Mondragon, Tabitha, HCA

From: Derek Carr <dcarr@vitalstrategies.org>
Sent: Thursday, July 25, 2024 6:36 PM
To: HCA-madrules
Cc: Kate Boulton; Julie Rwan; Donette Perkins
Subject: [EXTERNAL] Vital Strategies comment on proposed amendments to 8.321.2 NMAC
Attachments: VitalStrategies_NewMexicoMethadoneRule_PublicComment_FINAL.pdf

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Greetings,

On behalf of the Vital Strategies Overdose Prevention Program, I am submitting comments on HSD's proposed amendments to 8.321.2 NMAC ("Specialized Behavioral Health Provider Enrollment and Reimbursement"). We appreciate the opportunity to submit these public comments and the Department's consideration of our input. Should you have any questions or experience difficulties accessing the attached PDF, please do not hesitate to contact Julie Rwan at jrwan@vitalstrategies.org.

Best,

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July 25, 2024

Human Services Department
Office of the Secretary
Attn: Medical Assistance Division Public Comments
P.O. Box 2348
Santa Fe, NM 87504-2348

RE: Proposed amendments to rule 8.321.2 NMAC, "Specialized Behavioral Health Provider Enrollment and Reimbursement"

On behalf of the Vital Strategies Overdose Prevention Program, we write to offer input on the Human Service Department's ("Department") proposed amendments to 8.321.2.31 NMAC, regarding Medical Assistance Division (MAD) coverage of medication-assisted treatment for opioid use disorder (OUD) in federally certified opioid treatment programs (OTP). Vital Strategies is a registered 501(c)(3) nonprofit organization headquartered in the United States with a mission to support strong public health systems around the world. The Overdose Prevention Program works in various U.S. states, including New Mexico, to catalyze data-driven solutions for an equitable and sustainable reduction in overdose deaths and access to care for people with substance use disorder (SUD).

The country's overdose crisis continues unabated, with data from the Centers for Disease Control and Prevention (CDC) showing that overdose deaths surpassed 100,000 last year alone.[1] Treatment for opioid use disorder (OUD) with agonist medications buprenorphine and methadone[2] is most effective at reducing overdose and serious opioid-related acute care relative to other treatments, such as naltrexone or inpatient detoxification or residential services.[3] Agonist medications for OUD are associated with an estimated mortality reduction of 50% among people with OUD, supporting the conclusion of the National Academies of Sciences, Engineering, and Medicine in 2019 that "[t]he verdict is clear: effective agonist medication used for an indefinite period of time is the safest option for treating OUD."[4]

Vital Strategies commends the Department for seeking to align portions of the state's rules governing OTPs with the recently revised federal regulations at 42 CFR Part 8. Ensuring such alignment is critical to expanding access to lifesaving, evidence-based methadone treatment for OUD. Although Vital

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[1] Ahmad FB, Cisewski JA, Rossen LM, Sutton P. Provisional drug overdose death counts. National Center for Health Statistics. 2023.
[2] Also referred to throughout as "MOUD," meaning medications for opioid use disorder. MOUD is synonymous with medication assisted treatment ("MAT") and medications for addiction treatment.
[3] Wakeman SE, Larochelle MR, Ameli O, et al. Comparative Effectiveness of Different Treatment Pathways for Opioid Use Disorder. JAMA Network Open. 2020;3(2):e1920622.
[4] National Academies of Sciences, Engineering, and Medicine. Medications for opioid use disorder save lives. (Leshner AI, Mancher M, eds.). Washington, DC: The National Academies Press; 2019.

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Strategies fully supports the Department's efforts, we caution that the proposed amendments to 8.321.2.31 NMAC, which pertain to standards for Medicaid reimbursement, may not achieve their intended effect until corresponding changes are also made to the state's generally applicable OTP rules (codified at 8.321.10 NMAC as of July 1, 2024) to eliminate direct conflicts, such as those we identify in Section II below.

Vital Strategies offers these recommendations to further clarify and strengthen the proposed rules, and to identify additional regulatory changes to expand and protect access to lifesaving, evidence-based treatment for OUD.

I. Key Improvements in Proposed Amendments to 8.321.2.31 NMAC.

Vital Strategies strongly supports the Department's proposed amendments to 8.321.2.31 NMAC, most of which align with recently adopted changes to 42 CFR Part 8.[5]

a. Overall promotion of a more patient-centered approach to treatment.

Vital Strategies supports the substantive and linguistic changes made by the proposed rule to promote a more patient-centered approach to treatment in OTPs. This includes, for example, the elimination of stigmatizing language and emphasis on shared decision-making among patients and providers.

b. Protecting access to MOUD when a patient refuses counseling.

Although some patients may benefit from more intensive counseling supports, evidence does not support policies mandating that patients receive a pre-determined amount and type of counseling – or, in many cases, any counseling at all.[6,7,8,9,10] To the contrary, additional psychotherapy requirements for

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[5] *See* 89 Fed. Reg. 7528 (Medications for the Treatment of Opioid Use Disorder – Final Rule). *See also* Vital Strategies' New Federal Regulations for Opioid Treatment Programs – An Overview of Key Changes to 42 CFR Part 8.

[6] National Academies of Sciences, Engineering, and Medicine. Medications for opioid use disorder save lives. (Leshner AI, Mancher M, eds.). Washington, DC: The National Academies Press; 2019. "Patients receiving care through an OTP are mandated to receive counseling as part of their treatment … [but] studies of the effectiveness of this counseling have not demonstrated differences in treatment retention or opioid use among patients randomized to receive little or no interaction with clinic drug counselors."

[7] Centers for Disease Control and Prevention. Linking People with Opioid Use Disorder to Medication Treatment: A Technical Package of Policy, Programs, and Practices. National Center for Injury Prevention and Control, Centers for Disease Control and Prevention, Department of Health and Human Services, 2022. "Engaging in social supports or behavioral health interventions alongside MOUD does not consistently improve treatment outcomes and may not be an appropriate requirement or pre-requisite for MOUD."

[8] Weiss RD, Potter JS, Fiellin DA, et al. Adjunctive Counseling During Brief and Extended Buprenorphine-Naloxone Treatment for Prescription Opioid Dependence: A 2-Phase Randomized Controlled Trial. Arch Gen Psychiatry. 2011;68(12):1238–1246.

[9] Fiellin DA, Pantalon MV, Chawarski MC, Moore BA, Sullivan LE, O'Connor PG, Schottenfeld RS. Counseling plus buprenorphine-naloxone maintenance therapy for opioid dependence. N Engl J Med. 2006 Jul 27;355(4):365-74.

[10] Fiellin DA, Barry DT, Sullivan LE, Cutter CJ, Moore BA, O'Connor PG, Schottenfeld RS. A randomized trial of cognitive behavioral therapy in primary care-based buprenorphine. Am J Med. 2013 Jan;126(1):74.e11-7.

methadone treatment are associated with significantly lower retention rates.[11] Based on its review of this evidence, the National Academies concluded in 2019 that "psychosocial supports required at OTPs should be recalibrated."[12] The proposed rules effectuate such a recalibration by requiring that OTPs ensure the *availability* of counseling while making clear that "access to medication for an enrolled recipient is not contingent upon receipt of counseling services."[13] This approach is also consistent with federal law,[14] and with the American Society of Addiction Medicine's (ASAM) National Practice Guidelines, which recommend that a patient's decision to decline behavioral health treatment should not impede their access to medication treatment for OUD.[15]

c. Removal of nonevidence-based admission criteria.

Under existing rules, patients requesting maintenance treatment generally "must have been addicted for at least 12 months prior to starting OTP services."[16] Additionally, minor patients must have had "two documented unsuccessful attempts at short-term opioid treatment withdrawal procedures or drug-free treatment within a 12 month period."[17] Treatment with agonist medications is the safest, most effective option for people with opioid use disorder,[18] and requiring that an individual have become addicted at least 1 year before admission does not reflect current clinical standards.[19] Additionally, facilitating access to evidence-based medication treatment for young people is particularly important considering rising youth overdose rates and research showing that most young people with OUD do not receive effective treatment.[20] Vital Strategies strongly supports the proposed removal of these unnecessary and nonevidence-based admission criteria.

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[11] Hochheimer M, Unick GJ. Systematic Review and meta-analysis of retention in treatment using medications for opioid use disorder by medication, race/ethnicity, and gender in the United States. Addictive Behaviors. 2022;124:107113.
[12] National Academies of Sciences, Engineering, and Medicine. Medications for opioid use disorder save lives. (Leshner AI, Mancher M, eds.). Washington, DC: The National Academies Press; 2019.
[13] Proposed NMAC 8.321.2.31.
[14] 42 CFR § 8.12(f)(5)(i) ("Patient refusal of counseling shall not preclude them from receiving MOUD.")
[15] American Society of Addiction Medicine. The ASAM National Practice Guideline for the Treatment of Opioid Use Disorder: 2020 Focused Update. 2020:37; Accessed August 30, 2022. https://www.asam.org/quality-care/clinical-guidelines/national-practice-guideline ("A patient's decision to decline psychosocial treatment or the absence of available psychosocial treatment should not preclude or delay pharmacological treatment of opioid use disorder, with appropriate medication management.")
[16] NMAC 8.321.2.30(C)(1)(c). Current rules provide certain exemptions. *See* NMAC 8.321.2.30(C)(1)(c)(i)-(iii) ("was released from a penal institution within the last six months; is pregnant, as confirmed by the agency's physician; was treated for opioid use disorder within the last 24 months.")
[17] NMAC 8.321.2.30(C)(1)(c)(iv).
[18] National Academies of Sciences, Engineering, and Medicine. Medications for opioid use disorder save lives. (Leshner AI, Mancher M, eds.). Washington, DC: The National Academies Press; 2019.
[19] *See* 87 Fed. Reg. 77340 ("A significant change in OTP access is the removal of the requirement that patients must have had an addiction to opioids for at least one year prior to admission for MOUD; this is a vestige of prior versions of the DSM and has posed a barrier to access to treatment.")
[20] Andrew Terranella, Gery P. Guy, Christina Mikosz; Buprenorphine Dispensing Among Youth Aged ≤19 Years in the United States: 2015–2020. Pediatrics 2023; e2022058755.

d. Authorization for expanded take-home methadone.

The proposed rules make permanent and expand the take-home flexibilities first implemented during the COVID-19 public health emergency. More specifically, OTP patients would be permitted up to a 7-day take-home supply during the first 14 days of treatment, a 14-day supply starting on day 15 of treatment, and a 28-day supply starting on day 31 of treatment.[21] Studies show that increased take-home doses are associated with improved treatment retention, reduced urine drug screens positive for opioids, and reduced stigma.[22,23,24] Additionally, increased take-home doses do not increase medication non-adherence, diversion, methadone-related overdoses, or other negative treatment outcomes.[25,26,27] Vital Strategies strongly supports the proposed changes to increase patient access to take-home methadone, including the requirement that OTPs document the rationale for any decision to withdraw unsupervised doses.[28]

e. Explicit authorization for medication units.

OTP patients often must travel substantial distances to access treatment services,[29] which can directly and negatively affect treatment outcomes. A recent study in a U.S. metropolitan area found that even a "10-min drive was associated with a 33% reduction in the completion of methadone treatment plans."[30] Fixed-site and mobile medication units are critical to addressing these treatment barriers and many are equipped to provide the full range of OTP services. Vital Strategies supports proposed amendments that would explicitly allow OTPs to apply to add a medication unit to their existing registration,[31] and to

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[21] Proposed NMAC 8.321.2.31(D)(8)(c)-(e).
[22] Suen LW, Castellanos S, Joshi N, Satterwhite S, Knight KR. "the idea is to help people achieve greater success and Liberty": A qualitative study of expanded methadone take-home access in opioid use disorder treatment. Substance Abuse. 2022;43(1):1147-1154.
[23] Hoffman KA, Foot C, Levander XA, et al. Treatment retention, return to use, and recovery support following COVID-19 relaxation of methadone take-home dosing in two rural opioid treatment programs: A mixed methods analysis. Journal of Substance Abuse Treatment. 2022;141:108801.
[24] Walters SM, Perlman DC, Guarino H, Mateu-Gelabert P, Frank D. Lessons from the first wave of covid-19 for improved medications for opioid use disorder (MOUD) treatment: Benefits of easier access, extended take homes, and new delivery modalities. Substance Use & Misuse. 2022;57(7):1144-1153.
[25] Amram O, Amiri S, Panwala V, Lutz R, Joudrey PJ, Socias E. The impact of relaxation of methadone take-home protocols on treatment outcomes in the COVID-19 ERA. The American Journal of Drug and Alcohol Abuse. 2021;47(6):722-729.
[26] Figgatt MC, Salazar Z, Day E, Vincent L, Dasgupta N. Take-home dosing experiences among persons receiving methadone maintenance treatment during COVID-19. Journal of Substance Abuse Treatment. 2021;123:108276.
[27] Pessar SC, Boustead A, Ge Y, Smart R, Pacula RL. Assessment of state and federal health policies for opioid use disorder treatment during the COVID-19 pandemic and beyond. JAMA Health Forum. 2021;2(11).
[28] Proposed NMAC 8.321.2.31(D)(8)(g).
[29] Rosenblum A, Cleland CM, Fong C, Kayman DJ, Tempalski B, Parrino M. Distance traveled and cross-state commuting to opioid treatment programs in the United States. Journal of Environmental and Public Health. 2011;2011:1-10.
[30] Alibrahim A, Marsh JC, Amaro H, Kong Y, Khachikian T, Guerrero E. Disparities in expected driving time to opioid treatment and treatment completion: Findings from an exploratory study. BMC Health Services Research. 2022;22(1).
[31] Proposed NMAC 8.321.2.31(D)(7)(a).

allow the full range of OTP services be provided in such medication unit(s) if there is appropriate privacy and adequate space.[32]

The Department should, however, remove the requirement that a letter of intent seeking authorization for a medication unit "demonstrate[] how [the medication unit] will increase access to methadone in rural communities."[33] Although medication units are beneficial for increasing OTP access in rural communities, their benefits are not so limited. Medication units established in pharmacies, other community-based settings, and correctional institutions can improve access to OTPs in urban, suburban, rural, and frontier communities alike.

f. Authorization for initial medical examinations to be conducted via telehealth.

Research demonstrates the value and efficacy of telehealth-based access to MOUD treatment.[34] Patient access to OUD treatment via telehealth is associated with "improved MOUD retention and lower odds of medically treated overdose,"[35] and audio-only telehealth access is particularly important for reaching underserved populations.[36,37] Vital Strategies supports proposed amendments allowing initial medical examinations to be conducted via telehealth,[38] and recommends the Department make clear that this authorization includes audio-only telehealth to the full extent permitted by federal law.[39]

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[32] Proposed NMAC 8.321.2.31(D)(7)(d).
[33] Proposed NMAC 8.321.2.31(D)(7)(a)(i).
[34] Brian Chan, Christina Bougatsos, Kelsey C. Priest, Dennis McCarty, Sara Grusing & Roger Chou (2022) Opioid treatment programs, telemedicine and COVID-19: A scoping review, Substance Abuse, 43:1, 539-546.
[35] Jones CM, Shoff C, Hodges K, et al. Receipt of Telehealth Services, Receipt and Retention of Medications for Opioid Use Disorder, and Medically Treated Overdose Among Medicare Beneficiaries Before and During the COVID-19 Pandemic. JAMA Psychiatry. 2022;79(10):981–992.
[36] Frost MC, Zhang L, Kim HM, Lin L. Use of and Retention on Video, Telephone, and In-Person Buprenorphine Treatment for Opioid Use Disorder During the COVID-19 Pandemic. JAMA Netw Open. 2022;5(10):e2236298.
[37] Clark SA, Davis C, Wightman RS, Wunsch C, Keeler LAJ, Reddy N, Samuels EA. Using telehealth to improve buprenorphine access during and after COVID-19: A rapid response initiative in Rhode Island. J Subst Abuse Treat. 2021 May;124:108283.
[38] Proposed NMAC 8.321.2.31(C)(1)(b), (F)(2)(d). *See also* Proposed NMAC 8.321.2.31(D)(7)(d)(vi) ("in units that provide appropriate privacy and have adequate space, other OTP services, such as counseling, may be provided directly *or when permissible through use of telehealth services.*") (emphasis added).
[39] 42 CFR § 8.12(f)(2)(v) (authorizing conducting screening and full examination via audio-only telehealth when "evaluating patients for treatment with schedule III medications (such as Buprenorphine) or medications not classified as a controlled medication (such as Naltrexone)," and when "evaluating patients for treatment with schedule II medications (such as Methadone)" if an audio-visual telehealth platform is not available and "the patient is in the presence of a licensed practitioner who is registered to prescribe (including dispense) controlled medications").

II. Conflicts Between Proposed 8.321.2.31 NMAC and Current 8.321.10 NMAC.

Vital Strategies is concerned that many of the proposed amendments to 8.321.2.31 NMAC will not have their intended effect because they conflict with provisions in 8.321.10 NMAC, which provide the generally applicable rules governing OTPs in New Mexico. These conflicts include, for example:

- **Authorization for Medication Units:** NMAC 8.321.10.7(R) defines an "Opioid treatment program" as "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."[40] The reference to a "single location" could be read to conflict with the authorization for medication units in proposed NMAC 8.321.2.31(D)(7).
- **Admission Criteria:** NMAC 8.321.10.19(A)(3) maintains admission criteria that directly conflict with the proposed repeal of current NMAC 8.321.2.31(C)(1)(c).[41] This includes the requirement that a patient requesting maintenance treatment have "been addicted for at least 12 months before the admission" unless they meet an exception,[42] and that minors have "had two documented unsuccessful attempts at short term opioid withdrawal procedures or drug-free treatment within a 12-month period."[43]
- **Methadone Take-Home Criteria:** NMAC 8.321.10.23(B) maintains take-home criteria that reflect the federal regulations in effect prior to April 2, 2024,[44] and which directly conflict with the proposed criteria for methadone take-home doses in proposed NMAC 8.321.2.31(D)(8)(a).
- **Methadone Take-Home Schedule:** NMAC 8.231.10.23(D) maintains a schedule of permissible methadone take-home doses that reflect the federal regulations in effect prior to April 2, 2024,[45] and which directly conflict with the proposed schedule for methadone take-home doses in proposed NMAC 8.321.2.31(D)(8)(c)-(e).

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[40] NMAC 8.321.10.7(R) (emphasis added).
[41] The provision which the Department proposes to repeal is currently codified at NMAC 3.321.2.30(C)(1)(c). However, we refer to NMAC 3.321.2.31 for the sake of consistency and accurate reference to the proposed rulemaking.
[42] NMAC 8.321.10.19(A)(3).
[43] NMAC 8.321.10.19(A)(3)(d).
[44] *See* 89 Fed. Reg. 7528 (providing that the final rule updating 42 CFR Part 8 is effective April 2, 2024). *See also* Vital Strategies' New Federal Regulations for Opioid Treatment Programs – An Overview of Key Changes to 42 CFR Part 8, Page 8 (outlining stability criteria for methadone take-homes under the new and prior federal regulations). Current federal take-home criteria are codified at 42 CFR § 8.12(i)(2).
[45] *See* 89 Fed. Reg. 7528 (providing that the final rule updating 42 CFR Part 8 is effective April 2, 2024). *See also* Vital Strategies' New Federal Regulations for Opioid Treatment Programs – An Overview of Key Changes to 42 CFR Part 8, Page 9 (outlining stability criteria for methadone take-homes under the new and prior federal regulations). The current federal methadone take-home schedule is codified at 42 CFR § 8.12(i)(3).

- **Conditioning Medication Access on Counseling Services:** Although not a direct conflict, the language used throughout 8.231.10 NMAC does not clearly articulate that "access to medication for an enrolled recipient [of an OTP] is not contingent upon receipt of counseling services," in sharp contrast with proposed 8.321.2.31 NMAC.

The conflicts between proposed 8.321.2.31 NMAC and 8.321.10 NMAC are likely to undermine the Department's objectives and cause widespread confusion among OTP operators throughout New Mexico, particularly among OTPs that serve both Medicaid and non-Medicaid populations. Vital Strategies urges the Department to resolve these conflicts by proposing and finalizing corresponding amendments to 8.321.10 NMAC, including via emergency rulemaking if necessary.

III. Specific Recommendations to Clarify and Improve 8.321.10 NMAC.

In addition to addressing the conflicts between proposed 8.321.2.31 NMAC and 8.321.10 NMAC, Vital Strategies recommends the Department conduct a comprehensive evaluation and revision of 8.321.10 NMAC to align the state's OTP rules with evidence-based best practices. In this section, we offer specific recommendations for amending existing provisions of 8.321.10 NMAC.

a. Repeal NMAC 8.321.10.7(O)(4).

Current NMAC 8.321.10.7(O)(4) defines, in part, a "medical practitioner" as an individual who "may be a physician, physician's assistant, registered nurse, nurse practitioner, or licensed practical nurse." The Department should repeal this language to ensure the definition of "medical practitioner" is inclusive of all licensed health care professionals with a sufficient scope of practice.

b. Fully align 8.321.10 NMAC with current federal regulations at 42 CFR Part 8.

The Department should ensure that 8.321.10 NMAC fully aligns with current federal regulations.

- **Amend NMAC 8.321.10.19(A)** to clarify that qualified practitioners other than the program medical director may determine that a patient meets admission criteria.[46]

[46] The current rule provides that an OTP's policies and procedures must require "that an individual is only admitted for opioid dependency treatment *after the program medical director* determines and documents" that the individual meets the admission criteria. NMAC 8.321.10.19(A). The rule's definition of "program medical director" includes references to delegated authority. *See* NMAC 8.321.10.7(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.") (emphasis added). The Department should clarify whether all references to "program medical director" are inclusive of the authority to delegate to other authorized medical practitioners. An ability for qualified medical practitioners other than a program's medical director to make admissions determinations would be consistent with both current and historical federal regulations. *See* 42 CFR § 8.12(e)(1) ("An OTP shall maintain current procedures designed to ensure that patients are

- **Repeal NMAC 8.321.10.19(A)(3)**, which imposes additional admission criteria for maintenance treatment (e.g., 1-year history of addiction for adults, two documented unsuccessful attempts at short term opioid treatment withdrawal procedures or drug-free treatment within a 12-month period for minors).[47]
- **Repeal NMAC 8.321.10.19(B)**, which requires a program sponsor to ensure that an individual requesting withdrawal treatment who has had two or more unsuccessful withdrawal treatment episodes in a 12-month period is assessed for other forms of treatment.[48]
- **Amend NMAC 8.321.10.19(D)** to clearly allow medication treatment to commence after a screening examination rather than first requiring a fully documented physical examination.[49] The Department should allow the screening (and full medical examination) to occur via telehealth, including audio-only telehealth, to the full extent permitted by federal law.[50]
- **Amend NMAC 8.321.10.21(D)(4)** on initial methadone dosages to incorporate by reference (or, in the alternative, mirror) current 42 CFR § 8.12(h)(3)(ii).[51] This includes allowing up to a 50mg

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admitted to treatment *by qualified personnel* who have determined, using accepted medical criteria, that" the patient meets applicable criteria) (emphasis added); 42 CFR § 8.12(e)(1) (2023) (applying the same substantive requirement).

[47] These admission criteria are no longer required by federal law, effective April 2, 2024. *See* 89 Fed. Reg. 7536 ("The final rule removes the requirement, previously at 8.12(e)(2), that minors are required to have had two documented unsuccessful attempts at short-term 'detoxification', or withdrawal management, or drug-free treatment within a 12-month period to be eligible for maintenance treatment"), 7542 ("Criteria for admission to treatment … eliminates the requirement for a one-year history of OUD").

[48] This limitation is no longer required by federal law, effective April 2, 2024. *See* 89 Fed. Reg. 7536 ("The final rule removes the requirement … that those seeking withdrawal management, previously under 8.12(e)(4), cannot initiate methadone treatment more than twice per year").

[49] Current federal regulations provide that "[a]ssuming no contraindications, a patient may commence treatment with MOUD after the screening examination has been completed," with the "full in-person physical examination" being "completed within 14 calendar days following a patient's admission to the OTP." 42 CFR § 8.12(f)(2)(ii)-(iii). Current New Mexico rules are ambiguous as to whether this is already permitted. *Compare* NMAC 8.321.10.19(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") *with* NMAC 8.321.10.19(D)(6) ("the full medical examination including test results must be completed within 14 days of admission to the program"). The Department should, at minimum, clarify and harmonize these provisions.

[50] *See* 42 CFR §§ 8.12(f)(2)(v) ("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"); (f)(2)(v)(A) (authorizing conducting screening and full examination via audio-only telehealth when "evaluating patients for treatment with schedule II medications (such as Methadone)" if an audio-visual telehealth platform is not available and "the patient is in the presence of a licensed practitioner who is registered to prescribe (including dispense) controlled medications"); (f)(2)(v)(B) (authorizing conducting screening and full examination via audio-only telehealth when "evaluating patients for treatment with schedule III medications (such as Buprenorphine) or medications not classified as a controlled medication (such as Naltrexone)").

[51] 42 CFR § 8.12(h)(3)(ii) ("For each new patient enrolled in an OTP, the initial dose of methadone shall be individually determined and shall include consideration of the type(s) of opioid(s) involved in the patient's opioid use disorder, other medications or substances being taken, medical history, and severity of opioid withdrawal. The total dose for the first day should not exceed 50 milligrams unless the OTP practitioner, licensed under the appropriate State law and registered under

total dose for the first day without any additional documentation and a total dose exceeding 50mg on the first day if an OTP practitioner finds and documents sufficient medical rationale, with no separate limitations on initial dose (i.e., no requirement to provide an initial dose of less than 50mg).

- **Repeal NMAC 8.321.10.21(D)(5)**, which requires additional documentation for an OTP to provide an initial dosage of buprenorphine exceeding the instructions on the medication package insert. Federal law does not specifically impose any restrictions on the initial dosage of buprenorphine,[52] and the maximum dosages on buprenorphine medication package inserts is often inadequate based on the current drug supply.[53]
- **Amend NMAC 8.321.10.22(B)** to remove the requirement that long-term opioid treatment withdrawal procedure patients receive an initial and monthly random drug test,[54] and to require that drug testing be conducted "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."[55]
- **Amend NMAC 8.321.10.23(B)** to align with the criteria for take-home doses in current 42 CFR § 8.12(i)(2) and proposed NMAC 8.321.2.31(D)(8)(a).
- **Amend NMAC 8.321.10.23(D)** to align with the schedule for methadone take-home doses in current 42 CFR § 8.12(i)(3) and proposed NMAC 8.321.2.31(D)(8)(c)-(e).

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the appropriate State and Federal laws to administer or dispense MOUD, finds sufficient medical rationale, including but not limited to if the patient is transferring from another OTP on a higher dose that has been verified, and documents in the patient's record that a higher dose was clinically indicated.")

[52] Federal regulations do require that OTPs "ensure that any *significant* deviations from the approved labeling, including deviations with regard to dose, frequency, or the conditions of use described in the approved labeling, are specifically documented in the patient's record." 42 CFR § 8.12(h)(4) (emphasis added). This, at minimum, contrasts with New Mexico's *absolute* requirement to document *any* deviation. *See* NMAC 8.321.10.21(D)(5) ("and *any* deviation from the instructions is documented by the program clinician in the patient record") (emphasis added).

[53] Suboxone's medication package insert, for example, provides for only up to an 8mg/2mg dose on the first day of treatment. *See generally* Lei F, Lofwall MR, McAninch J, et al. Higher first 30-day dose of buprenorphine for opioid use disorder treatment is associated with decreased mortality. Journal of Addiction Medicine. 2024;18(3):319-326. doi:10.1097/adm.0000000000001300 ("Higher first 30-day buprenorphine doses were associated with reduced opioid-involved overdose death and death from other causes, supporting benefit of higher dosing in reducing mortality.")

[54] Although prior federal regulations specifically addressed the frequency of drug tests for patients receiving long-term detoxification treatment, current federal regulations apply the standard of a minimum of eight random drug tests per year to all OTP patients. *Compare* 42 CFR § 8.12(f)(6) (2023) ("For patients in short-term detoxification treatment, the OTP shall perform at least one initial drug abuse test. For patients receiving long-term detoxification treatment, the program shall perform initial and monthly random tests on each patient.") *with* current 42 CFR § 8.12(f)(6) (no such distinction).

[55] 42 CFR § 8.12(f)(6).

c. *Strengthen language throughout 8.321.10 NMAC regarding the voluntary nature of counseling and other ancillary services.*

The Department's proposed changes to NMAC 8.321.2.31 require OTPs to ensure the *availability* of counseling while making clear that "access to medication for an enrolled recipient is not contingent upon receipt of counseling services."[56] This change is consistent with federal law,[57] federal guidance,[58] and the overall evidence base.[59] **The Department should amend language throughout 8.321.10 NMAC to reinforce the voluntary nature of counseling services, and extend the language to also ensure OTPs do not make medication access contingent on patients' receipt of other, non-counseling ancillary services.[60]**

d. *Repeal unnecessary provisions related to local authority and community relations.*

New Mexico's current OTP rules place substantial and unnecessary emphasis on community relations and local authority, and, in doing so, reinforce unfounded stereotypes about OTPs and the people who receive care from them.[61,62] Community opposition to the establishment and operation of OTPs is

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[56] Proposed NMAC 8.321.2.31.
[57] 42 CFR § 8.12(f)(5)(i) ("Patient refusal of counseling shall not preclude them from receiving MOUD.")
[58] *See, e.g.,* Substance Abuse and Mental Health Services Administration. Low Barrier Models of Care for Substance Use Disorders. Advisory. Publication No. PEP23-02-00-005. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2023 ("Treatment engagement conditions or preconditions should not be placed on the patient. … While counseling should be offered to patients, the provision of medication should not be contingent upon participation or engagement in a set counseling schedule.")
[59] *See* citations in Section I(B) above.
[60] For example, the Department should amend the following sections to read as follows: NMAC 8.321.10.18(D)(17) ("criteria for determining the amount and frequency of counseling that is provided to a patient *that desires such counseling*; procedures to ensure that the facility's physical appearance is clean and orderly"); NMAC 8.321.10.20(D)(4) ("recommendations for treatment needed by the patient, such as psychosocial counseling or mental health treatment, if indicated *and desired by the patient*"); NMAC 8.321.10.20(D)(5) ("recommendations for ancillary services or other services needed by the patient, if indicated *and desired by the patient*"); NMAC 8.321.10.25(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*, if desired by the patient,* based upon the patient's individual needs, treatment plan and stage of readiness to change behavior:"); NMAC 8.321.10.28(B)(6) ("documentation of *voluntary* counseling *and other services* provided to the patient.")
[61] For example, NMAC 8.321.10.2 goes out of its way to note that counties and municipalities may adopt supplemental ordinances so long as they do not conflict with the Department's rules. *See* NMAC 8.321.10.2 ("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"). We could not identify any other Department rule on health care facilities or services in which it actively invites supplemental local regulation. We also note that in litigation pending before the New Mexico Supreme Court, the New Mexico Attorney General has argued that "state medical licensing provisions preempt local requirements for medical licensing" because state laws "establish a statewide, uniform system of qualifications and standards for the practice of medicine and the operation of health facilities." The Attorney General distinguishes ordinances that specifically target medical practice from those that "merely impose general regulations applicable to all or many entities, such as a general business license or a zoning provision applicable to the business community as a whole." Petitioner's Brief in Chief. *State of New Mexico v. Board of County Commissioners for Lea County et. al.* Supreme Court of New Mexico. April 20, 2023.
[62] *See* NMAC 8.321.10.6(C) (stating that the Department's rule is intended, in part, to "consider the possible adverse impact on communities in which OTP providers are located in making application approval decisions," presupposing that OTPs have a

rooted in stigma and discrimination against people who use drugs and often untethered from any objective assessment as to the impact of OTPs on communities. Additionally, local governments have a long history of using zoning and other regulatory measures to impede access to OTPs, including in ways that violate federal anti-discrimination laws.[63]

Vital Strategies is concerned that the Department's current rules reinforce these problematic assumptions and invite unwarranted scrutiny and regulation of OTPs throughout the state. Our concern is underscored by the fact that we could not identify any instance in which Department rules impose analogous requirements on other healthcare facilities. Methadone treatment for opioid use disorder is lifesaving, evidence-based health care, and the Department's rules should ensure facilities providing such care are treated the same as any other medical provider.

e. Ensure provisions throughout 8.321.10 NMAC encourage patient-centered practices that lower barriers to treatment and respect patient autonomy.

Vital Strategies recommends the Department conduct a comprehensive review of 8.321.10 NMAC to ensure all provisions align with and encourage patient-centered practices that lower barriers to treatment and respect patient autonomy. Specific recommendations include,

- **Amend NMAC 8.321.10.19(C)(3)(e)**, which requires OTPs to inform patients of "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." We do not object to the general requirement that OTPs inform patients of their responsibilities as mandated reporters. However, the Department should clarify that illicit drug use and issues related to an individual's participation in treatment (e.g., medication adherence, actual or suspected diversion, declining services including prenatal services) do *not* constitute sufficient grounds for suspecting child abuse or neglect.
- **Amend NMAC 8.321.10.22(C)** to clarify that the requirement to ensure that "laboratory drug detection tests and other toxicological testing specimens are collected in a manner that

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negative impact on communities); NMAC 8.321.10.29(A)(1) (requiring OTPs to establish "a mechanism for eliciting input from the community about the provider's impact on the community"); NMAC 8.321.10.29(A)(5) (requiring OTPs to establish "a mechanism for addressing and resolving community concerns about opioid treatment or the program's presence in the community"); NMAC 8.321.10.29(C) (requiring OTP program sponsors to comply with "county and municipal ordinances regarding community relations" and expressly providing that the Department "may consult with local governmental entities when enforcing this section").

[63] *See, e.g.,* New Directions Treatment Servs. v. City of Reading, 490 F.3d 293 (3d Cir. 2007) ("We agree with the Sixth and Ninth Circuits that a law that singles out methadone clinics for different zoning procedures is facially discriminatory under the ADA and the Rehabilitation Act.")

minimizes falsification" does not require the use of observed urine screenings, and that the Department does not encourage the use of observed screenings.

- **Amend NMAC 8.321.10.26(B)(1)** to emphasize bodily autonomy and the need to obtain informed consent. More specifically, the provision should read: "(1) pregnancy tests shall be administered *with the patient's informed consent* and reviewed for all *people* of childbearing age prior to initiating a opioid treatment withdrawal procedure or medically supervised withdrawal."

IV. Additional Recommendations to Expand and Protect Access to Lifesaving, Evidence-based Methadone Treatment for Opioid Use Disorder.

a. Establish and/or strengthen patient protections against punitive actions by OTPs.

Return to use (also commonly referred to as "relapse"), polysubstance use, missed appointments, and declining ancillary services are common reasons for providers to discharge patients from treatment. Patients' fatal overdose risk is increased in the period following termination from treatment.[64] Effective, evidence-based treatment should employ compassionate, patient-centered responses to return to use as a normal feature of the recovery process and the high prevalence of polysubstance use among people with OUD.[65,66] As an American Society of Addiction Medicine's (ASAM) consensus statement makes clear, "[d]rug testing should be used as a tool for supporting recovery rather than exacting punishment."[67]

New Mexico's current OTP rules establish a solid foundation, prohibiting the use of medication dosage "to reinforce positive behavior or punish negative behavior"[68] and requiring OTPs to establish a "process for resolution of patient complaints."[69] However, the rules provide little detail on the

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[64] Sordo L, Barrio G, Bravo M J, Indave B I, Degenhardt L, Wiessing L et al. Mortality risk during and after opioid substitution treatment: systematic review and meta-analysis of cohort studies BMJ 2017; 357:j1550.
[65] The National Institute on Drug Abuse defines addiction as "a chronic, relapsing disorder." https://nida.nih.gov/publications/drugs-brains-behavior-science-addiction/drug-misuse-addiction.
[66] In a sample derived from a nationally representative database, nearly 6 in 10 people with OUD had polysubstance use. Hassan AN, Le Foll B. Polydrug use disorders in individuals with opioid use disorder. Drug Alcohol Depend. 2019 May 1;198:28-33.
[67] American Society of Addiction Medicine. Appropriate Use of Drug Testing in Clinical Addiction Medicine. Adopted by the ASAM Board of Directors on April 5, 2017. Accessed February 9, 2023. Available at https://www.asam.org/quality-care/clinical-guidelines/drug-testing. *See also* 89 Fed. Reg. 7534-7535 ("Toxicology testing is a clinical tool that is used to inform the treatment process, *should never be used punitively*, and must be conducted in a way that is respectful of the individual and in accordance with clinical and professional standards") (emphasis added).
[68] NMAC 8.321.10.21(D)(6)(c).
[69] NMAC 8.321.10.18(D)(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"); 8.321.10.19(C)(3)(k) ("The OTP shall ensure that each patient at

requirements for the dispute resolution process, do not include permissible and prohibited grounds for involuntary termination (i.e., administrative discharge),[70] and do not otherwise establish any substantive patient protections.

Vital Strategies strongly recommends that the Department modify its rules to prohibit OTPs from discharging or otherwise taking punitive action against patients based on drug screen results, polydrug use, missed appointments, or a patient declining ancillary services.[71,72,73] OTP policies and procedures should also be required to provide patients adequate notice of and an opportunity to contest any disciplinary action such as reductions in take-home privileges or termination from treatment.[74]

b. Strengthen and expand access to take-home methadone.

New Mexico's OTP rules continue to grant OTPs vast discretion to determine the number of take-home doses a patient is permitted, or even whether to allow a patient to receive take-home doses at all. Although the rules require OTPs to develop, implement, and comply with policies and procedures that include "criteria for determining when a patient is ready to receive take-home medication" and "criteria

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the time of admission: 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"). *See also* NMAC 8.321.10.24(F) ("The program sponsor shall ensure that: 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").

[70] *See* NMAC 8.321.10.7(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.")

[71] We recognize that ceasing methadone treatment due to potential drug interactions can be clinically justified at times. Discharge based on polysubstance use should therefore be permitted only if the risk of co-use outweighs the risk of overdose death following termination of treatment.

[72] The American Society of Addiction Medicine's consensus statement on the appropriate use of drug testing in clinical addiction medicine notes that "[u]nexpected drug test results could indicate the need for 1 or more of the following responses: (1) a higher level of care; (2) a higher dose of medication; (3) a different schedule of testing, such as random rather than scheduled and/or more frequent; and/or (4) increased education for the patient." American Society of Addiction Medicine. Appropriate Use of Drug Testing in Clinical Addiction Medicine. Adopted by the ASAM Board of Directors on April 5, 2017. Accessed February 9, 2023. Available at https://www.asam.org/quality-care/clinical-guidelines/drug-testing. These recommended responses notably do *not* include dose reductions, termination from treatment, or other disciplinary measures.

[73] Several states have recently taken steps to minimize patient discharge from SUD treatment services. Kentucky, for example, reclassified things such as positive drug screens or failure to attend scheduling dosing or counseling appointments as "program non-compliance" that would result in modification of a patient's treatment plan rather than termination. 908 Ky. Admin. Regs. 1:374, Section 7(12)(c), 7(15)(a)-(b). Kentucky's regulations also provide that an OTP "shall not use drug screens as the sole criteria for involuntarily terminating a client's participation in the program" and that polydrug use is grounds for involuntary termination only if the "the risk of co-use outweighs risk of overdose death following termination of methadone treatment." 908 Ky. Admin. Regs. 1:374, Section 7(9)(f), 7(15)(d)(1). Similarly, regulations in Michigan prohibit SUD treatment providers from discharging "a recipient due to a return to use as long as the recipient reengages in treatment and complies with program policies and treatment protocol prospectively." Mich. Admin. Code r. 325.1331(2)(e).

[74] The opportunity to contest disciplinary action should generally occur *prior to* its imposition. *See, e.g.,* 105 CMR 164.311-.312 (Massachusetts regulations establishing procedural requirements and protections regarding involuntary termination from an opioid treatment program and state review of termination decisions).

for when a patient's take-home medication is increased or decreased," they do not specify what these criteria should or must be apart from the considerations required by federal law.[75] Many OTPs continue to treat take-home doses as a privilege to be earned by patients rather than a routine aspect of evidence-based care. OTPs are also frequently disinclined to support increased take-home doses due to financial incentives or outdated beliefs about effective treatment approaches,[76,77] making it unlikely their policies and procedures will enable most patients to be eligible for the maximum number of take-home doses.

Vital Strategies recommends that New Mexico reverse this framework by establishing a presumption that OTP patients are eligible for the maximum number of take-home doses corresponding with their time in treatment. OTP practitioners would still retain clinical discretion to allow fewer take-home doses or even deny take-home doses entirely, consistent with their responsibilities under state and federal law. However, the OTP practitioner would be required to justify and document any downward departure in allowable take-homes for *each individual patient* based on the criteria in 42 CFR § 8.12(i)(2) and state rules. Requiring OTP practitioners to justify why a patient should *not* receive take-home doses would more appropriately reflect the evidence-base by establishing that take-home doses should be the norm, not the exception. It would also reduce the likelihood of OTP providers systematically denying clinically appropriate take-home doses, a practice that was common with the COVID-19 flexibilities.[78]

Additionally, Vital Strategies recommends that the Department:

- Require OTPs to make their take-home policies and procedures publicly available and to disclose them to all patients prior to and upon admission.
- Establish a presumption that a patient may maintain their current take-home medication doses upon transferring from one OTP to another.

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[75] NMAC 8.321.10.23(A)(1)-(2), (B); proposed NMAC 8.321.2.31(D)(8)(a), (b)(i)-(ii).
[76] Joseph A. Under new rules, methadone clinics can offer more take-home doses. will they? STAT. https://www.statnews.com/2022/12/22/new-rules-methadone-clinics-take-home-doses/. Published December 22, 2022. "[C]linics have a financial incentive to maintain the status quo. They can bill insurance or charge patients (many clinics take cash) for more services, from drug tests to counseling sessions, when people come in more frequently. Giving patients more take-homes could amount to lost revenue…."
[77] Madden EF, Christian BT, Lagisetty PA, Ray BR, Sulzer SH. Treatment provider perceptions of take-home methadone regulation before and during COVID-19. Drug and Alcohol Dependence. 2021;228:109100. "[P]ost-pandemic efforts to extend looser methadone distribution policies will have to address apprehensive professionals if such policy changes are to be meaningfully adopted in community services."
[78] Joseph A. Under new rules, methadone clinics can offer more take-home doses. will they? STAT. https://www.statnews.com/2022/12/22/new-rules-methadone-clinics-take-home-doses/. Published December 22, 2022. Accessed February 9, 2023.

c. *Clarify authorization for guest dosing and medication units.*

Proposed NMAC 8.321.2.31(F)(2)(h) provides that "guest dosing may be reimbursed at medicaid-enrolled agencies per 7.32.8 NMAC."[79] This is the sole reference to guest dosing in either 8.321.2.31 NMAC or 8.321.10 NMAC,[80] making it unclear whether and how guest dosing is authorized. Vital Strategies strongly supports the ability of OTPs to provide guest dosing to patients of other OTPs, which facilitates patients' ability to remain in treatment while traveling, and the Department should modify its rules to explicitly authorize such practices.[81]

Additionally, proposed NMAC 8.321.2.31(D)(7) would establish an approval process for medication units and includes references to both mobile and non-mobile medication units.[82] However, these references are inconsistent, and the proposed rule fails to clearly articulate whether both mobile and non-mobile medication units are authorized and, if so, the full scope of services that may be provided in each. We recommend the Department modify its rules (both proposed NMAC 8.321.2.31 and 8.321.10 NMAC) to define and authorize mobile and non-mobile medication units consistent with federal law.[83]

d. *Authorize interim treatment in alignment with federal regulations.*

The recent changes to 42 CFR Part 8 included notable improvements regarding interim treatment.[84] Studies show that interim treatment reduces illicit drug use and increases the likelihood that patients

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[79] Currently codified at NMAC 8.321.2.30(F)(2)(h).

[80] 7.32.8 NMAC was recently repealed and reenacted in substantively identical form at 8.321.10 NMAC as part of the state's Health Care Authority transition.

[81] Federal regulations recently expanded the circumstances in which an individual may obtain treatment from an OTP that is not their home OTP. *See* 42 CFR § 8.12(g)(2) ("Such circumstances include, but are not limited to, travel for work or family events, temporary relocation, or an OTP's temporary closure.")

[82] *See, e.g.,* proposed NMAC 8.321.2.31(D)(7)(d) ("the following services may be provided where space allows for quality patient care *in mobile medication units*, assuming compliance with all applicable federal, state, and local law"), (D)(7)(e) ("any required services not provided in *mobile and non-mobile medication units* must be conducted at the OTP, including medical, counseling, vocational, educational, and other assessment, and treatment services") (emphasis added).

[83] *See* 42 CFR §§ 8.2 ("Medication unit means an entity that is established as part of, but geographically separate from, an OTP from which appropriately licensed OTP practitioners, contractors working on behalf of the OTP, or community pharmacists may dispense or administer MOUD, collect samples for drug testing or analysis, or provide other OTP services. *Medication units can be a brick-and-mortar location or mobile unit*.") (emphasis added); 8.11(h)(1) ("Certified OTPs may establish medication units that are authorized to dispense MOUD. … Medication units include both mobile and brick and mortar facilities."); 8.11(h)(2) ("Specifically, any services that are provided in an OTP may be provided in the medication unit, assuming compliance with all applicable Federal, State, and local law, and the use of units that provide appropriate privacy and have adequate space.").

[84] These changes include (1) increasing the maximum length of interim treatment from 120 to 180 days in any 12-month period; (2) reducing the minimum number of required drug screens; (3) authorizing take-home doses for patients in interim treatment: (4) requiring OTPs to provide information on "locally available, community-based resources for ancillary services;" and (5) prohibiting the discharge of a patient in interim treatment without the approval of an OTP practitioner. *Compare* 42 CFR § 8.12(j)(4)(ii) ("Interim treatment cannot be provided for longer than 180 days in any 12-month period") *with* 42 CFR § 8.12(j)(4)(v) (2023) ("Interim maintenance cannot be provided for longer than 120 days in any 12-month period"). *Compare* 42 CFR § 8.12(j)(1) ("At least two drug tests shall be obtained from patients during the maximum of 180 days permitted for interim treatment") *with* 42 CFR § 8.12(j)(1) (2023) ("An initial and at least two other urine screens shall be taken from interim patients

will enter comprehensive treatment.[85] **Vital Strategies recommends the Department explicitly authorize interim treatment in accordance with current federal regulations.[86]**

e. Establish a patient advisory structure.

The Department's proposed changes to 8.321.2.31 NMAC reflect a shift toward a more patient-centered model of care at OTPs. Various provisions of the proposed rule emphasize shared decision-making between patients and OTP practitioners and the voluntariness of services. **Vital Strategies recommends that the Department extend the shift toward patient-centered models of care even further so that people with direct experience receiving services at OTPs can guide the policies, procedures, and practices that directly affect them on a more systemic level.** This could be accomplished by establishing a Patient Advisory Board at the state level to inform the work of the Department, including the state's opioid treatment authority (SOTA).

f. Establish the provision of naloxone as the standard of care for all OTP patients.

Naloxone should be widely accessible to communities, particularly people who use drugs and their networks, yet access remains almost universally inadequate in the United States.[87] Proposed NMAC 8.321.2.31(B)(15) requires a practitioner who "prescribes, distributes, or dispenses an opioid analgesic" to "inform the patient of the availability of an opioid antagonist" and to co-prescribe an opioid antagonist if *prescribing* at least a five-day supply of opioid analgesics.[88] However, proposed 8.321.2.31 NMAC does *not* include any requirement to directly provide or prescribe an opioid antagonist to any individual directly *dispensed* an opioid analgesic, thereby excluding patients receiving methadone from its scope.[89] The generally applicable OTP rules in 8.321.10 NMAC do not address the provision of opioid antagonists at all. **We recommend the Department strengthen its rules by explicitly requiring**

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during the maximum of 120 days permitted for such treatment"). *Compare* 42 CFR § 8.12(j)(4) (no prohibition on take-home doses for patients in interim treatment) *with* 42 CFR § 8.12(j)(4)(i)-(ii) (2023) (providing that "[t]he opioid agonist treatment medication is required to be administered daily under observation" and that "[u]nsupervised or 'take-home' use is not allowed"); s*ee also* 89 Fed. Reg. 7543 (SAMHSA's Final Rule also repealed the language previously codified at 42 CFR § 8.12(i)(4) that provided that no medications may be dispensed to patients in short-term detoxification or interim maintenance treatment for unsupervised or take-home use). 42 CFR §§ 8.12(j)(4)(iv), (f)(2)(iv).

[85] McCarty, D., Chan, B., Bougatsos, C., Grusing, S., & Chou, R. (2021). Interim methadone – effective but underutilized: A scoping review. Drug and Alcohol Dependence, 225, 108766.

[86] SAMHSA's Final Rule also removed the prohibition on the provision of interim treatment by for-profit OTPs. 89 Fed. Reg. 7536 ("Language pertaining to public and not-for-profit OTPs has been removed from the final rule in order to expand access to interim treatment among all OTPs. This is done in recognition of a need to bring individuals into treatment and in response to public comment").

[87] Irvine MA, Oller D, Boggis J, Bishop B, Coombs D, Wheeler E, Doe-Simkins M, Walley AY, Marshall BDL, Bratberg J, Green TC. Estimating naloxone need in the USA across fentanyl, heroin, and prescription opioid epidemics: a modelling study. Lancet Public Health. 2022 Mar;7(3):e210-e218.

[88] Proposed NMAC 8.321.2.31(B)(15). Currently codified at NMAC 8.321.2.30(B)(15).

[89] This is because methadone cannot be *prescribed* for the treatment of opioid use disorder. 21 CFR § 1306.07(a).

OTPs to provide naloxone to all patients. Establishing the provision of naloxone as a standard of care among OTPs will better meet the needs of patients, and importantly gets this lifesaving tool directly into the hands of those at risk.

g. Authorize non-OTP practitioners to conduct initial screening and examinations outside of an OTP, including via telehealth.

Federal regulations now permit non-OTP practitioners to complete both the initial screening and full physical examination, including screenings and examinations that occur outside of OTP settings and/or via telehealth.[90] These changes have the potential to improve patient access to OTP services by allowing a patient's initial screening and full examination to occur in settings such as emergency departments and other hospital settings, primary care clinics, correctional facilities, or even through street medicine programs. Vital Strategies recommends New Mexico amend its OTP rules to explicitly allow such practices.

h. Ensure the availability of comprehensive ancillary services.

Recent changes to federal regulations broadened the types of services OTPs must offer, such as by revising the definition of "comprehensive treatment" to be "treatment that includes the continued use of MOUD provided in conjunction with an individualized range of appropriate harm reduction, medical, behavioral health, and recovery support services."[91] Vital Strategies recommends New Mexico build on these changes by requiring OTPs to more explicitly assess and address other unmet health, social, and economic needs that are common among people with OUD, including lack of stable housing, safety from violence, transportation challenges, food insecurity, enrollment in benefits, and current or former criminal-legal system involvement.[92] OTPs could address these unmet needs directly or through referrals to community-based resources.

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[90] 42 CFR § 8.12(f)(2)(ii) ("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"); (f)(2)(iii) ("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"); (f)(2)(v) ("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").

[91] 42 CFR § 8.2.

[92] Cambron, C., Gouripeddi, R., & Facelli, J.C. (2023). Healthcare Provider Reports on Social Determinants of Health in Opioid Treatment. Psych, 5(1):60-69.

Vital Strategies commends the Department's efforts to expand access to evidence-based treatment for opioid use disorder. We encourage you to consider our suggestions for improving the state's rules governing opioid treatment programs. Our organization also stands ready to provide technical assistance to the Department to help it advance these shared goals. Should you have any questions, please do not hesitate to contact jrwan@vitalstrategies.org.

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