negative results for drugs administered by the Opioid

Maintenance Therapy Program that shall, at a minimum, include the following specifications:

(i) Baseline drug testing results shall be discussed with the client and documentation of this discussion recorded as a progress note in the clinical record.

(ii) At his/her next scheduled clinic visit after receiving a positive alcohol/drug screen, clients shall be informed of drug testing results that are positive for substances of abuse, or negative for Opioid Maintenance Therapy medication. Following client notification, the entity shall implement the following procedures, as appropriate:

(I) New Clients. During the first ninety (90) days of treatment, the first drug testing report that is positive for substances of abuse or negative for treatment medication, after baseline testing, shall result in a meeting between the client and the client's primary counselor to review the treatment plan, and to modify or intensify treatment services as appropriate to the client's current needs.

(II) Clients with take-home privileges.

I. A positive toxicology report for illicit drugs or a negative toxicology result for treatment medication shall require that the client with take-home privileges, at a minimum:

A. Be placed on probation for ninety (90) days.

B. Receive a minimum of two (2) random drug screens per month during the probationary period.

C. Collaborate with his/her primary counselor for discussion of the toxicology results and for service plan modification as according to the client's needs.

II. A second toxicology result that is positive for substances of abuse or negative for treatment medication during a probationary period shall require that the client with take-home privileges, at a minimum:

A. Transfer to a lower dosing phase.

B. Receive a minimum of two (2) random drug screens per month.

C. Participate in a clinical staffing.

D. Collaborate with the treatment team to develop and implement a plan for remedial action.

(III) Subsequent Drug Tests for All Clients. For subsequent drug testing results that are positive for substances of abuse or negative for treatment medication the entity shall take steps to provide assistance for each client, as according to assessed needs, that shall include but shall not be limited to:

I. Treatment team staffings in collaboration with the client.

II. Continued assessment services of the client's biopsychosocial needs and levels of functioning.

III. Re-evaluation of the client's medication dosage, plasma levels, metabolic responses and adjustment of the dosage for adequacy and client comfort.

IV. Assessment for co-occurring disorders, prescribing therapy and psycho-pharmacotherapy as needed.

V. Intensify counseling or add of other types of services.

VI. Treatment of medical or other associated problems.

VII. Consideration of alternative opiate addiction treatment medications.

VIII. Detoxification from substances of abuse while maintaining the client on Opioid pharmacotherapy.

IX. Initiating a change of counselors when indicated.

X. Providing family intervention.

(IV) If any client has six (6) or more consecutive toxicology results that are positive for substances of abuse or negative for treatment medication, the entity shall inform the client that administrative withdrawal procedures will begin immediately and a referral will be made to an appropriate level of care unless the entity's medical director:

I. Provides objective clinical contraindications of the need for this action.

II. Develops a written intervention plan in consultation with the client and the client's treatment team that shall at a minimum, include provisions for:

A. Detoxification from substances other than the maintenance therapy drug; and/or

B. Intensified counseling and other services.

III. Documents all actions taken, in this regard, as appropriate.

IV. The entity shall maintain a data base of drug testing results which shall at a minimum:

V. List each client by unique client identifier, date of birth, gender, date of each drug test, identify each drug for which tests are completed and the results of each test.

VI. Allow for development of aggregate reports of each variable as well sorting of data by each variable.

9. Take Home Medication: The entity shall develop, maintain and document implementation of written policies and procedures that govern the processes utilized to provide clients with unsupervised use of program dispensed Opioid treatment medication. At a minimum, these policies and procedures shall include the following specifications:

(i) The entity’s medical director, in consultation with the client’s treatment team, shall make all decisions relative to dispensing Opioid treatment medication to clients for unsupervised use, in consideration of the following minimum criteria:

(I) Absence of recent abuse of drugs (narcotic or non-narcotic), including alcohol.

(II) Regularity of clinic attendance.

(III) No observed, reported, or otherwise known serious behavioral problems.

(IV) Absence of known recent criminal activity, e.g., drug dealing.

(V) Stability of the client's home environment and social relationships.

(VI) Length of time in treatment.

(VII) Assurance that take-home medication can be safely stored within the client's home.

(VIII) Whether the rehabilitative benefit to the client derived from decreasing the frequency of clinic attendance outweighs the potential risks of diversion.

(ii) Decisions to approve unsupervised use of Opioid medications, including the rationale for the approval, shall be documented in the clinical record.

(iii) Patients must have in their possession a secure locking storage device in order to receive take-home medication. There are no exceptions.

(iv) The amount of take-home medication shall be based on the clinical judgment of the physician in consultation with the multidisciplinary treatment team. If it is determined that a client meets the criteria for unsupervised dosing the supply shall be limited to the following schedule:

(I) Phase 1 Treatment. Clients who are not eligible for any take home medication shall be designated by the program as in Phase 1 of Opioid Maintenance Therapy.

I. During the first ninety (90) days of treatment, clients shall not be eligible for any take home medication.

II. Twice-a-month drug tests shall document that each client in Phase I is free of all substances of abuse including alcohol and positive for the prescribed maintenance drug for at least ninety (90) consecutive days in order to be eligible for consideration for unsupervised dosing.

(II) Phase 2 Treatment. Clients in treatment between ninety-one (91) and one hundred eighty (180) days, who satisfy the criteria specified in Rule 580-9-44-.29 8(i)(II) shall be eligible for a take-home supply that shall not exceed two (2) doses per week.

I. Clients who are eligible for a two (2) day take home medication supply shall be designated by the program as in "Phase 2" of Opioid Maintenance Therapy.

II. A minimum of one (1) random drug test per month must be conducted while the patient is in Phase 2.

III. It shall be documented that the client is free of all substances of abuse including alcohol and positive for the

prescribed maintenance drug for at least ninety (90) consecutive days in order to be considered for Phase 2 unsupervised dosing.

(III) Phase 3 Treatment. Clients in treatment between one hundred eighty-one (181) and two-hundred seventy (270) days, who satisfy the criteria specified in Rule 580-9-44-.29 8(i)(II) shall be eligible for a take-home supply that shall not exceed three (3) doses per week.

I. Clients who are eligible for a three (3) day take home medication supply shall be designated by the program as in Phase 3 of Opioid Maintenance Therapy.

II. A minimum of one (1) random drug test per month must be conducted while the patient is in Phase 3.

III. It shall be documented that the client is free of all substances of abuse including alcohol and positive for the prescribed maintenance drug for at least one hundred eighty (180) consecutive days in order to be considered for Phase 3 unsupervised dosing.

(IV) Phase 4 Treatment. Clients in treatment between two hundred seventy-one (271) and three hundred sixty-five (365) days, who satisfy the criteria specified in Rule 580-9-44-.29 8(i)(II) shall be eligible for a take-home supply that shall not exceed six (6) doses per week

I. Clients who are eligible for a six (6) day take home medication supply shall be designated by the program as in Phase 4 of Opioid Maintenance Therapy.

II. A minimum of one (1) random drug test per month must be conducted while the patient is in Phase 4.

III. It shall be documented that the client is free of all substances of abuse including alcohol and positive for the prescribed maintenance drug two hundred seventy (270) consecutive days in order to be considered for Phase 4 unsupervised dosing.

(V) Phase 5 Treatment. After two (2)years of continuous treatment with uninterrupted clean drug screens, client shall be eligible for up to a thirteen (13) day take home medication supply.

I. Clients who are eligible for a thirteen (13) day take home medication supply shall be designated by the program as in Phase 5 of Opioid Maintenance Therapy.

II. A minimum of one (1) random drug test per month must be conducted while the patient is in Phase 5.

(iv) Temporary Special Take-Home Medication for Non-Emergency: The entity shall develop, maintain and document implementation of written policies and procedures that govern the process utilized to provide temporary take home medication for exceptional circumstances, which shall at a minimum include the following specifications:

(I) The need for temporary special unsupervised take-home medication shall be clearly delineated with verifiable documentation in the clinical record.

(II) A client seeking approval for temporary special unsupervised take-home medication shall, at a minimum, meet the criteria to determine eligibility for take home medication specified in Rule 580-9-44-.29 9.

(III) Requests for temporary special take-home medication shall be approved in writing by the entity's medical director, the State Opioid Treatment Authority and SAMHSA.

(IV) The provision and supply of temporary special unsupervised take-home medication shall be at the direction of the State Opioid Treatment Authority.

(v) Temporary Special Take-Home Medication for Emergency: The entity shall develop, maintain and document implementation of written policies and procedures that govern the process utilized to provide emergency take-home medication for exceptional circumstances, which at a minimum include:

(I) The need for emergency unsupervised take-home medication shall be clearly delineated with verifiable documentation in the client's clinical record.

(II) Requests for emergency take-home medication shall be approved in writing by the entity's Medical Director and shall not exceed a three (3) day medication supply at any one time.

I. Situations that might warrant emergency take-home medication include:

A. Death in the family.

B. Illness.

C. Inclement weather.

D. Other uniquely identified situations.

(vi) Hardship Waiver. The entity shall develop, implement and document implementation of written policies and procedures to address requests for hardship exceptions to the rules for early phase advancement:

(I) Specify the conditions under which a client may request a hardship waiver and the conditions required for its consideration.

(II) Describe the process utilized to ensure continuity of care when a client is unable, due to a verifiable hardship, to report to the program for routine ingestion of medication.

(III) Describe the program's use of Chain-of Custody Record procedures and identify the specific persons/positions responsible in each step of the process, along with the specifications of their duties.

(IV) Include provisions for hardship exception requests to be authorized by the entity's medical director and submitted to the State Opioid Treatment Authority and to SAMHSA for review and approval.

(V) Provide for all considerations given, recommendations for and conditions of hardship waivers, as well as, denials of such to be documented in the clinical record.

(vii) Denial or Rescinding of Take Home Privileges. The entity shall develop, maintain and document implementation of policies and procedures which govern the process utilized to deny or rescind approval of take-home privileges.

10. Diversion Control: The entity shall develop, maintain and document implementation of a written plan to reduce the possibility of diversion of controlled substances from legitimate treatment to illicit use. The diversion control plan shall, at a minimum, include the following elements:

(i) A process for routine surveillance and monitoring of the internal and external treatment environment to identify diversion problems.

(ii) A process for continuous examination of dosing and take-home dispensing practices to identify weaknesses in the dispensing of medication that could lead to diversion problems.

(iii) Procedures for clients who are dispensed three (3) or more take home doses to receive a minimum of two (2) call-backs annually.

(iv) A process to address identified diversion problems through corrective and preventive efforts.

(v) Specific assignment to the entity's medical and administrative staff for implementation of the diversion control measures and functions identified in the diversion control plan.

11. Dosing: The entity shall develop, maintain and document implementation of written policies and procedures to govern the process of drug dispensing and administration that shall, at a minimum, include the following specifications:

(i) A standardized process that includes the use of identification by photograph shall be utilized to properly establish the identity of each individual before any Opioid Therapy Medication is administered.

(ii) The entity shall maintain current procedures adequate to ensure that each Opioid dependency treatment medication used by the program is administered and dispensed in accordance with approved product labeling.

(iii) Dosing and administration decisions, including prescribing, reassessment and regulation shall only be made by an authorized program physician who is familiar with the most up-to-date product labeling.

(iv) Any deviations from the approved labeling, including deviations with regard to dose, frequency, or the conditions of use described in the approved labeling shall be specifically documented in the case record.

(v) An authorized program physician shall employ clinical judgment to determine the individual dose of Opioid therapy medication, with consideration of the following stipulations, at a minimum:

(I) The initial dose of methadone administered on the first visit shall not exceed 25 mg.

(II) Subsequent doses of medication shall be:

I. Individually determined based upon the physician's evaluation of the history and present condition of the client.

II. Reviewed and updated as according to the client's treatment plan and in consideration of the following criteria:

A. Cessation of withdrawal symptoms.

B. Cessation of illicit Opioid use as measured by:

(A) Negative drug tests.

(B) Reduction of drug-seeking behavior.

C. Establishment of a blockade dose of an agonist.

D. Absence of problematic craving as measured by:

(A) Subjective report.

(B) Clinical observations.

E. Absence of signs and symptoms of too large an agonist dose after an interval adequate for the client to develop complete tolerance to the blocking dose.

(vi) A process shall be established wherein the dosage to be dispensed shall be verified with the current dosage ordered and ingestion observed and documented by the person who administers the Opioid dependency treatment medication.

(vii) Methadone shall be dispensed in oral form in one liquid or one dissolvable diskette dose per container.

(viii) Buprenorphine shall be dispensed in sub-lingual tablets.

(ix) A process shall be established to address the entity's response, in regard to dosing, to individuals who are objectively intoxicated or who are experiencing other problems that would render the administration of methadone unsafe.

12. Split Dosing: The organization shall have a written split dosage policy that shall:

(i) Include input from the program physician in consultation with the multidisciplinary treatment team and the SOTA.

(ii) Accurately reflect that split dosing is guided by outcome criteria that shall include:

(I) The client complains that the dosage level is not holding.

(II) The client exhibits signs and symptoms of withdrawal.

(III) The physician employs peak and trough criteria for split dosing, if appropriate.

(IV) The physician is unable to obtain a peak and trough ration for 2.0 or lower, increasing intervals of dosing may be appropriate.

(V) Addressing the failure of all avenues of stabilization.

(VI) Addressing stabilization failures with the client involving the physician and multidisciplinary team.

(iii) Include provisions for education of the client on the rationale for split dosing and take home medication.

13. Guest Dosing: The entity shall develop, maintain and document implementation of dosing policies and procedures for the provision of medication to a guest client in a program in which the client is not enrolled that shall, at a minimum specify:

(i) The sending program's responsibilities to, at a minimum:

(I) Develop a document to utilize in transmitting all relevant client and dosing information to the receiving agency to request guest dosing privileges.

(II) Forward this document to the receiving program.

(III) Provide the client with a copy of the document that was sent to the receiving agency.

(IV) Verify receipt of the information sent to the receiving program.

(V) Verify that the client understands all stipulations of the guest dosing process including, but not limited to, fees, receiving program contacts, dosing times and procedures.

(VI) Accept the client upon return from guest dosing unless other arrangements have been made.

(VII) Document all procedures implemented in the guest dosing process in each client's case record.

(ii) The receiving program's responsibilities to, at a minimum:

(I) Verify receipt of the sending program's request for guest dosing privileges and acceptance or rejection of the client for guest medication within forty-eight (48) hours of the request.

(II) Communicate any requirements of the receiving program that have not been specified on the document submitted by the sending program.

(III) Establish a process for medical personnel to verify dose prior to dosing.

(IV) Document all procedures implemented in the guest dosing process in each client's case record.

(iii) If guest dosing exceeds fourteen (14) days, a drug screen shall be obtained.

(iv) Guest dosing shall not exceed twenty-eight (28) days.

14. Multiple Client Enrollments: The entity shall develop, maintain and document implementation of written policies and procedures established to insure that it does not admit or provide medication for an individual who is enrolled in another Opioid Treatment Program. The policies and procedures shall include the following components, at a minimum:

(i) The State Opioid Treatment Authority shall establish written guidelines, incorporated herein by reference, for participation in a central registry process to aid in the prevention of multiple enrollment of a client in more than one Opioid Maintenance Therapy Program at the same time. Each OMT Program shall provide written documentation of adherence to the State Opioid Treatment Authority guidelines that shall, at a minimum, include the following specifications:

(I) The entity shall make a disclosure to the central registry at each of the following occurrences:

I. A client is admitted for Opioid Maintenance Therapy.

II. A client is transferred to another provider for Opioid Maintenance Therapy.

III. A client is discharged from Opioid Maintenance Therapy.

(II) The entity shall make disclosures in the format and within timeframes established by the State Methadone Authority.

(III) The entity shall limit disclosures to client identifying information and the dates of admission, transfer and discharge.

(IV) The entity shall obtain the client’s written consent, in accordance with 42 CFR Part 2, prior to making any disclosures to the central registry.

(V) The entity shall inform each client of the required written consent for participation in the central registry before services are initiated.

(VI) The entity shall deny admission to individuals who refuse to provide written consent for disclosures to the central registry and shall document these denials in the case record.

(ii) The entity shall obtain the client’s written consent, in accordance with 42 CFR Part 2, to photograph the applicant at the time of admission. The photograph shall be maintained in the client’s case record.

(iii) The entity shall require that all clients show proof of identification in the form of an official state driver's license or a non-driver's license issued by the state's Department of Public Safety. A copy of current identification will be maintained in the clinical record.

15. Medically Supervised Withdrawal: The entity shall develop, maintain and document implementation of written policies and procedures that govern the processes utilized to withdraw clients from Opioid maintenance medication. At a minimum, the policies and procedures shall include the following specifications:

(i) A process for voluntary medically supervised withdrawal shall be established that shall:

(I) Acknowledge that participation in Opioid Maintenance Therapy is voluntary and that a client is free to leave treatment at any time.

(II) Identify the steps to be taken by the entity when a client and program personnel agree on a need to initiate withdrawal procedures.

(III) Identify the steps to be taken by the entity when the client requests withdrawal against the medical advice of the program's personnel.

(IV) Ensure the availability of a variety of supportive options to improve the chances of a successful episode of medically supervised withdrawal.

(V) Establish the protocol wherein the Opioid Maintenance Therapy Program resumes medication assisted treatment if the client experiences impending or actual relapse.

(ii) A process for involuntary medically supervised withdrawal shall be established that shall:

(I) Identify the circumstance under which involuntary administrative withdrawal procedures will be implemented.

(II) Identify the steps to be taken and delineate the responsibilities of program personnel in implementation of involuntary administrative withdrawal procedures.

(III) Ensure the availability of a variety of supportive options to improve the chances of a successful episode of medically supervised withdrawal.

(IV) Provide for referral or transfer of the client to an appropriate treatment program upon completion of the withdrawal process.

(iii) The entity's medical director shall approve all requests for voluntary and involuntary withdrawal from Opioid Therapy medication.

(iv) Clients who have been determined by the program's medical director or other authorized program physician to be currently physiologically dependent on Opioids may participate in medically supervised withdrawal, regardless of age.

(v) The entity's medical director shall establish each individual's withdrawal schedule in accordance with sound medical treatment and ethical considerations.

(vi) No set dosage reduction schedules shall be established for any patient whether voluntarily or involuntarily

participating in medically supervised withdrawal. Dosage reduction schedules shall be based upon objective assessment of each client's unique needs.

(vii) A medically supervised withdrawal schedule for administrative withdrawal shall be for a time period of not less than thirty (30) days, unless otherwise clinically contraindicated. In cases of clinical contraindication, supporting documentation shall be entered in the client's case record by the medical director or a program physician operating under the supervision and authority of the medical director.

(viii) Take-home medications shall not be allowed during medically supervised withdrawal.

(ix) A history of one (1) year physiologic dependence shall not be required for admission to an Opioid Maintenance Therapy Program for supervised withdrawal.

(x) Clients who have two (2) or more unsuccessful detoxification episodes within a twelve (12) month period shall be assessed by the entity's medical director for other forms of treatment.

(xi) An entity shall not admit a client for more than two (2) detoxification episodes in one (1) year.

(xii) Drug screens during detoxification shall be performed as follows:

(I) An initial drug screen shall be performed at the beginning of the detoxification process.

(II) At least one (1) random screen shall be performed monthly during the detoxification process.

16. Women and Pregnancy Services: The entity shall develop, maintain and document implementation of written policies and procedures to address the needs of women which shall, at a minimum, include the following requirements:

(i) The entity shall acknowledge by policy and practice that pregnant women are the number one treatment priority and cannot be denied treatment access solely because of pregnancy.

(I) When an organization is unable to provide services for a pregnant woman, the State Opioid Treatment Authority shall be contacted immediately for assistance with placement.

(ii) The entity shall have a written description of the procedures utilized to:

(I) Inform each female client of the possible risks and benefits of the use of Opioid Maintenance Therapy during pregnancy.

(II) Document in the case record that this information has been provided to the client.

(iii) The entity shall describe in writing and document implementation of the process used to provide pregnant clients with access or referral to:

(I) Prenatal care.

(II) Pregnancy/parenting education.

(III) Postpartum follow-up.

(iv) The nature of services provided in relation to a client's pregnancy shall be documented in the case record and signed or countersigned by the entity's medical director.

(v) When the woman consents to a referral for pregnancy related care, or if the woman is already under the care of a physician for her pregnancy, the entity shall obtain the woman's informed consent to ensure reciprocity in the exchange of pertinent clinical information between the woman's perinatal specialist or obstetrician and the OMT Program.

(vi) When the woman refuses an appropriate referral for prenatal services, the entity shall:

(I) Utilize informed consent procedures to have the client formally acknowledge, in writing, that the Opioid Maintenance Therapy Program offered a referral to prenatal services, but the client refused the offer.

(II) Provide the client with basic prenatal instruction on maternal, physical, and dietary care as part of the Opioid Maintenance Therapy Program counseling services and document service delivery in the clinical record.

(vii) The entity shall provide written documentation of implementation of the following procedures in regard to care for pregnant women:

(I) Clients who become pregnant during treatment shall be maintained on the pre-pregnancy dosage, if effective as

determined by the entity's medical director and the client and shall apply the same dosing principles as used with any other non-pregnant person served.

(II) The initial methadone dose and the subsequent induction and maintenance dosing strategy for a person who is newly admitted and pregnant shall reflect the same effective dosing protocols used for all other persons served.

(III) The methadone dose shall be monitored carefully, especially during the third trimester and adjustments made as needed.

(viii) The entity shall describe in writing and document in the clinical record the process utilized if a pregnant woman elects to withdraw from methadone which shall, at a minimum, include the following requirements:

(I) A physician experienced in addiction medicine shall supervise the withdrawal process.

(II) Regular fetal assessments, as appropriate for gestational age, shall be part of the withdrawal process.

(III) Education shall be provided on medically supervised withdrawal and the impact of medically supervised withdrawal services on the health and welfare of unborn children.

(IV) Withdrawal procedures shall adhere to accepted medical standards of care for women who are pregnant.

(V) Withdrawal procedures shall adhere to accepted medical standards regarding adequate dosing strategies.

(VI) When providing medically supervised withdrawal services to pregnant women whose withdrawal symptoms cannot be eliminated, referrals to inpatient medical programs shall be made.

(ix) The entity shall describe in writing and document implementation of policies and procedures, including informed consent, to ensure appropriate post-pregnancy follow-up and primary care for the new mother and well-baby care for the infant.

17. Medication Management: The entity shall comply with all standards set forth in Rule 580-9-44-.13(23-24) of these rules, and, in addition, shall comply with the requirements of this section:

(i) The entity's clinical records and client outcomes shall indicate that medications used in the Opioid Maintenance Therapy Program are sufficient to:

(I) Produce the desired response.

(II) Provide freedom from adverse abstinence symptoms for the desired length of time.

(III) Block the effects of other Opiates without producing euphoria or other undesirable effects.

(ii) The program shall provide written documentation, which indicates all medications used in the Opioid Maintenance Therapy Program are:

(I) Approved by the Food and Drug Administration for the treatment of Opioid addiction.

(II) Dispensed according to product labeling.

(III) Managed using written procedures that ensure secure storage, accurate dosage and safe handling,

(IV) Controlled using a method to ensure that an accurate inventory of all medication in stock is available.

(iii) The entity shall develop, maintain and document implementation of written policies and procedures for dispensing medication used in Opioid Maintenance and Withdrawal Therapy, which shall, at a minimum:

(I) Ensure that the program's medical director or other program physician authorized by the medical director:

I. Initiates all medication orders and/or any dosage change.

II. Documents all medication orders and/or any dosage change in the clinical record.

(II) Ensures that each dose is recorded in the clinical record of the person served.

(III) Ensures that take-home medications are properly labeled, which shall include, at a minimum:

I. Name of Opioid Maintenance Therapy prescribing clinic.

II. Address of Opioid Maintenance Therapy prescribing clinic.

III. Telephone number of Opioid Maintenance Therapy prescribing clinic.

IV. Client’s name.

V. Medication name.

VI. Dose.

VII. Physician’s name.

VIII. Date filled.

IX. Directions for single use.

X. Warning: Caution; Federal law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed.

(iv) Ensure that that take-home medication is packaged in child-proof containers designed to reduce the risk of accidental ingestion.

18. Client Transfers: The Level I-O Program shall develop, maintain and document implementation of written policies and procedures to effect orderly transfer of clients between substance abuse programs, which shall, at a minimum, address the following specifications:

(i) The entity shall meet the standards set forth in these rules for client transfers.

(ii) A client’s request for transfer to another Level I-O Program shall be honored without restriction, even if the client has an outstanding financial balance.

(iii) Records to the receiving substance abuse program shall be provided promptly and shall include, at a minimum:

(I) Original date of admission for the current treatment episode.

(II) Current treatment phase and date entering phase.

(III) Urinalysis results for the past twelve (12) months.

(IV) Dose level, to be confirmed by nursing staff at transferring clinic and documented in the clinical record.

(V) Most recent TB test results and date of test.

(VI) Reason for transfer.

(VII) Other information as requested by the receiving program and specified in an appropriate client authorization for release of information.

(iv) All client records shall be complete and up to date at the time of transfer.

(v) Reports to the DMH Central Registry shall be completed at the time of transfer.

19. Documentation: The entity shall comply with all standards set forth in Rule 580-9-44-.13(21) of these rules, and, in addition, shall comply with the requirements of this section:

(i) Clinical records of clients receiving Opioid Maintenance or Withdrawal Therapy shall include the following documentation:

(I) That clients have been questioned about being pregnant and informed about pregnancy and physiological implications with Opiate maintenance drugs.

(II) Support services were recommended and utilized when needed.

(III) An individualized clinical note for each occurring clinical or medical encounter.

(IV) Each dose of medication administered, with a copy of the physician’s order for medication.

(V) Ongoing communication with physicians prescribing psychoactive and/or control medication to clients receiving Opioid Maintenance Therapy services.

(VI) Ongoing communication with Obstetrics and Gynecology physicians providing medical care to pregnant women receiving Opioid Maintenance Therapy services.

20. Support Systems: The entity shall develop, maintain and document implementation of written policies and procedures that define the process utilized to provide client access to support services.

(i) Support services shall include, at a minimum:

(I) Linkage with or access to psychological, medical and psychiatric consultation.

(II) Linkage with or access to emergency medical and psychiatric care.

(III) Linkage with or access to evaluation and ongoing primary medical care.

(IV) Ability to conduct or arrange for appropriate laboratory and toxicology tests.

(V) Direct affiliation with or coordination through referral to more and less intensive levels of care.

(ii) The entity shall maintain up-to-date, written Memoranda of Understanding, collaborative agreements or referral agreements with support systems.

21. Staffing:

(i) Program Sponsor: The Level I-O Program shall have a program sponsor who shall be an Alabama Licensed Practitioner of the Healing Arts with at least two (2) years supervised work experience in a substance related disorders treatment program.

(I) The entity shall provide written documentation of the program sponsor's responsibilities and the processes through which they are implemented, which shall, at a minimum, include:

I. Ensure compliance with all Federal, State and local laws and regulations regarding the use of Opioid agonist treatment medications in the treatment of Opioid addiction.

II. Assume responsibility for all Level I-O Program employees, including all practitioners, agents, or other persons providing medical, rehabilitative, or counseling services at the program.

III. Assign duties of the program coordinator.

IV. Meet the qualifications of a staff member and be included in the listing of personnel authorized access to the medication unit where he/she has access to the medication unit.

(ii) Program Coordinator: The Level I-O Program shall have a full-time program coordinator.

(I) The Opioid Maintenance Therapy Program coordinator shall be:

I. An Alabama licensed Registered Nurse, Nurse Practitioner, Physician, or Physician's Assistant, who has two (2) years direct care substance related disorders treatment experience, or

II. An individual with a master's degree in a behavioral health related field and at least two (2) years direct care substance use disorders treatment experience.

(II) The entity shall provide written documentation of the program coordinator's responsibilities and the processes through which they are implemented, which shall include, at a minimum:

I. Manage the day to day operation of the program as according to duties delegated by the program sponsor.

II. Maintain regular office hours, which coordinate with the operation of the program.

III. Be readily accessible to the State Opioid Treatment Authority.

(iii) Medical Director: The Level I-O Program shall have a medical director who shall be a physician who is licensed to practice in the State of Alabama and who has a minimum of one (1) year experience in the treatment of Opioid dependency.

(I) The entity shall provide written documentation of the medical director's responsibilities and the processes through which they are implemented, which shall, at a minimum, include:

I. Administration of all Level 1-0 medical services performed by the program.

II. Ensure that the Level I-O Program complies with all applicable federal, state and local laws and regulations relative to medical care.

III. Attend weekly staffings with counselors, or document in the client record alternative and equivalent supervisory contact on a weekly basis.

A. When the medical director is unable to attend a weekly staffings, the entity must date the occurrence and provide

written documentation of how equivalent supervisory contact was accomplished, e.g. by phone, electronic correspondence, etc.

IV. Maintain ongoing communication with clients' physicians regarding the prescription of psychoactive and/or control medication during Opioid Maintenance Therapy, and to coordinate client care in regard to other medical needs.

V. Maintain ongoing communication with Obstetrics and Gynecology physicians when providing Opioid Maintenance Therapy services to pregnant women.

VI. Perform client physical examinations prior to dosing and provide thorough documentation of each client's Opioid dependency at the time of admission.

VII. Perform annual client physical examinations.

VIII. Authorize:

A. All initial dose orders.

B. All dose and phase changes.

C. All take-home medications.

D. All changes in frequency of take-home medications.

E. Opioid withdrawal protocols.

IX. Delegate responsibility for medical care and procedures to other Opioid Maintenance Therapy Program physicians and physician extenders.

(II) The entity shall provide written documentation that the Level I-O Program's medical director, or a staff physician supervised and assigned by the medical director, is physically present in the clinic a minimum of two (2) hours per week for each fifty (50) clients enrolled in the program.

(iv) Pharmacist: The level I-O Program shall have an Alabama licensed pharmacist on its staff.

(I) The entity shall provide written documentation of the pharmacist's responsibilities and the processes through which they are implemented, which shall, at a minimum, include:

I. Prepare all take-home medication.

II. Conduct, at a minimum, an annual physical drug inventory.

III. Assist in the development of program policies and procedures governing medication administration, dispensing, use and security.

(v) Nursing Personnel: The entity shall have an adequate number of Alabama licensed nurses to assure that all medications utilized during Opioid Maintenance and Withdrawal Therapy are administered in compliance with Alabama Board of Nursing regulations.

(i) Supervise and delegate responsibilities to the Licensed Practical Nurses (LPNs) on staff.

(ii) There shall be a Registered Nurse (RN) or Licensed Practical Nurse (LPN) on site during all hours of the Level 1-0 Program's operation.

(vi) Clinical Supervision: The entity shall have a clinical director who shall provide routine clinical supervision of each Level I-O Program employee who provides treatment and recovery support services.

(vii) All direct care personnel shall have the qualifications as a qualified paraprofessional to provide the specific services delineated in the entity's program description for this level of care.

(viii) The entity shall document the daily availability of an adequate number of personnel to sustain the Level I-O Program as delineated in its operational plan and the rules specified, herein.

(ix) All clients will be assigned to the caseload of a primary counselor. The caseload of each primary counselor shall not exceed forty (40) individuals.

(x) The entity shall document the daily availability of the medical director, or a physician under the supervision and authority of the medical director, during medication dispensing and clinic operating hours, either in person or by telephone.

(xi) The entity shall establish a written protocol for notifying the State Opioid Treatment Authority, within forty-eight (48) hours, of any replacement or other change in the status of the program sponsor or medical director.

22. Training. The entity shall provide written documentation that:

(i) All Level I-O Program personnel complete the core training curriculum, as specified in Rule 580-9-44-.02(3).

(ii) The entity shall provide written documentation that all clinical and medical services staff in a Level I-O Program receive training during the initial twelve (12) months employment and develop basic competencies in the following areas:

(I) Opioid addiction treatment methodologies.

(II) Regulatory requirements for Opioid addiction treatment.

(III) Biopsychosocial dimensions of alcohol and drug use disorders.

(IV) Motivational and engagement strategies.

(V) Pharmacotherapy for Opioid dependency.

(VI) ASAM Patient Placement Criteria.

(VII) Assessment of and service planning to address biopsychosocial needs of individuals with Opioid dependency and related disorders.

(iii) Physicians who dispense methadone and other Opiate replacement drugs must receive a minimum of eight (8) hours of training each year relevant to Opioid Maintenance Therapy approved by SAMHSA and the State Opioid Treatment Authority.

23. Service Intensity: The entity shall develop, maintain and document implementation of written policies and procedures relative to Level I-O service intensity, which shall, at a minimum, include the following specifications:

(i) The dose and intensity of Level I-O Treatment Services shall be established on the basis of the unique assessed needs of each client served.

(ii) The program shall demonstrate appropriate staffing to provide core counseling services.

(I) Issues identified through the assessment and ongoing reassessment process must be addressed directly in a therapeutic setting or referred to an appropriate, qualified entity.

(II) If no clinical services are indicated for a client, appropriate identification shall be documented in the clinical record.

(III) In no case shall counseling services be scheduled less frequent than one session (individualized or group) per month.

24. Length of Service: The entity shall provide written documentation that the duration of treatment in each Level I-O Program shall vary as determined by:

(i) The severity of the client's illness.

(ii) The client's ability to comprehend the information provided and use that information to implement treatment strategies and attain treatment goals.

(iii) The appearance of new problems that require another level of care.

(iv) The client's desire to continue treatment.

Author: Substance Abuse Services Division
Statutory Authority: Code of Ala. 1975, §22-50-11.
History: **New Rule:** Filed January 26, 2012; effective March 1, 2012.