Expanding Access to Methadone for Opioid Use Disorder

Model 1: Pharmacy-based Medication Unit

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Purpose:

This policy brief explores an approach to expanding community pharmacies' role in dispensing methadone for opioid use disorder (OUD) treatment that is allowable under current federal law, "medication units." A medication unit is a satellite site of an opioid treatment program (OTP) that can be located in various settings, including in a pharmacy where any appropriately licensed persons (including community pharmacists) may dispense or administer methadone for OUD. Two companion policy briefs explore models that require changes to federal law or significant regulatory changes to be implemented: a model where methadone is prescribed by properly licensed physicians and dispensed as all other medicines are at the pharmacy, and a third that expands the second model by adding medical services provided and billed by pharmacists.

Background:

In 2023, there were nearly six million people in the United States (US) with an opioid use disorder (OUD) who may benefit from medication treatment, yet less than one in five people received medication treatment for their condition. (1) When accessible, methadone is a highly effective medication treatment for OUD (MOUD) which decreases all-cause mortality in OUD patients by more than 50%. (2) Globally, methadone is considered an essential medication. (3,4) In the 1960's in the US, community pharmacists stocked and dispensed methadone for pain management and OUD. (5–7)

> *"I go to the pharmacy and pick up HIV meds, blood pressure meds, meds for addiction... and they treat me great... It would be so convenient to go to the pharmacy for methadone"*
> -Community Advisory Board Participant

Since the early 1970's, federal statutory and regulatory changes have made methadone for OUD treatment exclusively available within opioid treatment programs (OTPs) also known as methadone maintenance or narcotic treatment programs. (8) Methadone for OUD is the only medication in the US that is completely siloed from the rest of the healthcare system. (9–11) Although there are ~2,100 OTPs in the US, 80% of counties and the entire state of Wyoming lack even one. (12) The distance a client has to travel to an OTP is a risk factor for missed doses and treatment non-adherence; this disproportionately impacts people in rural areas. (13,14)

People with OUD want an alternative to receiving methadone at OTPs. (15) We conducted interviews with a community advisory board comprised of people who have received methadone at OTPs about what it would be like to receive methadone treatment at the pharmacy. Advisory board participants embraced pharmacy methadone models over those that perpetuated restrictive OTP practices, emphasizing the accessibility and convenience of pharmacies, that pharmacies are more private, and that there is less stigma associated with getting medications at a pharmacy.

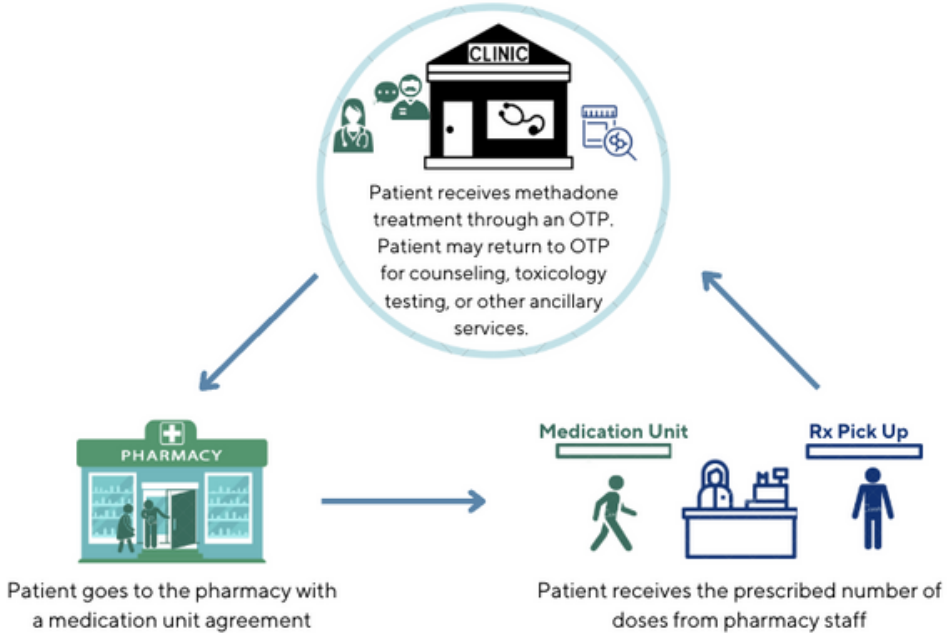
While current law prohibits pharmacies from dispensing methadone for the treatment of OUD like other medication, one legal pathway to do this is by partnering with an OTP as a medication unit. This brief summarizes findings from a return on investment analysis involving 110 revenue- and cost-related items to simulate different possible financial outcomes. This brief informs interested OTPs, pharmacies, policymakers, and payers on policy and financial considerations for this avenue of methadone treatment expansion.

Description of Model:

In the Medication Unit model (Figure 1), OTPs and pharmacies form cost-sharing partnerships that allow the operation of an OTP satellite methadone dispensing site at the pharmacy. (16) In this model the pharmacist essentially operates as part-time staff for the OTP allowing them to dispense methadone for OUD at the pharmacy. The person with OUD remains a patient with the OTP and goes to the OTP for any required counseling, urine toxicology screening, and ancillary services, while being able to pick up methadone for OUD at the pharmacy with frequency determined by the OTP (i.e., daily, weekly, or monthly).

Medication units must follow regulations promulgated by the Drug Enforcement Administration (DEA) and Substance Abuse and Mental Health Services Administration (SAMHSA). One of these regulations currently requires methadone for OUD be stored and tracked separately from methadone the pharmacy dispenses for pain. (16) Thus, pharmacies would need a separate costly specialized safe or vault, tracking documentation, and disposal process. Although medication units in pharmacies and other locations are allowable under current law, very few medication units exist and none in pharmacies. (13) Clarification to the federal regulations that clearly outline the steps to establish medication units in pharmacies might facilitate model uptake. Moreover, changes that streamline the DEA and SAMHSA approval processes and allow the pharmacy to integrate their supply, tracking, and disposal processes for methadone for OUD and pain would make this model more feasible to implement.

Figure 1. The pharmacy-based medication unit process



Critical success factors:

- A formal partnership established between OTPs and pharmacies with mutually agreed upon processes for methadone delivery to and inventory, record-keeping, and reporting systems at the pharmacy-based medication unit.
- Arrangement for toxicology testing and other support services by the OTP.

Anticipated clientele and visit intensity:

As of 2023, there were an approximately 380,000 people receiving methadone treatment for OUD at 2,074 OTPs. (17) The medication unit within a pharmacy model is not for everyone. Based on interviews with community advisory board members, OTP employees, and other informants,[1] we estimated that clients on methadone at maintenance levels may consider shifting to a pharmacy for convenience, curiosity, or due to geographic and transportation-related barriers.

To produce the client base, we assumed a shift of 10-13% OTP methadone-receiving clients plus a modest market growth, represented by 2% of the US population who have a substance use disorder and perceived need for treatment. That estimation led to a starting client base in year one of 5-15 people per month per participating pharmacy. We then assumed a 40% growth in clients for year two, and a 20% growth for year three. Further, we assumed more new-to-the-pharmacy clients in year one, gradually decreasing by 20% each year for years two and three. Visit intensity varied between four and 28 visits per month. Additional details can be found in the Technical Appendix.

[1] We spoke with eight people with lived/living experience, five OTP informants, seven pharmacy informants, six payers, and five policymakers. None of the interviews were managed by a potential methadone distribution market participant (i.e., not by a pharmacy chain, PBM, or distributor).

Financial Assessment:

Startup costs for pharmacy:

Startup costs for pharmacy: Startup costs included initial staff training by staff type to account for wage-level differences. Specifically, we included anti-stigma and OTP procedures (e.g., documentation, reporting, ordering, inventory management) training for pharmacists and anti-stigma training for technicians. We also included legal services for contract review. In a sensitivity analysis, costs included increased training hours for the pharmacist technician for setting up telemedicine services.

Additional pharmacy costs included in sensitivity analysis:

- A locked container for safe and secure disposal of methadone
- A high security safe that meets DEA requirements for storage
- Telemedicine equipment and software (sensitivity analysis only)
- Liquid dispensing machine (sensitivity analysis only)
- OTP-specific labeling machine (sensitivity analysis only)
- Training and wages for certified security guard (sensitivity analysis only)

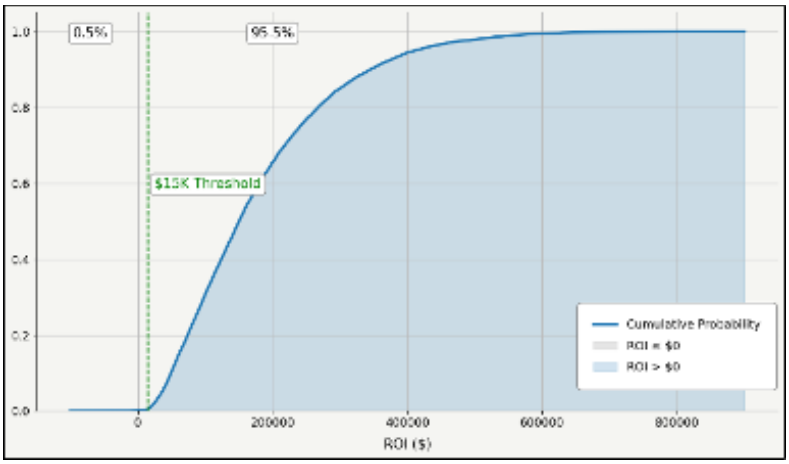
Annual costs:

Annual costs consisted of staff wages plus other reoccurring costs such as DEA licensing fees, maintaining a parallel documentation and management system, medication, alcohol wipes (sensitivity analysis only). A flat overhead percentage (12%) was charged to all costs, including the startup costs. See Technical Appendix for additional details.

Income sources:

We assumed a flat monthly fee paid by the OTP to the pharmacy as part of a profit-sharing agreement. The flat fee was based on a floor using the Medicare reimbursement rate to OTPs for the drug-portion of a methadone treatment payment bundle (i.e., $40.71), varied in parallel with expected year-three client levels. Thus, the range used was $1,368-$4,924 per month. Additionally, we included fair market rate for the rental of the equivalent of 18 square feet (e.g., space required for the safe and dispensing preparation), paid by the OTP monthly. **Figure 2** shows the return on investment (ROI) from the perspective of the pharmacy.

Figure 2. Three-year cumulative probability of pharmacy profits at $15,000 or more



We found that over 3 years, there was $6.43 returned to the pharmacy for every $1 spent (95% uncertainty interval, UI: $1.92-$13.02). We found that a participating pharmacy would have a 99.5% likelihood of netting $15,000 or more by year three and 89.7% likelihood of netting $50,000 or more by year three.

Potential competitors:

We estimated this model would reduce income for a participating OTP by around $2,000 per month. This is because the profit sharing with the pharmacies would be offset by the new clients enrolled (thus increasing the market size), who are attracted by the new "product" of receiving methadone in the community pharmacy. Further, OTPs can use this extra service as a competitive edge over other OTPs. The reduced income estimate would be greater if not offset by new clients. Shifting some existing long-term OTP clients to the pharmacy could also increase capacity to serve clients in need of more comprehensive (and reimbursable) services at the OTP. (18)

Key differentiators from the status quo:

- Makes access to methadone treatment more convenient compared to status quo.
- Requires fewer regulatory changes compared to other possible reforms.

Implementation Considerations:

Requirements for successfully implementing a medication unit model include a trusting partnership between the pharmacy and OTP, willingness of pharmacists to learn OTP procedures and implement workflow changes, and a private space for dispensing methadone for OUD. Policymakers and regulators at the DEA and SAMHSA could make the process more feasible by clarifying language and reducing regulatory requirements; indeed, addressing these regulatory complexities is likely essential for broader adoption, as they would help alleviate burdens on pharmacies and OTPs. Payers and state agency leaders could consider supplemental payments to facilitate expanding access to methadone treatment in pharmacies. Potential funding sources to alleviate startup costs include state opioid response grants and opioid settlement funds.

Receiving methadone for OUD at the pharmacy can make methadone more accessible for patients, though adequate privacy is critical. For pharmacies adopting the Medication Unit model, patients may need to continue to go to the OTP for some services but would likely go less frequently. For pharmacies, the medication unit offers an opportunity to better serve their community, to differentiate themselves from other pharmacies for competitive advantage, and to generate additional revenue through medication dispensing.

For OTPs, advantages include increasing capacity at the OTP by shifting some eligible patients to the pharmacy, particularly those who are stable. This model also allows for responsiveness to patient demand for more accessible methadone treatment, while remaining a necessary partner that treatment. For payers, expanded access to methadone treatment may yield cost savings if people remain on methadone for a longer period, potentially reducing emergency visits related to substance use.

Specifically, some of the required actions that each sector would need to complete include the following:

Pharmacies:

- Advocate to state and federal officials to reduce regulations to better realize the benefits of medication units in pharmacies, particularly for underserved populations
- Identify OTPs for potential partnership.
- Seek comprehensive anti-stigma training to mitigate the significant barriers faced by people seeking OUD treatment.
- Create a private space for the medication unit if one is not available.

OTPs:

- Identify pharmacies for potential partnership.
- Train key pharmacists leading medication unit activities.
- Advocate to state officials for policy changes to induce the establishment of a medication unit in a given community pharmacy.
- Advocate to state or federal officials for increased bundle rate to offset profit-sharing.

Policymakers:

- State officials assist OTP and pharmacy leadership to establish relationships.
- DEA and SAMHSA clarify regulations for medication units and consider simplifying the approval process.
- States lower regulatory barriers e.g., by explicitly authorizing medication units.
- State agencies consider subsidizing start-up costs.

Payers:

- Maintain the status quo; payment models to OTPs can remain as they are.
- Consider supplementing bundle rates for OTPs to offset modest loss in profits.

Clients:

- Gain access to more sources of regular care for OUD.
- Experience fewer barriers to methadone treatment, including stigma and punitive requirements.
- Obtain increased convenience in obtaining medication.
- Feel encouraged by the market responding to consumer demand.

Conclusion:

The need for increased methadone access for treatment of OUD is an apparent and urgent national issue. (1,15) Through small, actionable, regulatory changes, this model will provide not only increased access to methadone for OUD but simultaneously add new market value and business development opportunities for existing OTPs and pharmacies. Please see associated policy briefs for other approaches to expand access to methadone through pharmacies.

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