HEALTH CARE AUTHORITY

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Letter of Direction #35

Date: **December 5, 2024**

To: **Turquoise Care Managed Care Organizations**

From: **Dana Flannery, Director, Medical Assistance Division**

Subject: **Medications for Treatment of Opioid Use Disorder**

Title: **Opioid Treatment Program Changes to align 42 CFR Part 8 Final Rule**

The purpose of this Letter of Direction (LOD) is to provide clarification to the Managed Care Organizations (MCOs) regarding federal changes that affect Opioid Treatment Programs (OTP) and is effective October 1, 2024. New Mexico is adopting the Federal Regulation by reference: 42 CFR Part 8.

1. Medications for Opioid Use Disorder (MOUD)
    a. The term medication assisted treatment (MAT) is updated to MOUD.

2. OTP Certification
    a. OTPs are required to maintain certification with the Department of Health and Human Services as outlined in 42 CFR Part 8, Medications for the Treatment of Opioid Use Disorder.
    b. Conditions for interim treatment program approval.
        i. Before an OTP may provide interim treatment, the OTP must receive the approval of both the Secretary of Health and Human Services (HHS) and the NM State Opioid Treatment Authority (SOTA). The OTP shall not provide interim treatment until it has received approval from the Secretary of Health and Human Services (HHS).
            1. The OTP will arrange for each individual's transfer to a comprehensive treatment program no later than 180 days from the date on which each individual first requested treatment.
                a. Individuals enrolled in interim treatment shall not be discharged without the approval of an OTP practitioner, who shall consider on-going and patient-centered treatment needs, which are to be documented in the patient record, while awaiting transfer to a comprehensive treatment program.

    c. 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").

i. 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.

ii. "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.

d. Medication Units

i. Certified OTPs may establish medication units that are authorized to dispense MOUD. Before establishing a medication unit, a certified OTP must notify the Secretary of Health and Human Services by submitting form SMA–162. The OTP must also comply with the provisions of 21 CFR part 1300 before establishing a medication unit. Medication units shall comply with all pertinent State laws and regulations.

1. Medication units include both mobile and brick and mortar facilities.
2. Any services that are provided in an OTP, assuming compliance with all applicable federal, state, and local law, may be provided directly in the Medication Unit if the Medication Unit has appropriate privacy and adequate space, or when permissible through use of telehealth services.
3. Any required services not provided at a Medication Unit must be conducted at the OTP, including medical, counseling, vocational, educational, and other screening, assessment, and treatment services to meet patient needs.

ii. Interested applicants must receive approval from the NM SOTA prior to seeking approval from the Secretary of Health and Human Services to add a medication unit component to their existing registration. The application includes the following:

1. A written letter of intent that demonstrates how this service will increase access to MOUD and avoid duplication with other OTP services;
2. A copy of Medication Unit's(s) operating procedures;
3. Commitment to obtaining approval from the NM Board of Pharmacy and the US Drug Enforcement Agency;
4. BHSD shall approve or deny the application within 30 working days of submission, unless BHSD and applicant mutually agree to extend the application review period.
    a. Behavioral Health Services Division may require the applicant to provide additional written or verbal information to reach its decision. Such further information shall be considered an integral part of the application and may extend the application review period.

3. <u>Opioid Use Disorder Treatment Standards</u>

a. Expanding the Definition of a Practitioner

i. A Practitioner is defined as a health care professional who is appropriately

licensed by New Mexico to prescribe and/or dispense medication for opioid use disorder and, as a result, is authorized to practice within an OTP.

1. Practitioners must continue to adhere to State requirements that may apply to provision of methadone and scope of practice.
2. This rule does not apply to the prescribing of methadone for OUD outside of OTPs.

b. Patient admission criteria
    i. An OTP shall maintain current procedures designed to ensure that patients are admitted to treatment by qualified personnel who have determined, using accepted medical criteria, that the basis for the admission decision must be documented in the patient's clinical record and a health care practitioner shall ensure that each patient voluntarily chooses treatment with MOUD and that all relevant facts concerning the use of MOUD are clearly and adequately explained to the patient, and that each patient provides informed consent to treatment.
    ii. Individuals are no longer required to have a one-year history of OUD prior to admission to treatment.
    iii. Individuals under the age of 18, are no longer required to have two (2) documented unsuccessful attempts at short-term opioid treatment withdrawal procedures or drug-free treatment prior to admittance to an OTP.
    iv. The HCA has established an internet-based central registry (NM STAR) of all persons in New Mexico who are current patients of a New Mexico OTP program, for the purpose of preventing patients from inappropriately receiving medication from more than one OTP. Each OTP, as a condition of approval to operate, shall participate in the central registry with daily uploads on client dosing as directed by the HCA.

c. Withdrawal Management
    i. Individuals seeking withdrawal management are no longer limited to initiating methadone treatment to two (2) times per year.
        1. An OTP shall maintain current procedures that are designed to ensure that those patients who choose to taper from MOUD are provided the opportunity to do so with informed consent and at a mutually agreed-upon rate that minimizes taper-related risks. Such consent must be documented in the clinical record by the treating practitioner.
d. Comprehensive Treatment for Persons Under the Age of 18
    i. NM state law does not grant persons under 18 years of age the ability to consent to OTP treatment without the consent of another, including parent and/or legal guardian. As such, no person under 18 years of age may be admitted to OTP treatment unless a parent, legal guardian, or responsible adult designated by the relevant State authority consents in writing (electronically or hard copy) to such treatment.
e. Required Services
    i. Access to MOUD to an individual for medically managed withdrawal from opioids and maintenance treatment is no longer contingent upon the individual's engagement in counseling services.

1. While OTPs are still required to offer counseling services to all enrolled patients, a patient's access to MOUD cannot be contingent upon the patient's engagement in (receipt of) counseling services.
2. The administration/supervision of MOUD must be delivered in conjunction with the overall treatment based upon a treatment plan that reflects shared decision making between the patient and health care practitioner and/or counselor, to include the availability of counseling, as well as case review, drug testing, and medication monitoring.

ii. OTPs are expected to offer adequate medical, counseling, vocational, educational, and other assessment, and treatment services either onsite or by referral to an outside agency or practitioner with a documented agreement to provide such services.

iii. Initial Medical Examination is composed of two (2) parts.
    1. A screening examination to ensure the patient meets the criteria for admission and that there are no contraindications to treatment with MOUD.
        a. Assuming no contraindications, a patient may commence treatment with MOUD after the screening examination has been completed.
    2. A full history and medical examination, to determine the patient's broader health status, with lab testing as determined to be required by an appropriately licensed practitioner.
        a. A patient's refusal to undergo lab testing for co-occurring physical health conditions should not preclude them from access to treatment, provided such refusal does not have potential to negatively impact treatment with medications.
    3. Both the screening examination and full examination must be completed by an appropriately licensed practitioner. If the licensed practitioner is not an OTP practitioner, the screening examination must be completed no more than seven days prior to OTP admission. Where the examination is performed outside of the OTP, the written results and narrative of the examination, as well as available lab testing results, must be transmitted, consistent with applicable privacy laws, to the OTP, and verified by an OTP practitioner.
    4. A full, in-person physical examination, including the results of serology and other tests that are considered to be clinically appropriate, must be completed within 14 calendar days following a patient's admission to the OTP. The full exam can be completed by a non-OTP practitioner, if the exam is verified by a licensed OTP practitioner as being true and accurate and transmitted in accordance with applicable privacy laws.
    5. Serology testing and other testing as deemed medically appropriate by the licensed OTP practitioner based on the screening or full history and examination, drawn not more than 30 days prior to admission to the OTP, or up to 14 days after admission to the OTP, may form part of the full history and examination.

6. The screening and full examination may be completed via telehealth for those patients being admitted for treatment at the OTP with either buprenorphine or methadone, if a practitioner or primary care provider, determines that an adequate evaluation of the patient can be accomplished via telehealth.
    a. When using telehealth, the following caveats apply:
        i. In evaluating patients for treatment with schedule II medications (such as Methadone), audio-visual telehealth platforms must be used, except when not available to the patient. When not available, it is acceptable to use audio-only devices, but only when the patient is in the presence of a licensed practitioner who is registered to prescribe (including dispense) controlled medications. The OTP practitioner shall review the examination results and order treatment medications as indicated.
        ii. In evaluating patients for treatment with schedule III medications (such as Buprenorphine) or medications not classified as a controlled medication (such as Naltrexone), audio-visual or audio only platforms may be used. The OTP practitioner shall review the examination results and order treatment medications as indicated.

iv. Special services for pregnant patients
    1. OTPs must maintain current policies and procedures that reflect the special needs and priority for treatment admission of patients with OUD who are pregnant.
        a. Pregnancy should be confirmed.
            i. Refusal of pregnancy testing should not preclude access to treatment.
        b. Evidence-based treatment protocols for the pregnant patient, such as split dosing regimens, may be instituted after assessment by an OTP practitioner and documentation that confirms the clinical appropriateness of such an evidence-based treatment protocol.
        c. Prenatal care and other sex specific services, including reproductive health services, for pregnant and postpartum patients must be provided and documented either by the OTP or by referral to appropriate healthcare practitioners.
        d. Specific services, including reproductive health services, for pregnant and postpartum patients must be provided and documented either by the OTP or by referral to appropriate healthcare practitioners.

v. Initial and periodic physical and behavioral health assessment services
    1. Each patient admitted to an OTP shall be given a physical and behavioral health assessment, which includes but is not limited to

screening for imminent risk of harm to self or others, within 14 calendar days following admission, and periodically by appropriately licensed/ credentialed personnel.

2. These assessments must address the need for and/or response to treatment, adjust treatment interventions, including MOUD, as necessary, and provide a patient-centered plan of care. The full, initial psychosocial assessment must be completed within 14 calendar days of admission and include preparation of a care plan that includes the patient's goals and mutually agreed-upon actions for the patient to meet those goals, including harm reduction interventions; the patient's needs and goals in the areas of education, vocational training, and employment; and the medical and psychiatric, psychosocial, economic, legal, housing, and other recovery support services that a patient needs and wishes to pursue. The care plan also must identify the recommended frequency with which services are to be provided.
    a. The plan must be reviewed and updated to reflect responses to treatment and recovery support services, and adjustments made that reflect changes in the context of the person's life, their current needs for and interests in medical, psychiatric, social, and psychological services, and current needs for and interests in education, vocational training, and employment services.
3. The periodic physical examination should occur not less than one time each year and be conducted by an OTP practitioner. The periodic physical examination should include review of MOUD dosing, treatment response, other substance use disorder treatment needs, responses and patient-identified goals, and other relevant physical and psychiatric treatment needs and goals. The periodic physical examination should be documented in the patient's clinical record.

vi. Counseling and psychoeducational services

1. OTPs must provide adequate substance use disorder counseling and psychoeducation to each patient as clinically necessary and mutually agreed-upon, including harm reduction education and recovery-oriented counseling. This counseling shall be provided by a program counselor, qualified by education, training, or experience to assess the psychological and sociological background of patients, and engage with patients, to contribute to the appropriate care plan for the patient and to monitor and update patient progress.
    a. Patient refusal of counseling shall not preclude them from receiving MOUD.
2. OTPs must provide counseling on preventing exposure to, and the transmission of, human immunodeficiency virus (HIV), viral hepatitis, and sexually transmitted infections (STIs) and either directly provide services and treatments or actively link to treatment each patient admitted or readmitted to treatment who has received positive test results for these conditions from initial and/or periodic medical examinations.

3. OTPs must provide directly, or through referral to adequate and reasonably accessible community resources, vocational training, education, and employment services for patients who request such services or for whom these needs have been identified and mutually agreed-upon as beneficial by the patient and program staff.

vii. Relapse Prevention Program
   1. Because of the risks of relapse following medically managed withdrawal from medication or other opioids, patients must be offered a relapse prevention program that includes, but is not limited to counseling, naloxone, and MOUD.

viii. Drug testing services
   1. When conducting random drug testing, OTPs must use drug tests that have received the Food and Drug Administration's (FDA) marketing authorization for commonly used and misused substances that may impact patient safety, recovery, or otherwise complicate substance use disorder treatment, at a frequency that is in accordance with generally accepted clinical practice and as indicated by a patient's response to and stability in treatment, but no fewer than eight random drug tests per year patient, allowing for extenuating circumstances at the individual patient level.
      a. This requirement does not preclude distribution of legal harm reduction supplies that allow an individual to test their personal drug supply for adulteration with substances that increase the risk of overdose.

ix. Unsupervised or ''take-home'' medication doses
   1. Unsupervised or ''take-home'' medication doses may be provided under the following circumstances:
      a. Any patient in comprehensive treatment may receive their individualized take-home doses as ordered for days that the clinic is closed for business, including one weekend day (e.g., Sunday) and State and Federal holidays, no matter their length of time in treatment.
      b. OTP decisions on dispensing MOUD to patients for unsupervised use beyond that set forth in section ix.1.a of this section shall be determined by an appropriately licensed OTP medical practitioner or the medical director.
         i. In determining which patients may receive unsupervised medication doses, the medical director or program medical practitioner shall consider, among other pertinent factors that indicate that the therapeutic benefits of unsupervised doses outweigh the risks, the following criteria:
            1. Absence of active substance use disorders, other physical or behavioral health conditions that increase the risk of patient harm as it relates to the potential for overdose, or the ability to

function safely;
2. Regularity of attendance for supervised medication administration;
3. Absence of serious behavioral problems that endanger the patient, the public or others;
4. Absence of known recent diversion activity;
5. Whether take-home medication can be safely transported and stored; and
6. Any other criteria that the medical director or medical practitioner considers relevant to the patient's safety and the public's health.

ii. Such determinations and the basis for such determinations consistent with the criteria outlined in paragraph ix.1.a.i of this section shall be documented in the patient's medical record.

iii. If it is determined that a patient is safely able to manage unsupervised doses of MOUD, the dispensing restrictions set forth in paragraphs ix.1.a.ii.1 through 3 of this section apply. The dispensing restrictions set forth in this section do not apply to buprenorphine and buprenorphine combination products that have been approved for use in the treatment of OUD.
1. During the first 14 days of treatment, the take-home supply (beyond that of paragraph ix.1.a of this section) is limited to 7 days. It remains within the OTP practitioner's discretion to determine the number of take-home doses up to 7 days, but decisions must be based on the criteria listed in paragraph ix.1.b of this section. The rationale underlying the decision to provide unsupervised doses of methadone must be documented in the patient's clinical record.
2. From 15 days of treatment, the take-home supply (beyond that of paragraph ix.1.a of this section) is limited to 14 days. It remains within the OTP practitioner's discretion to determine the number of take-home doses up to 14 days, but this determination must be based on the criteria listed in paragraph ix.1.b of this section. The rationale underlying the decision to provide unsupervised doses of methadone must be documented in the patient's clinical record.
3. From 31 days of treatment, the take-home supply (beyond that of paragraph ix.1.a of this section) provided to a patient is not to exceed 28 days. It remains within the OTP practitioner's

discretion to determine the number of take-home doses up to 28 days, but this determination must be based on the criteria listed in paragraph ix.1.b of this section. The rationale underlying the decision to provide unsupervised doses of methadone must be documented in the patient's clinical record.

4. Split dosing is allowable for take home supplies at the discretion of the prescriber

x. Interim treatment

1. The program sponsor of an OTP may admit an individual, who is eligible for admission to comprehensive treatment, into interim treatment if comprehensive services are not readily available within a reasonable geographic area and within 14 days of the individual's seeking treatment. At least two drug tests shall be obtained from patients during the maximum of 180 days permitted for interim treatment. A program shall establish and follow reasonable criteria for establishing priorities for moving patients from interim to comprehensive treatment. These transition criteria shall be in writing and shall include, at a minimum, prioritization of pregnant patients in admitting patients to interim treatment and from interim to comprehensive treatment. Interim treatment shall be provided in a manner consistent with all applicable Federal and State laws, including sections 1923, 1927(a), and 1976 of the Public Health Service Act (21 U.S.C. 300x–23, 300x– 27(a), and 300y–11).
2. The program shall notify the SOTA when a patient begins interim treatment, when a patient leaves interim treatment, and before the date of transfer to comprehensive services, and shall document such notifications.
    a. The Secretary of Health and Human Services may revoke the interim authorization for programs that fail to comply with the provisions of this paragraph
3. All requirements for comprehensive treatment apply to interim treatment with the following exceptions:
    a. A primary counselor is not required to be assigned to the patient, but crisis services, including shelter support, should be available;
    b. Interim treatment cannot be provided for longer than 180 days in any 12-month period;
    c. By day 120, a plan for continuing treatment beyond 180 days must be created, and documented in the patient's clinical record; and
    d. Formal counseling, vocational training, employment, economic, legal, educational, and other recovery support services are not required to be offered to the patient. However, information pertaining to locally available, community-based

resources for ancillary services should be made available to individual patients in interim treatment.

4. Dosage

The program sponsor shall ensure that:

a. a dose of opioid treatment medication is administered only after an order from the OTP prescriber
b. a patient's dosage of opioid 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:
    i. preventing the onset of subjective or objective signs of withdrawal for 24 hours or more;
    ii. reducing or eliminating the drug craving that is experienced by opioid dependent individuals who are not in opioid treatment;
    iii. a patient receiving comprehensive maintenance treatment receives an initial dose of opioid treatment medication based upon the program prescriber physical examination and with consideration for local issues, such as the relative purity of available illicit opioid drugs;
    iv. for initial prescribing, OTPs must consider the type(s) of opioid(s);
    v. the total dose for the first day should not exceed 50 mg unless the OTP prescriber finds and documents sufficient medical rationale for a higher dose;
    vi. OTP prescribing practitioners may prescribe split doses of methadone where such dosing regimens are indicated.

Implementation

MCOs are directed to implement changes associated with these instructions, including system changes and provider contract negotiations as needed no later than 90 days from the date of issuance of this directive. HCA directs the MCOs to provide biweekly updates to HCA on the status of implementation every other Friday beginning November 1, 2024, until otherwise directed by HCA. This LOD will sunset upon inclusion in 8.321.2 and 8.321.10 NMAC and the Behavioral Health Policy and Billing Manual.