

OPPM Buprenorphine Access Recommendation

05/08/2024

It is recommended the New Mexico Governor issue an executive order to ensure pharmacies can access sufficient quantities of buprenorphine to provide timely access to this lifesaving, evidence-based treatment for opioid use disorder. The council recommends the executive order describe the scope and impact of buprenorphine shortages; call for intrastate and interstate collaboration among state governors and state attorneys general; direct the New Mexico Secretary of Health to issue a public health order to address pharmacy buprenorphine shortages; and urge pharmaceutical distributors to use the emergency authorities contained in the Opioid Distributor Settlement Agreement to remove barriers to buprenorphine access.

1. **The purpose of this recommendation is to:**

- a. Address statewide barriers to pharmacies stocking adequate amounts of buprenorphine, an evidence-based medication for opioid use disorder (OUD).
- b. Increase access to and retention in opioid use disorder treatment with buprenorphine, thereby mitigating the heightened risk of fatal and non-fatal overdose among individuals recently released from incarceration, detoxification, inpatient treatment, and hospital settings.

2. **Rationale for this recommendation:**

a. **Ordering thresholds prevent pharmacies from stocking an adequate supply of buprenorphine**

Even as the recent elimination of the federal X-waiver increased buprenorphine treatment capacity, nationwide reports suggest Medications for Opioid Use Disorder (MOUD) patients and prescribers are reporting difficulties in filling their buprenorphine prescriptions at the pharmacy due to stocking issues. (Weiner, 2023; Jewett & Gabler, 2023; Mahr and Leonard, 2023).

These difficulties result in large part from a national settlement agreement entered into by states (including New Mexico) and the three largest drug distributors to resolve state and local government lawsuits regarding the distributors' role in the overdose crisis. The settlement requires these three distributors to implement a variety of monitoring controls, including pharmacy-specific thresholds limiting the quantities of controlled substances – including buprenorphine – a pharmacy may order. Individual pharmacies are most likely to run out of buprenorphine where the amount of buprenorphine being requested exceeds their threshold, which is set internally by the drug distributors.

If a pharmacy places an order exceeding its threshold, the distributors will generally cancel the order and potentially report the order as “suspicious” to state and federal law enforcement. Moreover, the settlement agreement prohibits distributors from informing individual pharmacies of their specific threshold levels, how they are calculated, or when

existing orders approach them. This limits a pharmacy's ability to proactively request an increase to its buprenorphine threshold to ensure it can meet local needs.

Although intended to prevent the unlawful diversion of prescription opioid analgesics, these settlement terms have had the unintended consequence of impeding pharmacies' ability to fill legitimate prescriptions. The settlement terms have also exacerbated challenges posed by distributors' implementation of federal suspicious order reporting requirements (Qato, et al, 2022; Mahr & Leonard, 2023). Rural and frontier communities with limited numbers of pharmacies are acutely affected by these supply shortages, reinforcing health disparities and inequities in access to lifesaving, evidence-based treatment for opioid use disorder.

b. Buprenorphine shortages pose barriers for New Mexico Department of Health and New Mexico Corrections Department MOUD expansion initiatives

Buprenorphine shortages pose barriers to both New Mexico Department of Health (NMDOH) and Department of Corrections (NMCD) initiatives expanding access to MOUD. Prescribers embedded at public health and primary care offices have reported that patients who must navigate buprenorphine pharmacy shortages are experiencing undue transportation burdens, risk of relapse, and damaged trust in treatment for opioid use disorder more broadly. Insufficient access to buprenorphine in community settings has also impeded efforts to promote MOUD treatment in NMCD facilities.

c. The DEA and other federal agencies have expressed support for distributors to evaluate and address barriers to buprenorphine access

On January 20, 2023, the Drug Enforcement Administration (DEA) issued a [guidance document](#) explaining that the federal law requiring pharmaceutical distributors to design and operate systems to identify suspicious orders of controlled substances does *not* inherently require these distributors to establish specific quantitative thresholds for the amount of controlled substances a customer (e.g., a pharmacy) may order. In a March 2024 [joint letter](#) from DEA, the Department of Health and Human Services (HHS), and the Substance Abuse and Mental Health Services Administration (SAMHSA), these agencies noted an expected and welcome increase in the use of schedule III MOUD products like buprenorphine and recommended distributors "carefully examine quantitative thresholds they have established to ensure that individuals with OUD who need buprenorphine are able to access it without undue delay."

3. The data supporting this recommendation:

a. Buprenorphine reduces overdose fatalities

Opioid agonist treatments like buprenorphine and methadone are an effective treatment for opioid use disorder, associated with a mortality reduction of up to 50% among people with opioid use disorder (Sordo, et al, 2017). A Rhode Island pilot project demonstrated maintaining continuity for buprenorphine patients who enter the prison system has the potential to decrease post-release overdose death for incarcerated persons by as much as 60% (Mace, et al, 2020).

b. Pharmacy availability of buprenorphine

Despite the proven efficacy of buprenorphine in reducing overdose mortality, a recent large-scale study of pharmacies in 32 states reported only 57.9% of pharmacies nationwide reported having buprenorphine in stock at the time of patient request, with wide variations in buprenorphine availability across states (Weiner, et al, 2023).

c. NMDOH survey of impact on New Mexicans

Unspecified suspicious ordering thresholds impact New Mexicans in the following self-reported ways: lengthy drives from pharmacy to pharmacy, risk of relapse, and damaged trust in treatment for opioid use disorder more broadly (NMDOH, 2023). Nearly one of eight (12%) of the reports made to DOH about unfilled buprenorphine prescriptions indicated that the patient did not return for treatment after they could not fill their prescription, relapsed, or indicated to the provider that they were likely to relapse (NMDOH, 2023).

4. Current statute, rules, regulations, or recently proposed legislation related to this recommendation:

a. Settlement emergency authorities

The Distributor Settlement includes emergency authorities allowing for the suspension of its terms. More specifically, distributors may “temporarily modify their respective [Controlled Substance Monitoring Program (CSMP)] processes to meet the critical needs of the supply chain” in “the circumstances of declared national or state emergencies in which the healthcare community relies on the Distributors for critical medicines, medical supplies, products, and services.” It is understood these changes “may conflict with the requirements” of the settlement agreement. Distributors must provide the State Compliance Review Committee with notice of “any temporary material changes to their CSMP processes which may conflict with the requirements of the [settlement] and specify the sections of the [settlement] which will be affected by the temporary change.” They also must “document all temporary changes to their CSMP processes and appropriately document all customer-specific actions taken as a result of the declared national or state emergency.” If these requirements are followed, distributors are immune from liability “for any deviations from the requirements of the [settlement] taken in good faith to meet the critical needs of the supply chain in response to the declared national or state emergency.”

b. Federal Opioid Public Health Emergency

The federal government first [declared](#) a nationwide opioid public health emergency on January 26, 2017. This declaration was subsequently renewed on multiple occasions, including the [most recent renewal](#) occurring on March 25, 2024 (renewal effective March 27, 2024).

c. **Medications for opioid use disorder in New Mexico prisons**

In 2023, New Mexico adopted [SB425](#), which requires the New Mexico Corrections Department (NMCD) to provide MOUD to incarcerated individuals with OUD. More specifically, NMCD must continue MOUD for all individuals with an MOUD prescription when booked into a state correctional facility by December 31, 2025, and offer to initiate MOUD treatment for incarcerated individuals with OUD, regardless of whether the individual has an existing prescription, by the end of fiscal year 2026. N.M. Stat. Ann. § 24-1-5.11(D)(2)-(3). Buprenorphine shortages are likely to affect the implementation of these requirements, as well as to complicate continuity of care following an individual's release. Some hospitals have also reported being denied medications, including buprenorphine, due to unknown thresholds.

d. **MOUD settlement agreement with the New Mexico Corrections Department**

On March 5, 2024, a federal district court approved a [settlement](#) between Disability Rights New Mexico (represented by ACLU New Mexico) and the New Mexico Corrections Department (NMCD). The settlement will require NMCD to continue buprenorphine for individuals who enter NMCD custody with a prescription for MOUD as well as for postpartum individuals who were initiated on buprenorphine during their pregnancy. As with the requirements established by 2023 New Mexico SB425, buprenorphine shortages are likely to negatively affect implementation of the settlement terms.

5. Implementation requirements of this recommendation include:

- a. As the entities responsible for enforcing the Distributor Settlement, State Attorneys General can encourage distributors to use these emergency authorities to ensure pharmacies can access enough buprenorphine to address the immense unmet need for this evidence-based treatment. This may include, but is not limited to, suspending any applicable thresholds for buprenorphine and modifying red flags as necessary (e.g., to account for increased use of telehealth). Distributors could rely on either the federal declared opioid public health emergency or a state-specific emergency declaration. State Attorneys General can make clear they will consider these modifications a good faith effort by distributors to meet the critical needs of the buprenorphine supply chain in response to the ongoing overdose public health emergency.
- b. The State of New Mexico, Office of the Governor, the New Mexico Department of Justice, Office of the Attorney General, and other New Mexico stakeholders can engage in ongoing intrastate collaboration to address barriers to timely access to buprenorphine in pharmacies. The State of New Mexico, Office of the Governor and the New Mexico Department of Justice, Office of the Attorney General can also engage in ongoing collaboration with their counterparts in other states to address buprenorphine shortages.

6. References

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- Regis C, Gaeta JM, Mackin S, et al. (2020) Community Care in Reach: Mobilizing Harm Reduction and Addiction Treatment Services for Vulnerable Populations. *Frontiers in Public Health* 8:501 • Partnership between Massachusetts General Hospital (MGH) & Boston Health Care for the Homeless program, including HR and treatment (buprenorphine, naltrexone, referrals for methadone). Results of initial

evaluation (reach and accessibility) from 2018-2020 note challenges including loss to follow-up, sustainability (funding) and “bridging patients to office based addiction treatment programs where they do not have existing relationships.” Advantages include acceptability to clients & flexibility to address emerging community needs.

Fine DR, Weinstock K, Plakas I, et al. (2021) Experience with a Mobile Addiction Program among People Experiencing Homelessness. *Journal of Healthcare for the Poor and Underserved* 32(3): 1145-1154 • Same MGH-affiliated program regularly providing HR & access to treatment (buprenorphine) at 4 Boston hotspots for opioid overdose with “limited brick-and-mortar addiction services.” Survey results emphasized importance of non-judgmental care & tangible services (e.g. food) to build connection and trust. Authors suggest mobile units should not just be considered a stopgap or link to fixed locations.

O’Gurek DT, Jatres J, Gibbs J, Lathan I, Udegbe B, and Reeves K. (2021) Expanding buprenorphine treatment to people experiencing homelessness through a mobile, multidisciplinary program in an urban, underserved setting. *Journal of Substance Abuse Treatment* 127: 108342 • Low barrier, trauma-informed program in Philadelphia including peers & counseling. ACES assessment at intake, mean score 4.6. Over 6 months, 147 clients received care, 37% retained in care at 3 months.

Krawczyk N, Buresh M, Gordon MS, et al. (2019) Expanding low-threshold buprenorphine to justice-involved individuals through mobile treatment: Addressing a critical care gap. *Journal of Substance Abuse Treatment* 103:1-8 • Low-threshold buprenorphine treatment in a mobile van outside Baltimore City Jail, taking both referrals from jail staff & walk-ins. 220 clients served in 1 year, 190 began taking buprenorphine/naloxone, 32% still in treatment at 30 days. Barriers this program sought to address included lack of photo ID, unstable housing, lack of insurance, logistics, trauma & stigma.