Public Policy Statement on Reducing Federal Bureaucratic Barriers to Methadone for Opioid Use Disorder and Empowering State Innovation

Purpose

Methadone treatment (MT) is a lifesaving treatment for opioid use disorder (OUD), decreasing the risk of all-cause mortality and opioid-related overdose by 50% among people with OUD.[1] Longer retention on MT is predictive of better health outcomes.[2] As the US continues to face the opioid overdose epidemic, largely driven by high potency synthetic opioids (HPSO), expanding access to MT is critical. People who use HPSO may be retained in treatment longer with MT, as compared to other FDA-approved medications for OUD (MOUD).[3] Yet, in 2021 fewer than 500,000 people received MT,[4] despite an estimated 7.6 million people in the US having OUD in 2019.[5] **This public policy statement recommends reducing federal bureaucratic barriers to MT, allowing states to design their own safe and effective models to improve access to MT to meet the needs of their patient populations.**

Background

Stringent federal regulations contribute to the underutilization of MT, particularly the requirement for MT to be administered or directly dispensed from federally regulated opioid treatment programs (OTPs).[6] With limited exceptions, the federal Controlled Substances Act, regulations issued by the Substance Abuse and Mental Health Services Administration (SAMHSA), and regulations issued by the Drug Enforcement Administration (DEA), in combination, only permit MT administration or direct dispensing for OUD from OTPs or medication units (which may be mobile or fixed sites) associated with OTPs. Requirements for opening and operating OTPs are onerous, likely contributing to the fact that 80% of US counties lack an OTP, with half of the counties without an OTP being rural counties.[7]

Even when an OTP exists in the community, patients often face burdensome take-home medication policies and practices that are not based in evidence, limiting patient interest in and access to lifesaving MT.[8-10] Accessibility is a key factor in patient decisions about MOUD;[11] yet, historically, federal regulations required near-daily visits to OTPs for observed dosing, contributing to the derogatory term "liquid handcuffs" for MT.[12] OTPs also typically have only limited hours during which a patient may receive observed dosing.[13] The insufficient number of OTPs nationally contributes to long travel times for many patients;[14] patients are 29% more likely to miss a dose

if they live more than 10 miles from the nearest OTP, as compare to within 5 miles from the OTP.[15] In-person dosing visits can be particularly inconvenient for patients with childcare or employment responsibilities.[16] Recent changes to federal regulations have increased the amount of MT take-home doses permitted, but OTPs are under no legal obligation to expand the use of take-home medication doses.[17] Many continue to have restrictive policies.[18,19] Patient receipt of extended take-home doses is more strongly associated with historical OTP practices than with patients' clinical responses to MT.[20] Additionally, patients report feeling stigmatized when visiting OTPs, as the setting essentially "outs" the patient as having OUD.[21,22] In contrast, research indicates patients would feel more comfortable receiving MT dispensed from pharmacies.[22,23] Qualitative research also suggests some patients feel "triggered" by the environment of OTPs, where they may regularly see peers with whom they previously used substances.[24]

Federal regulations[25] and at least eleven states expressly allow OTPs to establish medication units within independently owned pharmacies or to locate a mobile medication unit in the pharmacy parking lot.[26] Federal policy allows adding the medication unit to an existing OTP registration.[25,27] In this treatment model, the OTP forms a partnership with the independently owned pharmacy, and patients initiate MT at the "brick and mortar" OTP but later receive MT through the medication unit associated with the pharmacy. Patients periodically return to the OTP for ancillary services, such as physical examinations, counseling, or toxicology testing.

Despite the legality of OTP medication units associated with separately owned pharmacies, few such units exist, likely due to legal and logistical barriers.[23] For example, since OTP medication units require storage and security infrastructure beyond typical pharmacies,[6] most pharmacies likely cannot meet the medication unit requirements without significant infrastructure alteration and financial investment. Additionally, some state laws regarding the legality of medication units in separately owned pharmacies are currently unclear.[26] Federal regulations require mobile units to return to the OTP site daily, in practice requiring the pharmacy to be located near the OTP.[26]

Some federally qualified health centers (FQHCs) and certified community behavioral health clinics [collectively "community-based health centers"] have included OTPs in their practice model. FQHCs already provide treatment for physical health conditions and/or mental health conditions for almost 10% of Americans and 20% of rural Americans.[28] Community-based health centers provide critical services for people with low incomes, with Medicaid, or without health insurance. Expanding MT into more of these centers could increase MT utilization nationally.[29] For example, a recent study found that while 53% of US census tracts lack an OTP, expanding MT into FQHCS would leave only 14% of census tracts without MT.[29] For example, Wyoming has no OTPs[30] but has at least eight FQHCs.[31] Few community-based health centers currently operate OTPs, likely due to higher standards required for storage and security for MT than for other treatments provided by community-based health center pharmacies.[32]

Pharmacy administration or dispensation of MT pursuant to a prescription issued by a qualified prescriber could dramatically improve MT access, if federally permitted. Approximately 90% of Americans live within five miles of a community pharmacy.[33] Notably, a pilot study on OTP practitioner prescribing and pharmacy dispensing revealed that between 80% and 100% of patients (depending data collection timing) preferred the pharmacy setting over the OTP setting for MT dispensing; and almost all patients were willing to accept fewer days of take-home doses and to pay extra in exchange for receiving MT at the pharmacy.[34] Some research also suggests

community pharmacists would be willing to dispense MT if federal law allowed it in a manner similar to that of other Schedule II medications (i.e., without the pharmacy becoming an OTP or operating an OTP medication unit).[35] Widespread MT dispensing at pharmacies would likely necessitate changes to existing DEA "red flag" policies, which currently disincentivize pharmacies from stocking large amounts of controlled substances.[36] Addressing stigma among pharmacists toward patients with OUD would be essential,[37] such as through increased OUD education in pharmacy colleges.

MT is the only area where the federal government has explicitly set standards for medical practice;[38] all other areas of medicine are primarily regulated by the states. As the US continues to grapple with the need to expand lifesaving MT during the opioid overdose crisis, different models of MT across states could create a natural experiment. With states serving as laboratories of policy activity, policy evaluators could assess the risks and benefits of alternative models, and findings from evaluations could help states adopt models most beneficial to their population.

Below are some examples of models US states could adopt if the federal bureaucracy surrounding MT were significantly reduced. These models would support fewer burdensome restrictions, reduced stigma, and increased access to MT. In the models below, the federal government would not be involved in MT regulation beyond its role of regulating practitioners (including pharmacies) and Medicare and Medicaid coverage. In other words, the federal government would not require a separate registration for MT compared to other Schedule II controlled substances. The models below are not an exhaustive list. Different models could be combined, or states could begin with a more restrictive model, with a plan to transition to a less restrictive model based on outcomes.

Model 1: Universal access.

In this model, states would regulate MT like other Schedule II medications, meaning any prescriber authorized to prescribe Schedule II medications could issue a prescription for MT from any setting, including primary care clinicians in office-based settings, and patients would obtain MT from a pharmacy. States could regulate quantities allowable for unsupervised use. Level of care recommendations for patients could be based on strength-based multidimensional assessments, considering a patient's needs, obstacles and liabilities, as well as their strengths, assets, resources, and support structure, regardless of medication selection. Adoption of this model in Britain has ensured widespread MT access without increasing overdose deaths.[39] Moreover, studies of MT prescribing in office-based settings in Britain have revealed positive patient outcomes, although prescriber adherence to treatment guidelines vary.[40,41] Further policy changes, such as increased reimbursement rates and training opportunities about OUD for practitioners, would likely be necessary to facilitate MT prescribing. Since primary care practitioners could initiate MT and since primary care specialties (i.e., family medicine and internal medicine) have the largest number of practitioners in the US,[42] this model would increase MT access more than other models below.

Model 2: Patients could initiate and receive MT in a state-defined OTP, or patients could be prescribed MT by the OTP practitioner or a board-certified addiction specialist physician with administration/dispensing at community pharmacies. The model would be similar to the one contemplated by the Modernizing Opioid Treatment Access Act or MOTAA.[43]

In this model, a patient could be evaluated by a board-certified addiction specialist physician in that practitioner's practice setting or at a state-defined OTP, and the addiction specialist physician or OTP practitioner could prescribe MT to be administered/dispensed from a pharmacy. Patients could also initiate and receive MT at the OTP. States could regulate the quantities allowable for unsupervised use. Geographic access to MT prescribing and dispensing would increase. State-defined OTPs and addiction specialist physicians could collaborate, transferring patients between distinct levels of care based on stability. To fully benefit from this model, the US would need more addiction specialist physicians,[29] necessitating incentives for more practitioners to train in addiction psychiatry or addiction medicine, and more funding for fellowships in those areas.[44] A 2023 study estimated MT prescribing by addiction specialist physicians would expand access to an extra 12% of urban, 18% of suburban, and 16% of rural areas.[29] Additional changes, like increased reimbursement rates and enhanced OUD training opportunities for addiction specialist physicians would likely be necessary to facilitate prescribing.

Model 3: Patients initiate MT in a state-defined OTP (with administration/dispensing at the OTP or at a pharmacy, depending on state law) but can transfer to primary care settings when stable.

In this model, patients would be evaluated for and initiate MT in a state-defined OTP, where they would continue receiving MT until stable. Once stable, patients would have the option to transfer to office-based settings, such as primary care clinics or offices of addiction specialist physicians, with treatment administration/dispensing occurring at a pharmacy pursuant to a prescription issued by a qualified practitioner. The opportunity to move to non-OTP settings could serve as an incentive for treatment adherence. A similar model exists in France, where, although all MT patients begin in a specialized setting (with administration/dispensing either in the specialized setting or at the pharmacy), currently 60% receive MT in primary care settings.[6] In the US, several pilot studies – including four randomized controlled trials – have directly compared outcomes and satisfaction among stable patients at federally defined OTPs who have moved to office-based settings, finding no differences in toxicology testing or clinical results between the settings but higher patient satisfaction in office-based settings.[45-49] A key limitation of this model, however, could be the limited geographic availability of state-defined OTPs; therefore, concurrent policies facilitating the opening of state-defined OTPs (e.g., by reducing burdensome regulations for opening and operating OTPs, including permitting administration/dispensing at community pharmacies) would be necessary. Additionally, the model would require a financial incentive or other policy to prevent state-defined OTPs from "hoarding" patients rather than allowing them to transfer to office-based settings once stable.[50] Changes to reimbursement would likely be needed to encourage non-OTP practitioners to prescribe MT. Coordination between authorized office-based practitioners and state-defined OTPs would also need to be adequately compensated.

Model 4: MT is only available through state-defined OTPs, but the process for becoming a state-defined OTP (or operating a medication unit) becomes more flexible.

In this model, MT would only be available through state-defined programs that administer or dispense directly. The state, however, would have wide latitude in setting those program standards to ensure that the process of opening and managing an OTP is not unduly onerous. Therefore, the number of OTPs available would be higher than under the status quo.

Recommendation: The federal government reduces federal bureaucratic barriers to methadone treatment (MT), a lifesaving treatment for opioid use disorder, allowing states to design their own safe and effective models to improve access to MT to meet the needs of their patient populations.

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