

TITLE 8 SOCIAL SERVICES
CHAPTER 321 SPECIALIZED BEHAVIORAL HEALTH SERVICES
PART 10 OPIOID TREATMENT PROGRAMS

8.321.10.1 ISSUING AGENCY: New Mexico Health Care Authority.
[8.321.10.1 NMAC - N, 7/1/2024]

8.321.10.2 SCOPE: This rule is applicable to opioid treatment programs. These regulations are not intended to preempt county or municipal ordinances that supplement and do not conflict with these regulations. County and municipal ordinances are preempted when they conflict with these regulations.
[8.321.10.2 NMAC - N, 7/1/2024]

8.321.10.3 STATUTORY AUTHORITY: Section 9-8-1 et seq. NMSA 1978 establishes the health care authority (authority) as a single, unified department to administer laws and exercise functions relating to health care facility licensure and health care purchasing and regulation.
[8.321.10.3 NMAC - N, 7/1/2024]

8.321.10.4 DURATION: Permanent.
[8.321.10.4 NMAC - N, 7/1/2024]

8.321.10.5 EFFECTIVE DATE: July 1, 2024, unless a later date is cited at the end of a section.
[8.321.10.5 NMAC - N, 7/1/2024]

8.321.10.6 OBJECTIVE: This rule establishes standards for opioid treatment programs to be consistent with the SAMHSA/CSAT regulations and the OTP accreditation requirements of nationally recognized accreditation bodies approved by SAMSA/CSAT, such as CARF and JCAHO. The intent is to:

- A.** be consistent with, and complimentary to, the substance abuse and mental health services administration/center for substance abuse treatment (SAMHSA/CSAT) regulations, and the OTP accreditation requirements of nationally recognized accreditation bodies approved by SAMHSA/CSAT, such as commission on accreditation of rehabilitation facilities (CARF) and the joint commission on accreditation of healthcare organizations (JCAHO);
 - B.** reduce the stigma sometimes associated with opioid dependency treatment and ensure access to it comparable to treatment availability for other chronic medical conditions;
 - C.** consider the possible adverse impact on communities in which OTP providers are located in making application approval decisions, and to provide measures to promote mutually satisfactory relationships between OTP providers and their communities.
- [8.321.10.6 NMAC - N, 7/1/2024]

8.321.10.7 DEFINITIONS:

- A.** **“Accrediting bodies”** means nationally recognized organizations, such as the joint commission on accreditation of healthcare organizations (JCAHO) and the commission on accreditation of rehabilitation facilities (CARF), which promulgate standards for OTPs that are approved by the substance abuse and mental health services administration/center for substance abuse treatment (SAMHSA/CSAT), and offer accreditation to programs that meet these standards.
- B.** **“Administrative withdrawal”** means the procedure for withdrawal of a patient’s opioid treatment medication coinciding with the patient’s involuntary discharge from opioid treatment, typically resulting from non-payment of fees, violent or disruptive behavior or incarceration or other confinement.
- C.** **“Application form”** means the form created by the health care authority, which must be completed by a program sponsor who wishes to obtain approval to operate an opioid treatment program.
- D.** **“Approval” and “approval to operate”** means the written permission given by the health care authority to a program sponsor to operate an opioid treatment program.
- E.** **“Behavioral health services division”** (BHSD) is the division of the New Mexico health care authority that is the single state authority for mental health and substance use treatment and prevention programs and methadone authority.
- F.** **“Comprehensive initial assessment”** means the collection and analysis of a patient’s social, medical, psychological and treatment history.

G. “Comprehensive maintenance treatment” means a program designed with the intention of lasting longer than six months, for the purpose of maintaining the patient such that they will be free of opioid withdrawal and cravings; such programs are typified by:

(1) dispensing or administering an opioid treatment medication at stable dosage levels for a period in excess of 21 days to an individual for opioid addiction; and
(2) providing medical, therapeutic and supportive services to the individual with opioid dependence.

H. “Dispense” has the same meaning as in Subsection I of Section 61-11-2 NMSA 1978 as amended or renumbered.

I. “Diversion” means the unauthorized transfer of an opioid agonist treatment medication, such as a street sale.

J. “Dosage” means the amount, frequency and number of doses of medication for an individual.

K. “Dose” means a single unit of opioid treatment medication.

L. “Illicit opioid drug” means an illegally obtained opioid drug, such as heroin, that causes dependence and reduces or destroys an individual’s physical, social, occupational, or educational functioning, or misuse of legally prescribed medication.

M. “Intake screening” means determining whether an individual meets the initial criteria for receiving opioid treatment.

N. “Long-term opioid treatment withdrawal procedure” means a treatment program designed to dispense opioid treatment medication to a patient in decreasing doses, after first possibly achieving a stable dose, for a period of more than 30 days but less than 180 days as a method of bringing the individual to a drug-free state.

O. “Medical practitioner” means an individual who:

(1) has been accredited through appropriate national procedures as a health professional;
(2) fulfills the national requirements on training and experience for prescribing procedures;
(3) is a registrant or a licensee, or a worker who has been designated by a registered or licensed employer for the purpose of prescribing procedures;
(4) may be a physician, physician’s assistant, registered nurse, nurse practitioner, or licensed practical nurse.

P. “Opioid treatment” means:

(1) opioid treatment withdrawal procedure/treatment; and
(2) comprehensive maintenance treatment.

Q. “Opioid treatment medication” means a prescription medication that is approved by the U.S. food and drug administration under 21 U.S.C. section 355 and by the code of federal regulations title 42, part 8.12 for use in the treatment of opiate addiction.

R. “Opioid treatment program” (OTP) means a single location at which opioid dependence treatment medication, such as methadone and rehabilitative services, are provided to patients as a substantial part of the activity conducted on the premises.

S. “Opioid treatment withdrawal procedure” is dispensing or administering an opioid dependence treatment medication in decreasing medication levels 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.

T. “Physiologically dependent” means physically addicted to an opioid drug, as manifested by the symptoms of withdrawal in the absence of the opioid drug.

U. “Program clinician” means a behavioral health clinician practicing at an opioid treatment program who is licensed to practice substance abuse treatment in New Mexico

V. “Program medical director” means a physician licensed to practice medicine in New Mexico, who assumes responsibility for administering all medical services, either by performing them directly or by delegating specific responsibility to authorized program medical practitioners functioning under the medical director’s direct supervision.

W. “Program sponsor” means the person named in the application as responsible for the operation of the opioid treatment program and who assumes responsibility directly, by personal oversight, or through policy and procedure, or a combination of both, for the acts and omissions of staff members or employees of the opioid treatment program.

X. “Short-term opioid treatment withdrawal procedure” means a treatment program designed to dispense opioid treatment medication to a patient in decreasing doses, over a continuous period of 30 days or less, as a method of bringing the individual to a drug-free state.

Y. “State methadone authority,” (SMA) means the single state agency for substance abuse designated by the governor or another appropriate official designated by the governor to exercise authority within the state for governing treatment of opiate addiction with an opioid drug. In New Mexico it is the health care authority, behavioral health services division.

Z. “Take-home medication” means one or more doses of an opioid treatment medication dispensed to a patient for use off the premises.
[8.321.10.7 NMAC - N, 7/1/2024]

8.321.10.8 APPROVAL TO OPERATE AN OPIOID TREATMENT PROGRAM REQUIRED:

Providers who receive written approval by the health care authority, shall be permitted to provide opioid dependency treatment services.
[8.321.10.8 NMAC - N, 7/1/2024]

8.321.10.9 ELIGIBILITY FOR APPROVAL TO OPERATE AN OPIOID TREATMENT PROGRAM:

Only applicants who possess all of the following shall be eligible to receive approval to operate from the New Mexico health care authority (HCA):

- A.** drug enforcement agency (DEA) approval to operate an OTP;
- B.** SAMHSA/CSAT approval to operate an OTP;
- C.** accreditation by a SAMHSA/CSAT-approved nationally recognized accreditation body, such as JCAHO or CARF, to operate an OTP:

(1) if the applicant is a start-up program unable to obtain such accreditation prior to beginning operation because the accreditation body requires a period of program operation, typically six months, before it will grant accreditation:

(a) the HCA shall grant provisional approval to operate pending accreditation, provided that all other requirements of these regulations are met; and

(b) the program demonstrates in its application to the HCA that it is taking the steps necessary to become accredited as quickly as possible, and provides a timeline for the anticipated accreditation;

(2) during this interim period, the provisional approval to operate is contingent on the ongoing progress of the program, as determined by the HCA, to obtain accreditation within the timeline contained in the application; the program shall immediately inform the HCA of anything that will delay or prevent accreditation according to that timeline;

(3) the HCA shall withdraw its provisional approval if it concludes that accreditation will not be forthcoming; in any event, the program shall obtain accreditation within 12 months of beginning operation, or the provisional approval shall be withdrawn, unless the HCA elects to extend the provisional approval period after consultation with the appropriate federal and accrediting entities.

D. a license from the New Mexico state board of pharmacy to operate an OTP;

E. other permits and licenses such as a business license from the applicant’s local governmental entity, as required by local ordinances;

F. evidence of appropriate liability insurance coverage for the program and its employees.

[8.321.10.9 NMAC - N, 7/1/2024]

8.321.10.10 APPLICATION FOR APPROVAL TO OPERATE AN OPIOID TREATMENT PROGRAM:

A. Each OTP sponsor applicant shall submit to the HCA an application for approval to operate an opioid treatment program application using the form provided by the HCA. This application shall be in addition to the application to drug enforcement agency, SAMHSA/CSAT, the NM board of pharmacy, local government, etc.

B. The HCA shall approve or deny the application within 45 working days of submission, unless the HCA and applicant mutually agree to extend the application review period.

C. The HCA may require the applicant to provide additional written or verbal information in order to reach its decision to grant or deny approval. Such further information shall be considered an integral part of the application.

D. Approval shall be for a duration of three years, except as otherwise provided below for initial grandfathered approvals.

E. The HCA shall not grant approval to operate an OTP to any program sponsor who has been convicted of any crime related to controlled substances laws or any felony within the last five years. No person who

has been convicted of any felony in the last five years shall be employed by the OTP in any capacity that gives that person access to controlled medications.

F. The HCA shall not grant approval to any entity that poses a risk to the health and safety of the public based on a history of noncompliance with state and federal regulations as verified by the DEA, New Mexico state board of pharmacy, FDA, SAMSHA approved accreditation bodies, or the state licensure agency in any state in which the program sponsor currently operates.

G. The HCA may deny approval if there is a documented history of repeated and serious negative neighborhood impact with respect to other OTP programs currently operated by the program sponsor or by any corporation, LLC or partnership with whom the program sponsor has been associated in the past five years.

H. As a condition of approval to operate an OTP, the OTP must maintain or obtain accreditation with a SAMHSA/CSAT-approved nationally recognized accreditation body, (e.g. CARF or JCAHO.) In the event that such accreditation lapses, or approval of an application for accreditation becomes doubtful, or continued accreditation is subject to any formal or informal finding of need for improvement, the OTP program will notify the HCA within two business days of such event. The OTP program will furnish the HCA with all information related to its accreditation status, or the status of its application for accreditation, upon request.

I. The application for approval shall be accompanied by a needs assessment, specifying the proposed geographical area to be served, estimated number of patients anticipated, and such other information as may assist the HCA in review of the application. The HCA shall take into consideration in making its decision the need for an OTP in a given geographic area and the impact on the community.

J. The HCA shall perform on-site inspection of the proposed OTP facility as part of the review and approval process.

K. In the event of change of ownership of an approved opioid treatment program, the HCA approval is not transferable; the new ownership must institute an application for approval as a new program, in accordance with these regulations.

[8.321.10.10 NMAC - N, 7/1/2024]

8.321.10.11 DENIAL OF HCA APPROVAL TO OPERATE; APPEAL OF DENIAL:

A. The HCA shall not deny approval to operate until the applicant has been notified in writing of the deficiency in the application resulting in the contemplated denial, and given opportunity to remedy the application deficiency within a specified time period.

B. The HCA shall provide a written explanation for any denied application. Denial may be appealed to the secretary of the HCA, whose decision shall be final.

C. An applicant who is denied approval may re-apply by submitting a new application 90 days or more after notification of denial.

D. Failure to complete the application form in its entirety, including requests for additional information as specified above, shall be grounds for denial of approval.

[8.321.10.11 NMAC - N, 7/1/2024]

8.321.10.12 RENEWAL OF HCA APPROVAL TO OPERATE:

A. OTP providers who wish to renew their approval shall submit an application form and requested documentation no less than 90 calendar days, and no more than 180 calendar days, before its expiration date.

B. The HCA shall consider the operating history of the OTP provider in making its determination to grant or deny an application to a previously approved provider.

[8.321.10.12 NMAC - N, 7/1/2024]

8.321.10.13 APPROVAL FOR OTPS IN EXISTENCE PRIOR TO THESE REGULATIONS: Opioid treatment programs operating in New Mexico prior to the effective date of these regulations shall be granted approval on the effective date of these regulations (“grandfathered in”).

A. The term of these initial grandfathered approvals shall be not less than 24 months nor more than 36 months, and may have staggered expiration dates to avoid simultaneous expiration.

B. “Grandfathered” opioid treatment programs shall provide the HCA with all written policies, procedures and other documentation required of new opioid treatment programs under these regulations within 45 days of the effective date of these regulations.

[8.321.10.13 NMAC - N, 7/1/2024]

8.321.10.14 RENEWAL OF GRANDFATHERED OPERATING PERMITS: Renewal of grandfathered approvals shall follow the ordinary renewal process. Such approvals shall have a term of 36 months.
[8.321.10.14 NMAC - N, 7/1/2024]

8.321.10.15 INSPECTION AUTHORITY: The HCA shall have the authority to conduct inspections of the records, policies, procedures, physical plant or any other aspect of an OTP for the purpose of determining its compliance with these regulations or the presence of any factor posing a danger to the health or welfare of its patients or the public. Failure of an OTP to cooperate with such inspection shall be grounds for immediate suspension of the approval.
[8.321.10.15 NMAC - N, 7/1/2024]

8.321.10.16 NONCOMPLIANCE WITH REGULATIONS:

- A.** If an inspection conducted by the HCA shows that an OTP is not in compliance with these regulations, the HCA shall deliver to the program a written notice of the deficiencies identified.
 - B.** The program shall respond to the notification of deficiencies within 30 days of the notification. The program response shall include a corrective action plan together with timeline for implementation, or an explanation, satisfactory to the HCA, of the reason for any deviations from the requirements of these regulations.
 - C.** Failure of the OTP to respond within 30 days of receipt of the notification of deficiencies shall be grounds for immediate suspension of the approval.
- [8.321.10.16 NMAC - N, 7/1/2024]

8.321.10.17 IMMEDIATE SUSPENSION OF OTP OPERATING APPROVAL:

- A.** The HCA, at its discretion, may immediately suspend the approval of any OTP found to be in a substantial violation of this regulation that results in danger to the health and welfare of any patient or of the public, until such time as the violation(s) are corrected to the satisfaction of the HCA.
 - B.** In the event of such suspension, the OPT shall immediately:
 - (1) cease accepting new patients; and
 - (2) consult with the HCA regarding the orderly transfer of patients to other OTPs and implementation of the program closure action plan required under the “preparedness planning” section of these regulations in order to minimize adverse impact on its patients; notwithstanding the suspension of the approval, the HCA may allow the OTP to conduct limited operations of its program as the HCA finds necessary to minimize adverse impact on patients.
- [8.321.10.17 NMAC - N, 7/1/2024]

8.321.10.18 ADMINISTRATION: The program sponsor shall ensure that:

- A.** a physician licensed to practice in New Mexico is designated to serve as medical director and to have authority over all medical aspects of opioid treatment;
- B.** the medical director is responsible for ensuring that the OTP is in compliance with all applicable federal, state and local laws and regulations;
- C.** the OTP shall be open for patients every day of the week except for federal and state holidays, and Sundays, and be closed only as allowed in advance in writing by CSAT and the state methadone authority;
- D.** written policies and procedures are developed, implemented, complied with and maintained at the OTP and include:
 - (1) procedures to prevent a patient from receiving opioid dependency treatment from more than one agency or physician concurrently;
 - (2) procedures to meet the unique needs of diverse populations, such as pregnant women, children, individuals with communicable diseases, (e.g. hepatitis C, tuberculosis, HIV or AIDS), or individuals involved in the criminal justice system;
 - (3) procedures for conducting a physical examination, assessment and laboratory tests;
 - (4) procedures for establishing substance abuse counselor caseloads, based on the intensity and duration of counseling required by each patient;
 - (5) criteria for when the patient’s blood serum levels should be tested and procedures for having the test performed;
 - (6) procedures for performing laboratory tests, such as urine drug screens or toxicological tests, including procedures for collecting specimens for testing;

- drugs;
- (7) procedures for addressing and managing a patient’s concurrent use of alcohol or other
 - (8) procedures for providing take home medication to patients;
 - (9) procedures for conducting opioid treatment withdrawal;
 - (10) procedures for conducting an administrative withdrawal;
 - (11) procedures for voluntary discharge, including a requirement that a patient discharged voluntarily be provided or offered follow-up services, such as counseling or a referral for medical treatment;
 - (12) procedures for making temporary or permanent transfer of a patient from the OTP to another OTP;
 - (13) procedures for receiving the temporary or permanent transfer of a patient from another OTP to the OTP;
 - (14) procedures to minimize the following adverse events:
 - (a) a patient’s loss of ability to function;
 - (b) a medication error;
 - (c) harm to a patient’s family member or another individual resulting from ingesting a patient’s medication;
 - (d) sales of illegal drugs on the premises;
 - (e) diversion of a patient’s medication;
 - (f) harassment or abuse of a patient by a staff member or another patient; and
 - (g) violence on the premises;
 - (15) procedures to respond to an adverse event, including:
 - (a) a requirement that the program sponsor immediately investigate the adverse event and the surrounding circumstances;
 - (b) a requirement that the program sponsor develop and implement a plan of action to prevent a similar adverse event from occurring in the future; monitor the action taken; and take additional action, as necessary, to prevent a similar adverse event;
 - (c) a requirement that action taken under the plan of action be documented; and
 - (d) a requirement that the documentation be maintained at the agency for at least two years after the date of the adverse event;
 - (16) procedures for infection control;
 - (17) criteria for determining the amount and frequency of counseling that is provided to a patient; procedures to ensure that the facility’s physical appearance is clean and orderly;
 - (18) a process for resolution of patient complaints, including a provision that complaints which cannot be resolved through the clinic’s process may be referred by either party to the HCA:
 - (a) the complaint process shall be explained to the patient at admission;
 - (b) the patient complaint process shall be posted prominently in its waiting area or other location where it will be easily seen by patients, and include the HCA contact information for use in the event that the complaint cannot be resolved through the clinic’s process.
 - E. a written quality assurance plan is developed and implemented;
 - F. all information and instructions for the patient are provided in the patient’s primary language, and, when provided in writing, are clear and easily understandable by the patient.

[8.321.10.18 NMAC - N, 7/1/2024]

8.321.10.19 ADMISSION:

A. The program sponsor shall ensure through policy and procedure that an individual is only admitted for opioid dependency treatment after the program medical director determines and documents that:

- (1) the individual meets the definition of opioid dependence using generally accepted medical criteria such as those contained in the diagnostic and statistical manual for mental disorders (DSM-IV or subsequent editions);
- (2) the individual has received a physical examination as required by Subsection D of 8.321.10.19 NMAC below; and
- (3) if the individual is requesting maintenance treatment, the individual has been addicted for at least 12 months before the admission, unless the individual receives a waiver of this requirement from the program medical director because the individual:
 - (a) was released from a penal institution within the last six months;
 - (b) is pregnant, as confirmed by the agency physician;

(c) was treated for opioid dependence within the last 24 months; or
(d) is under the age of 18, has had two documented unsuccessful attempts at short term opioid treatment withdrawal procedures or drug-free treatment within a 12-month period, and has informed consent for treatment provided by a parent, guardian, custodian or responsible adult designated by the relevant state authority.

B. A program sponsor shall ensure that an individual requesting long-term or short-term opioid treatment withdrawal treatment who has had two or more unsuccessful opioid treatment withdrawal treatment episodes within a 12-month period is assessed by the program medical director for other forms of treatment.

C. The OTP shall ensure that each patient at the time of admission:

- (1) provides written, voluntary, program-specific informed consent to treatment;
- (2) is informed of all services that are available to the patient through the program and of all policies and procedures that impact the patient's treatment; and
- (3) is informed of the following:
 - (a) the progression of opioid dependency and the patient's apparent stage of opioid dependence;
 - (b) the goal and benefits of opioid dependency treatment;
 - (c) the signs and symptoms of overdose and when to seek emergency assistance;
 - (d) the characteristics of opioid dependency treatment medication, such as its effects and common side effects, the dangers of exceeding the prescribed dose, and potential interaction effects with other drugs, such as other non-opioid agonist treatment medications, prescription medications, and illicit drugs;
 - (e) the requirement for a staff member to report suspected or alleged abuse or neglect of a child or an incapacitated or vulnerable adult according to state law;
 - (f) the requirement for a staff member to comply with the confidentiality requirements of title 42 CFR part 2 of the code of federal regulations, incorporated by reference;
 - (g) drug screening and toxicological testing procedures;
 - (h) requirements to receive take-home medication;
 - (i) testing and treatment available for HIV and other communicable diseases, the availability of immunization for hepatitis A and B, and the availability of harm reduction services;
 - (j) availability of counseling on preventing exposure to and transmission of human immunodeficiency virus (HIV), sexually transmitted diseases, and blood-borne pathogens;
 - (k) the patient's right to file a complaint with the program for any reason, including involuntary discharge, and to have the patient's complaint handled in a fair and timely manner.

D. A program sponsor shall ensure that the program medical director or medical practitioner designee conducts a complete, fully documented physical examination of an individual who requests admission to the program before the individual receives a dose of opioid dependency treatment medication, and that the physical examination includes:

- (1) reviewing the individual's bodily systems;
- (2) obtaining a medical and family history and documentation of current information to determine chronic or acute medical conditions such as diabetes, renal diseases, hepatitis, HIV infection, tuberculosis, sexually transmitted disease, pregnancy or cardiovascular disease;
- (3) obtaining a history of behavioral health issues and treatment, including any diagnoses and medications;
- (4) initiating the following laboratory tests:
 - (a) a mantoux skin test;
 - (b) a test for syphilis;
 - (c) a laboratory drug detection test for at least opioids, methadone, amphetamines, cocaine, barbiturates, benzodiazepines and other substances as may be appropriate, based upon patient history and prevailing patterns of availability and use in the local area;
- (5) recommending additional tests based upon the individual's history and physical condition, such as:
 - (a) complete blood count;
 - (b) EKG, chest X-ray, pap smear or screening for sickle cell disease;
 - (c) a test for hepatitis B and C; or
 - (d) HIV testing.
- (6) the full medical examination including test results must be completed within 14 days of admission to the program;

(7) a patient re-admitted within three months after discharge does not require a repeat physical examination unless requested by the program medical director.

E. A program sponsor shall ensure that the results of a patient's physical examination are documented in the patient record.

F. A patient may not be enrolled in more than one OTP program except under exceptional circumstances, such as residence in one city and employment that requires extended absences from that city, which must be documented in the patient chart by the medical directors of both programs:

(1) an OTP shall make and document good faith efforts to determine that a patient seeking admission is not receiving opioid dependency treatment medication from any other source, within the bounds of all applicable patient confidentiality laws and regulations;

(2) the OTP shall confirm that the patient is not receiving treatment from any other OTP, except as provided in Subsection F of 8.321.10.19 NMAC, within a 50 mile radius of its location, by contacting any such other program, or by using the central registry described in Subsection G of 8.321.10.19 NMAC, when established.

G. The HCA may establish an internet-based central registry of all persons in New Mexico who are current patients of a New Mexico OTP program, for the purpose of creating a system that prevents patients from surreptitiously receiving medication from more than one OTP. Each OTP as a condition of approval to operate shall participate in the central registry as directed by the HCA.

[8.321.10.19 NMAC - N, 7/1/2024]

8.321.10.20 ASSESSMENT AND TREATMENT PLANS: The program sponsor shall ensure that:

A. each patient receives a comprehensive intake assessment upon admission, conducted by a qualified professional, to determine the most appropriate combination of services and treatment, which results in an intake treatment plan based on the patient's goals; the results of the comprehensive intake assessment and the intake treatment plan are documented in the patient record within 24 hours of admission;

B. an individualized treatment plan shall replace the intake treatment plan within 30 days of admission or the third face-to-face contact with the client, and be documented in the patient record;

C. all updates or revisions to any treatment plan or assessment shall be documented in the patient record within seven working days;

D. all assessments and treatment plans shall include, but not necessarily be limited to:

(1) a description of the patient's presenting issue, identification of the patient's behavioral health symptoms and the behavioral health issue or issues that require treatment;

(2) a list of the medical services, including medication, needed by the patient, as identified in the physical examination;

(3) recommendations for further assessment or examination of the patient's needs if indicated;

(4) recommendations for treatment needed by the patient, such as psychosocial counseling or mental health treatment, if indicated;

(5) recommendations for ancillary services or other services needed by the patient, if indicated;

(6) the signature, professional credential, printed name, and date signed of the staff member conducting and developing the assessment, treatment plan, update or revision;

(7) in the case of updated or revised treatment plans, a summary of the patient's progress or lack of progress toward each goal on the previous plan and the program's response; and any new goals;

(8) the signature and date signed, or documentation of the refusal to sign, of the patient or the patient's guardian or agent or, if the patient is a child, the patient's parent, guardian, or custodian;

E. treatment plans shall be reviewed at least every 90 days for the first two years of continuous treatment, and at least every 6 months thereafter, in accordance with the program's established policy and procedure, and the treatment plan modified accordingly, except initial treatment plans must be replaced with individualized plans as provided for in Subsection B of 8.321.10.20 NMAC above;

F. adequate medical, psychosocial counseling, mental health, vocational, educational and other assessment and treatment services are fully and reasonably available to patients, either by the program directly, or through formal, documented referral agreements with other providers.

[8.321.10.20 NMAC - N, 7/1/2024]

8.321.10.21 DOSAGE: The program sponsor shall ensure that:

- A. a dose of opioid dependency treatment medication is administered only after an order from the program medical director;
- B. a patient's dosage of opioid dependency treatment medication is individually determined;
- C. a dose of opioid dependency treatment medication is sufficient to produce the desired response in a patient for the desired duration of time and with consideration for patient safety;
- D. a dose of opioid dependency medication is prescribed to meet a patient's treatment needs by:
 - (1) preventing the onset of subjective or objective signs of withdrawal for 24 hours or more;
 - (2) reducing or eliminating the drug craving that is experienced by opioid dependent individuals who are not in opioid treatment;
 - (3) a patient receiving comprehensive maintenance treatment receives an initial dose of opioid dependency treatment medication based upon the program medical director or medical practitioner designee's physical examination and with consideration for local issues, such as the relative purity of available illicit opioid drugs;
 - (4) a patient receiving methadone in comprehensive maintenance treatment receives an initial dose of methadone that does not exceed 30 milligrams; and
 - (a) if the patient's withdrawal symptoms are not suppressed after the initial dose of 30 milligrams, a patient receives an additional dose that does not exceed 10 milligrams only if a program clinician documents in the patient record that 30 milligrams did not suppress the patient's withdrawal symptoms; and
 - (b) if the patient's withdrawal symptoms are not suppressed by a total dose of 40 milligrams, a patient receives an additional dose only if the program medical director or medical practitioner designee documents in the patient record that 40 milligrams did not suppress the patient's withdrawal symptoms;
 - (5) a patient receiving buprenorphine in opioid treatment withdrawal procedure or comprehensive maintenance treatment receive an initial dose according to the instructions on the opioid dependency treatment medication package insert, and any deviation from the instructions is documented by the program clinician in the patient record;
 - (6) a patient receives subsequent doses of opioid dependency treatment medication:
 - (a) based on the patient's individual needs and the results of the physical examination and assessment;
 - (b) sufficient to achieve the desired response for at least 24 hours, with consideration for day-to-day fluctuations and elimination patterns;
 - (c) that are not used to reinforce positive behavior or punish negative behavior;
 - (d) as long as the patient benefits from and desires comprehensive maintenance treatment; and
 - (e) that are adjusted if a provider changes from one type of opioid dependency treatment medication to another.

[8.321.10.21 NMAC - N, 7/1/2024]

8.321.10.22 DRUG SCREENING: The program sponsor shall ensure that:

- A. staff members have knowledge of the benefits and limitations of laboratory drug detection tests and other toxicological testing procedures;
- B. a patient in comprehensive maintenance treatment receives at least eight random laboratory drug detection tests per year; short-term opioid withdrawal procedure patients receive at least one initial drug abuse test; long-term opioid withdrawal procedure patients receive an initial and monthly random tests; and other toxicological tests are performed according to written orders from the program medical director or medical practitioner designee;
- C. laboratory drug detection tests and other toxicological testing specimens are collected in a manner that minimizes falsification;
- D. laboratory drug detection tests for:
 - (1) opioids;
 - (2) methadone;
 - (3) amphetamines;
 - (4) cocaine;
 - (5) barbiturates;
 - (6) benzodiazepines; and
 - (7) other substances as may be appropriate, based upon patient history and prevailing patterns of drug availability and use in the local area;

E. the results of a patient's laboratory drug detection tests or other toxicological test and any action taken relating to the results are documented in the patient record.
[8.321.10.22 NMAC - N, 7/1/2024]

8.321.10.23 TAKE-HOME MEDICATIONS:

A. The program sponsor shall ensure that policies and procedures are developed, implemented, and complied with for the use of take-home medication and include:

- (1) criteria for determining when a patient is ready to receive take-home medication;
- (2) criteria for when a patient's take-home medication is increased or decreased;
- (3) a requirement that take-home medication be dispensed according to federal and state law;
- (4) a requirement that the program medical director review a patient's take-home medication regimen at intervals of no less than 90 days and adjust the patient's dosage, as needed;
- (5) procedures for safe handling and secure storage of take-home medication in a patient's home; and

(6) criteria and duration of allowing a physician to prescribe a split medication regimen.
B. Treatment program decisions on dispensing OTP medications to patients for unsupervised use, beyond that set forth in Subsection C of 8.321.10.23 NMAC below, shall be made by the program medical director, based on the following criteria:

- (1) absence of recent abuse of drugs, including alcohol;
- (2) regularity of program attendance;
- (3) length of time in comprehensive maintenance treatment;
- (4) absence of known criminal activity;
- (5) absence of serious behavioral problems at the program;
- (6) special needs of the patient such as physical health needs;
- (7) assurance that take-home medication can be safely stored in the patient's home;
- (8) stability of the patient's home environment and social relationships;
- (9) the patient's work, school, or other daily activity schedule;
- (10) hardship experienced by the patient in traveling to and from the program; and
- (11) whether the benefit the patient would receive by decreasing the frequency of program attendance outweighs the potential risk of diversion.

C. A patient in comprehensive maintenance treatment may receive a single dose of take-home medication for each day that a provider is closed for business, including Sundays and state and federal holidays.

D. A program sponsor shall ensure that take-home medication is only issued to a patient in compliance with the following restrictions:

- (1) during the first 90 days of comprehensive maintenance treatment, take-home medication is limited to a single dose each week, in addition to any doses received as described in Subsection C of 8.321.10.23 NMAC above;
- (2) during the second 90 days of comprehensive maintenance treatment, a patient may receive a maximum of two doses of take-home medication each week in addition to any doses received as described in Subsection C of 8.321.10.23 NMAC above;
- (3) during the third 90 days of comprehensive maintenance treatment, a patient may receive a maximum of three doses of take-home medication each week in addition to any doses received as described in Subsection C of 8.321.10.23 NMAC above;
- (4) in the remaining months of the patient's first year, a patient may receive a maximum of six days of take-home medication each week;
- (5) after one year of continuous treatment, a patient may receive a maximum two week supply of take-home medication;
- (6) after two years of continuous treatment, a patient may receive a maximum of one month's supply of take-home medication but must make monthly visits;
- (7) exceptions to the above take-home medication restrictions shall be made only as provided for in center for substance abuse treatment (CSAT) regulations and as approved by the state methadone authority.

E. A program sponsor shall ensure that a patient receiving take-home medication receives:

- (1) take-home medication in a child-proof container; and
- (2) written and verbal information on the patient's responsibilities in protecting the security of take-home medication.

F. The program sponsor shall ensure that the program medical director's determination made under Subsection B of 8.321.10.23 NMAC and the reasons for the determination are documented in the patient record.

G. In accordance with DEA regulations, the program shall not use U. S. mail or express services such as fedex or united parcel service to transport, furnish or transfer opioid treatment medication to any patient, agency, facility or person.

H. The program shall establish policy and procedure to provide for the safe and secure transportation of opioid treatment medication from its facility to another agency where the program's patient temporarily resides, (e.g., from the university of New Mexico's addiction and substance abuse program (ASAP) to the turquoise lodge treatment program.).

[8.321.10.23 NMAC - N, 7/1/2024]

8.321.10.24 WITHDRAWAL TREATMENT AND MEDICALLY SUPERVISED DOSE REDUCTION:

The program sponsor shall ensure that:

A. policies and procedures are developed, implemented, and complied with for withdrawal treatment and:

- (1) are designed to promote successful withdrawal treatment;
- (2) require that dose reduction occur at a rate deemed medically appropriate by the program medical director;
- (3) require that a variety of ancillary services, such as self-help groups, be available to the patient through the program or through referral;
- (4) require that the amount of counseling available to the patient be increased before discharge; and
- (5) require that a patient be re-admitted to the program or referred to another program if relapse occurs;

B. a patient's withdrawal treatment:

- (1) for a patient involved in comprehensive maintenance treatment, is only initiated as administrative withdrawal, or when voluntarily requested by the patient and approved by a program medical director; and
- (2) is planned and supervised by the program medical director;

C. before a patient begins withdrawal treatment, whether with or against the advice of the program medical director, the patient:

- (1) is informed by the program medical director or a medical practitioner designee:
 - (a) that the patient has the right to leave opioid treatment at any time; and
 - (b) of the risks of withdrawal treatment; and
- (2) upon request, receives a schedule for withdrawal treatment that is developed by the program medical director with input from the patient;
- (3) receives a copy of the program policy regarding withdrawal of opioid medication against medical advice and a verbal explanation of that policy;

D. if a patient who is receiving withdrawal treatment, other than a patient experiencing administrative withdrawal, appears to a staff member to relapse, the patient is permitted to begin comprehensive maintenance treatment, if otherwise eligible;

E. if a patient who has completed withdrawal treatment within the past 30 days appears to a staff member to relapse, the patient may be re-admitted without a physical examination or assessment with the consent of the program medical director;

F. a patient experiencing administrative withdrawal is referred or transferred to any program that is capable of or more suitable for meeting the patient's needs, and the referral or transfer is documented in the patient record;

G. the following information is documented in the patient record:

- (1) the reason that the patient sought withdrawal treatment or was placed on administrative withdrawal; and
- (2) the information and assistance provided to the patient in medical withdrawal or administrative withdrawal.

[8.321.10.24 NMAC - N, 7/1/2024]

8.321.10.25 COUNSELING AND MEDICAL SERVICES: The program sponsor shall ensure that:

- A. substance abuse counseling and behavioral health treatment planning is provided by a practitioner licensed in the state of New Mexico to provide behavioral health treatment services to each patient based upon the patient's individual needs, treatment plan and stage of readiness to change behavior;
- B. the program has substance abuse counselors in a number sufficient:
 - (1) to ensure that patients have access to counselors;
 - (2) to provide the treatment in patients' treatment plans; and
 - (3) to provide unscheduled treatment or counseling to patients;
- C. each patient seeking opioid treatment is screened for the presence of a co-occurring mental health disorder by means approved by the HCA, and if indicated, referred for assessment and possible treatment if the program is not able to provide mental health services; an OTP referring a patient to another provider for mental health assessment shall make and document its good faith efforts to follow up with that provider on the results of the referral, and to co-ordinate its treatment with any subsequent treatment by other providers, within the limits of all applicable laws and regulations pertaining to release of patient information and confidentiality;
- D. a program sponsor shall ensure that a patient is offered medical, psychiatric and psychological services, if needed, either at its program or through referral:
 - (1) if a patient receives medical, psychiatric or psychological services, from provider(s) not affiliated with the program, program staff members shall make a good faith effort to communicate and coordinate its treatment services with such provider, including monitoring and evaluating interactions between the patient's opioid treatment medication and medications used to treat the patient's mental disorder, if any;
 - (2) the OTP shall have a procedure to ensure that such good faith coordination efforts are made, in accordance with all state and federal laws and regulations for the release of patient records or information;
- E. a program sponsor shall make good faith efforts to establish effective working relationships with the relevant behavioral health treatment providers in its patient catchment area in order to facilitate patient access to the services available through those providers;
- F. a program sponsor shall ensure that a patient has access to a self-help group or support group, such as narcotics anonymous, either at the agency or through referral to a community group;
- G. treatment services are provided by appropriately licensed staff.

[8.321.10.25 NMAC - N, 7/1/2024]

8.321.10.26 DIVERSE POPULATIONS:

- A. The program sponsor shall ensure that:
 - (1) opioid treatment is provided regardless of race, ethnicity, gender, age, or sexual orientation;
 - (2) the program facility is compliant with the Americans with Disabilities Act (ADA);
 - (3) opioid treatment is provided with consideration for a patient's individual needs, cultural background, and values;
 - (4) provider staff members are culturally competent;
 - (5) unbiased language is used in the provider's print materials, electronic media, and other training or educational materials;
 - (6) HIV testing and education are available to patients either at the provider or through referral;
 - (7) a patient who is HIV-positive and who requests treatment for HIV or AIDS:
 - (a) is offered treatment for HIV or AIDS either at the provider or through referral;
 - (b) has access to an HIV- or AIDS-related peer group or support group and to social services either at the provider or through referral to a community group; and
 - (8) for patients with a communicable disease such as HIV, AIDS, or hepatitis C, the provider has a procedure for transferring a patient's opioid treatment to a non-program medical practitioner treating the patient for the communicable disease when it becomes the patient's primary health concern;
 - (9) an individual who requires administration of opioid treatment medication only for relief of chronic pain is:
 - (a) identified during the physical examination or assessment;
 - (b) not admitted for opioid medication treatment; and
 - (c) referred for medical services; and

(d) for a patient with a chronic pain disorder who is also physically dependent the OTP makes a good faith effort to coordinate treatment and services with the medical practitioner treating the patient for pain management.

B. A program sponsor shall ensure that a policy and procedure is developed, implemented, and complied with for the treatment of female patients, to include requirements that:

- (1) pregnancy tests shall be administered and reviewed for all women of childbearing age prior to initiating a opioid treatment withdrawal procedure or medically supervised withdrawal;
- (2) appropriate staff members be educated in the unique needs of female patients; and
- (3) each female patient be informed about or referred to an appropriate support group, at the provider or in the community.

C. The program sponsor shall ensure that a policy and procedure is developed, implemented, and complied with for the treatment of pregnant patients, to include:

- (1) a requirement that priority be given to pregnant individuals seeking opioid treatment;
- (2) a requirement that the reasons for a pregnant individual's denial of admission to a provider be documented;
- (3) a requirement that a pregnant patient be offered prenatal care to include fetal assessment either at the program or through referral to a non-program medical practitioner;
- (4) a requirement that the program communicate with any non-program medical practitioners who are providing prenatal care to a pregnant patient, to coordinate opioid treatment and prenatal care, in accordance with all state and federal laws and regulations for the release of patient records or information; and document all such communications in the patient records;
- (5) a requirement that a staff member make a good faith effort to educate a pregnant patient who refuses prenatal care services on the importance of prenatal care;
- (6) a requirement that a staff member obtain a written refusal of prenatal care services that are offered either directly by the program or by referral, from a pregnant patient who refuses such services or referral to such services;
- (7) a requirement that a pregnant patient receiving comprehensive maintenance treatment before pregnancy be maintained at the pre-pregnancy dose of opioid medication, if effective;
- (8) a requirement that a pregnant patient be monitored by the program medical director to determine if pregnancy-induced changes in the elimination or metabolism of opioid treatment medication may necessitate an increased or split dose;
- (9) a requirement that withdrawal treatment:
 - (a) is strongly advised against before 14 weeks or after 32 weeks of gestation;
 - (b) the program medical director reviews the case before initiating withdrawal and monitor it until withdrawal is complete;
- (10) a requirement that a pregnant patient discharged from the program be referred to a non-program medical practitioner and that a staff member document the name, address, and telephone number of the medical practitioner in the patient record.

D. A program sponsor who is officially notified by a correctional facility that a patient is in their custody shall ensure that the program:

- (1) makes efforts to obtain approval from the criminal justice system for the continued treatment of the patient by the program while the patient is incarcerated; and
- (2) if approval is obtained the program continues to treat the patient while the patient is incarcerated, within the limits of the program's ability to provide such treatment to the incarcerated patient; and
- (3) if approval is not obtained, the program's attempts to obtain approval are documented in the patient's record.

[8.321.10.26 NMAC - N, 7/1/2024]

8.321.10.27 PREPAREDNESS PLANNING:

A. The program sponsor shall ensure that the program has:

- (1) a written plan to ensure uninterrupted dispensing of medication in the event of dispensing staff turnover; and
 - (2) a written agreement with at least one other provider for the provision of opioid treatment medication to program patients in the event that the program is unable to provide services;
 - (3) 24-hour telephone answering service or other method to reach the program at all times;
- and

(4) a list of all patients and the patients' dosage requirements available and accessible to program on-call staff members.

B. A program sponsor shall ensure that a written plan is developed and implemented for continuity of patient services if the program is voluntarily or involuntarily closed. Such planning shall include a disaster plan that addresses unforeseeable circumstances such as natural disaster or involuntary closure from any cause, and:

(1) includes steps for the orderly transfer of patients to other programs, individuals, or entities that provide opioid treatment;

(2) includes procedures for securing, maintaining, and transferring patient records according to federal and state law; and

(3) the plan is reviewed and updated, as appropriate, at least once every 12 months.

[8.321.10.27 NMAC - N, 7/1/2024]

8.321.10.28 PATIENT RECORDS:

A. The OTP program shall establish and maintain a recordkeeping system that is adequate to document and monitor patient care. The system shall comply with all federal and state requirements relevant to OTPs and to confidentiality of patient records.

B. Each patient record shall include:

(1) the results of the physical examination;

(2) the results of all assessments;

(3) the treatment plan and all updates or revisions;

(4) the results of laboratory tests and a description of any action taken based upon the results;

(5) documentation of the patient's current dose and dosage history;

(6) documentation of counseling provided to the patient;

(7) dates and results of meetings or conferences regarding the patient's treatment;

(8) documentation of the process used and factors considered in making decisions that impact a patient's treatment, such as whether to allow take-home medication and the frequency of laboratory drug detection tests; and

(9) documentation of the agency's efforts to learn of multiple opioid treatment program enrollment;

(10) documentation that the patient has received and understood information regarding the harmful effects of diversion of opioid treatment medication.

[8.321.10.28 NMAC - N, 7/1/2024]

8.321.10.29 COMMUNITY RELATIONS:

A. A program sponsor shall ensure that policies and procedures are developed, implemented, and complied with to educate and promote understanding in the community about opioid treatment and include:

(1) a mechanism for eliciting input from the community about the provider's impact on the community;

(2) a requirement that the program sponsor or designee interface with community leaders to foster positive relations;

(3) a requirement that the program sponsor or designee establish a liaison with community representatives to share information about the program;

(4) a requirement that the agency have information on substance abuse and related health and social issues available to the public;

(5) a mechanism for addressing and resolving community concerns about opioid treatment or the program's presence in the community; and

(6) a mechanism that addresses getting approval for continued treatment in treatment or care facilities and correctional facilities.

B. A program sponsor shall ensure that community relations efforts are documented and are evaluated at least once every six months.

C. A program sponsor shall comply with all valid county and municipal ordinances regarding community relations, and the HCA may consult with local governmental entities when enforcing this section.

[8.321.10.29 NMAC - N, 7/1/2024]

8.321.10.30 DIVERSION CONTROL: The program sponsor shall ensure that a written plan is developed, implemented, and complied with to prevent diversion of opioid treatment medication from its intended purpose to

illicit purposes. This plan shall assign specific responsibility to licensed and administrative staff for carrying out the diversion control measures and functions described in the plan. The program shall develop and implement a policy and procedure providing for the reporting of theft or diversion of medication to the relevant regulatory agencies, and law enforcement authorities.

[8.321.10.30 NMAC - N, 7/1/2024]

HISTORY OF 8.321.10 NMAC: [RESERVED]