Pew

March 24, 2026

New Mexico Health Care Authority
Office of the Secretary
ATTN: Behavioral Health Services Division Public Comments
P.O. Box 2348
Santa Fe, New Mexico 87504-2348

Dear Secretary Kari Armijo,

Thank you for the opportunity to comment on the proposed repeal and replace of NMAC 8.321.10. We commend the state for aligning proposed rules with federal regulations 42 CFR Part 8 and with evidence-based practices for opioid use disorder (OUD) treatment. Additional revisions related to harm reduction services and administrative discharge, as well as the removal of pharmacy requirements for opioid treatment programs (OTPs) by the responsible state agency, would further strengthen the proposed regulatory approach. An analysis of the draft rule and existing regulations is provided in the Appendix of this document.

The Pew Charitable Trusts (Pew) is an independent, nonpartisan research and policy organization. Through its Substance Use Prevention and Treatment Initiative, Pew works with states and at the federal level to address the nation's overdose crisis by developing solutions that improve access to timely, comprehensive, evidence-based, and sustainable prevention and treatment for substance use disorders (SUD). New Mexico is one of seven states in Bloomberg Philanthropies' Overdose Prevention Initiative; states participating in the initiative receive policy support and recommendations from Pew based on the State Financing Principles for Financing Substance Use Care, Treatment, and Support Services to improve the states' SUD treatment system.

In February 2024, the U.S. Department of Health and Human Services (HHS), through the Substance Abuse and Mental Health Services Administration (SAMHSA), revised federal regulations 42 CFR Part 8 that govern the establishment, operation, and provision of care at OTPs. OTPs are the only facilities that can offer patients all three forms of FDA-approved medications for OUD (also known as MOUD) — methadone, buprenorphine, and naltrexone. Methadone, which has proven safe and effective for OUD treatment through decades of research, can generally only be offered in OTP settings. OTPs are also subject to state rules and regulations. To ensure people with OUD can access treatment, state-level requirements should not go beyond those imposed by the federal government.

Pew strongly supports the proposed rules NMAC 8.321.10 as they align with revised federal regulations and repeal and replace previous state regulations, which were more restrictive than what the federal government requires. These changes are aligned with national best practices and will result in improved patient care and outcomes.

To further these efforts, the New Mexico Health Care Authority could consider strengthening the provision of harm reduction services at these treatment programs, including by offering opioid overdose reversal medications, such as naloxone, and drug testing equipment, such as fentanyl test strips. Additionally, the Health Care Authority should consider strengthening regulatory language to prohibit administrative discharge without an individualized assessment for patients who miss doses to ensure providers reassess patient care needs rather than terminate treatment, in line with evidence-based practice.

Lastly, while out of the scope of this rulemaking, we encourage the Health Care Authority to update regulations requiring pharmacy licensure and mandating pharmacist staffing if the New Mexico Legislature removes pharmacy-related restrictions on OTPs.

The Appendix below presents a detailed analysis of the proposed amendments to current regulations, supporting evidence, and areas for further improvement. Thank you again for the opportunity to provide feedback on this important issue. If you have any questions, please contact Courtney Chambers, Senior Associate, Substance Use Prevention and Treatment Initiative at (202) 540-6261 or cchambers@pewtrusts.org.

Sincerely,

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Appendix

Below is an analysis of elements of the current rule at NMAC 8.321.10 that are more restrictive than what federal government requires; evidence supporting their replacement and/or repeal; and an assessment of how the proposed rule aligns with federal standards and best practices. These changes have been incorporated into the proposed regulation, with the exception of some components of items 9 and 10. Additionally, item 11 is outside the scope of this rulemaking as it would first require action from the New Mexico state legislature.

1. **Certificate of Need**

   Pew supports the removal of requirements for a certificate of need or needs assessment to open a new OTP. The removal of this requirement aligns with federal rules which do not require new OTPs to demonstrate a need for services when requesting certification from SAMHSA. Further, requiring a certificate of need is not considered best practice and can discourage new OTPs from entering the market.

   Proposed rules remove Subsection I of current rule NMAC 8.321.10.10, thereby removing unnecessary restrictions on new OTPs.

2. **Medication Units**

   Pew supports the New Mexico Health Care Authority's decision to align with federal standards at 42 CFR Part 8, which explicitly permit OTPs to operate medication units and allows these units to offer the full range of services available at a typical OTP. NMAC 8.321.10 does not have regulatory language to explicitly allow this.

   Medication units are satellite sites of an OTP, either mobile or brick-and-mortar. These settings can increase patient access to care by expanding the number and geographic distribution of locations where they can receive methadone (and other MOUD) services, especially in rural and underserved areas. For example, a treatment provider in Kentucky reported that treatment options increased by 28% after they opened several medication units.

   Proposed rules add a new provision "8.321.10.18 Medication Units", thereby providing clarity and explicit direction to New Mexico OTPs interested in operating medication units.

3. **Admission Criteria**

   Federal regulations under 42 CFR Part 8 no longer require a one-year history of OUD to initiate care at an OTP. Furthermore, new federal standards loosen restrictions for those under 18 seeking treatment by 1) removing requirements for two documented unsuccessful attempts at short-term withdrawal management and 2) only requiring written parental or legal guardian consent to treatment. Pew supports the New Mexico Health Care Authority's decision to align with federal rules. Studies show that delays in initiating opioid agonist treatments such as methadone or buprenorphine are associated with negative outcomes including death, infectious disease transmission, and criminal

activity. Further, for patients under 18, research demonstrates that MOUD is associated with greater retention in care among youth.

Proposed rules remove all requirements for previous one-year history of OUD and two documented unsuccessful attempts at short-term detoxification (for patients under 18) as conditions for OTP admission. Further, the proposed rules explicitly allow patients under 18 to be admitted to OTP treatment with written parental, legal guardian, or responsible adult consent. These changes remove barriers to treatment and support appropriate clinical judgement for the OTP provider.

4. **Interim Maintenance**

Pew supports the New Mexico Health Care Authority's decision to align with federal standards at 42 CFR Part 8, which allows interim maintenance treatment for patients up to 180 days. NMAC 8.321.10 does not have regulatory language to explicitly permit this. Interim maintenance, in which clients receive some services such as methadone dosing while waiting to receive additional services, prevents delays to treatment caused by long waitlists for comprehensive care. As previously mentioned, when patients experience delays in initiating opioid agonist treatments such as methadone or buprenorphine, they are at significant risk for morbidity and mortality.

Proposed rules add a new provision "8.321.10.25 Interim Treatment", thereby reducing patient barriers and delays to care.

5. **Telehealth**

Pew supports the inclusion of regulatory language that allows OTPs to provide services through telehealth, including medication initiation and patient assessment. Federal rules at 42 CFR Part 8 permanently allow OTPs to provide services through telehealth, including the initiation of buprenorphine and assessment of methadone patients. NMAC 8.321.10 does not have regulatory language to explicitly allow telehealth for intake examinations. Telehealth services enhance the patient experience by allowing increased privacy, reducing stigma, and encouraging the continuity of treatment. Furthermore, telehealth services can improve access to treatment for historically marginalized communities.

Proposed rules now explicitly allow screening and full physical examinations to be performed via telehealth, thereby improving the patient experience, reducing delays to care, and improving treatment access disparities.

6. **Take-Home Medications**

Pew supports the inclusion of regulatory language that allows OTP clinicians to provide take-home doses of medication as clinically appropriate. Federal rules allow up to 28 days of take-home doses and simplify eligibility criteria for receiving them. Take-home medications can enhance the patient experience by allowing treatment flexibility. Research also suggests that allowing take-home medication results in high patient satisfaction, which is associated with higher retention in treatment. NMAC 8.321.10 places numerous restrictions on the patient's eligibility for receiving take-home

medications. The current rules also outline a schedule for allowable doses of take-home medications which is far stricter than federal rules.

Proposed rules remove all previously mentioned patient eligibility criteria for receiving take-home medication and adopt the federal schedule for allowable doses of take-home medications. These changes will remove barriers to OTP attendance and increase treatment engagement.

7. **Dosage**

Federal regulations at 42 CFR Part 8 permit a total dose of up to 50 milligrams as a patient's initial dose. NMAC 8.321.10 only allows up to 30 milligrams for initial dosage. Doses that are too low may not effectively reduce drug cravings or drug use. Restricting or discouraging higher doses of medication may cause patients to discontinue treatment. This restriction is also not aligned with evidence, as higher doses can lead to greater reductions in drug use among patients with OUD.

Proposed rules remove all provisions that would limit initial doses under 50 milligrams. These changes support appropriate clinical judgement for the OTP provider and ensure that patients can receive individualized treatment.

8. **Guest Dosing**

Pew supports the inclusion of regulatory language that would explicitly allow guest dosing to enhance the patient experience. Guest dosing is the practice of allowing patients to receive methadone from an OTP other than the one at which someone is a patient. Guest dosing provides flexibility for patients who may have difficulty accessing services at their home OTP. NMAC 8.321.10 does not explicitly permit guest dosing.

Proposed rules add new regulatory language to permit guest dosing and define OTPs' responsibilities for facilitating guest dosing, thereby improving the patient experience and encouraging continuity in treatment.

9. **Lifesaving Strategies and Patient Centered Care**

Pew supports the inclusion of regulatory language that requires the addition of lifesaving strategies for client treatment planning. Federal rules at 42 CFR Part 8 now require the provision of clinically necessary and mutually agreed-upon services, including lifesaving strategies and recovery support services. Lifesaving strategies, also known as harm reduction, is defined by SAMHSA as "a practical and transformative approach that incorporates community-driven public health strategies — including prevention, risk reduction, and health promotion — to empower people who use drugs (and their families) with the choice to live healthy, self-directed, and purpose-filled lives." Decades of research point to the efficacy of these strategies in preventing overdose and increasing sterile syringe access.

Proposed rules add "harm reduction" to the list of defined terms, require that all patients be informed of the availability of harm reduction services, and include harm reduction interventions as part of patients' treatment planning. These changes bolster the range of interventions available to patients who may be at varying stages of treatment. **The New**

Mexico Health Care Authority can further improve regulations by ensuring that patients receive harm reduction supplies, such as opioid overdose reversal medications like naloxone and drug testing equipment such as fentanyl test strips, as part of their treatment.

10. **Administrative Discharge**

Pew supports the inclusion of language that explicitly prohibits administrative discharge policies due to missed doses, non-participation in ancillary services, and continued drug use unless the risk of continued use outweighs the risk of overdose death following termination of methadone treatment. NMAC 8.321.10 does not explicitly prohibit administrative discharge for these reasons.

While the proposed rules add some provisions that protect patients from administrative discharge, there is room for further improvement. For instance, proposed rules include provisions that prohibit administrative discharge for patients pursuant to non-prescribed substance use or for any displayed symptoms of mental or physical illness. Proposed rules would also ensure that a patient's access to methadone is not contingent upon their engagement in counseling services. These provisions are important as they offer protections for patients and ensure patients cannot be removed from treatment without cause. **However, regulatory language should also explicitly ensure access to methadone treatment for patients that miss doses. The New Mexico Health Care Authority should add language that further clarifies this and ensures an individualized assessment occurs before termination of treatment.**

According to federal guidelines, OTPs may consider reassessing a patient who experiences an interruption in care (planned or unplanned). Overall, continuing MOUD is generally safer than terminating it. Furthermore, 42 CFR Part 8 emphasizes that discharge planning must take a patient-centered approach and aim to avoid treatment disruption.

11. **Pharmacy Requirements**

To further align with federal regulations, responsible state entities should consider removing pharmacy-related restrictions on OTPs. Pharmacy-related regulations are not federally required to administer MOUD in OTPs. Currently, New Mexico requires OTPs to be licensed or registered as pharmacies, in addition to oversight from HCA, DEA, SAMHSA and other accrediting bodies. Further, New Mexico OTPs must employ a pharmacist or engage the services of a consultant pharmacist. These requirements place additional burdens on OTP operators, increase operational costs, and increase barriers for patients. Notably, New Mexico also has a pharmacist shortage, which further strains OTPs' abilities to operate and the health care system at large. Federal law allows methadone administration by a variety of licensed health care professionals and does not require OTPs to be licensed or registered as pharmacies. **The New Mexico Health Care Authority should revise language to reflect any future action taken by the New Mexico Legislature to remove pharmacy-related restrictions on OTPs.**