Expanding Access to Methadone for Opioid Use Disorder

Model 2: Pharmacy-Dispensed Methadone

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Purpose:

This policy brief examines expanding community pharmacies' role in dispensing methadone for opioid use disorder (OUD) treatment. Under current federal statutes and regulations, only opioid treatment programs (OTPs) certified by the Substance Abuse and Mental Health Services Administration (SAMHSA) and registered with Drug Enforcement Administration (DEA) may dispense methadone for OUD treatment. Limited exceptions exist, e.g., temporary administration of methadone by hospital providers for up to 72 hours while arranging referral to an OTP, as permitted under the 'three-day rule.' (1,2) In this brief, we describe an approach that could be implemented if current federal laws or regulations were amended (and states matched federal policy). In this model, community pharmacies fill and dispense methadone for OUD when prescribed by a DEA registered medical provider, i.e., Pharmacy-dispensed methadone model. Two companion policy briefs explore other models: one that expands this model by adding medical services provided and billed by pharmacists, and one available under current law where an OTP partners with a pharmacy for satellite dispensing, i.e., a Pharmacy-based medication unit.

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; less than one in five people received medication treatment for their condition. (3) When accessible, methadone is a highly effective medication treatment for OUD (MOUD) which decreases all-cause mortality in OUD patients by more than 50%. (4) Global health authorities consider methadone an essential medication. (5,6) In the 1960's in the US, a few hundred patients were treated with methadone for OUD at more than a dozen community pharmacies. (7,8) In the early 1970's, federal statutory and regulatory changes resulted in making methadone for OUD treatment exclusively available within opioid treatment programs (OTPs), also known as methadone maintenance or narcotic treatment programs. (9) Methadone for OUD is the most heavily restricted addiction medication in the US, operating largely separate from the general healthcare system. (9,10) Although there are ~2,100 OTPs in the US, as of 2018, 80% of counties and the entire state of Wyoming lack even one. (11–13) The distance a client has to travel to an OTP is a risk factor for missed doses; this disproportionately impacts people in rural areas. (14)

Some people with OUD want alternatives to receiving methadone at OTPs. (15,16) 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. People with lived experience embraced pharmacy methadone models over those that perpetuated restrictive OTP practices, emphasizing the accessibility and convenience of pharmacies, that pharmacies are more private, and there is less stigma associated with getting medications at the pharmacy.

> *"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

One option for closing the treatment gap is by making methadone available in pharmacies – since over 90% of people in the U.S. live within 5 miles of a community pharmacy. (17,18) In Canada, Australia, the United Kingdom (UK), France, Germany, Switzerland, and the Netherlands, community pharmacies provide methadone for OUD treatment. (19–24) In Australia, pharmacists may supervise dosing administration once they have received required orientation, training, and support to provide such services in jurisdictions that mandate such training. (20) Most prescriptions for methadone are written by general practitioners, and over 70% of prescriptions are dispensed by community and retail pharmacists. (20) This pharmacy-enhanced system of distributing opioid agonist treatment in Australia has also been associated with a reduction of hospitalizations due to injection-related infections, and overall heroin use. (20) In Canada, pharmacists can dispense methadone with a valid written order or prescription provided they meet the training and other requirements established by their provincial/territorial licensing authority, which typically include specialized OUD treatment courses. (21,25) In the UK, any prescriber can write a prescription for methadone, and any pharmacy is permitted to fill that prescription. (24,26) Additionally, as outlined from the substance use disorder guidelines, the "Orange Book", from the UK Department of Health and Social Care, initial dosing requires supervision, usually in the presence of a community pharmacist – however, the provider can prescribe take-home doses depending on individual progress. (24)

The Board of Directors of the American Society of Addiction Medicine (ASAM) adopted the following public policy statement on October 23, 2021: "SAMHSA [Substance Abuse and Mental Health Services Administration] and DEA [Drug Enforcement Administration] regulations should allow pharmacy dispensing and/or administration of methadone that has been prescribed for patients who meet certain criteria by a legally authorized prescriber of controlled medications who is affiliated with an OTP, is an addiction specialist physician, or is a physician who has met specific qualifications." (27) In a US-based pilot study where community pharmacy dispensing of methadone for OUD was permitted, participants reported strong satisfaction and 100% adherence to pharmacy-based appointments among people retained for three months. (28) A meaningful gap exists in access to effective OUD treatment in the U.S., with many regions lacking OTPs, highlighting the opportunity to allow existing pharmacies these proposed capacities through new legislation or similar models where methadone for OUD is prescribed as any other controlled substance. (11)

While current regulations prohibit pharmacies from dispensing methadone for the treatment of OUD, a change to those regulations (or the federal statue those regulations implement) could allow pharmacies to engage in this practice. 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 pharmacies, OTPs, policymakers, and payers on key policy and financial considerations for this avenue of methadone treatment expansion.

Description of model:

In the Pharmacy-dispensed methadone model, shown below in Figure 1, a pharmacy can dispense methadone for OUD prescribed by a DEA-registered medical provider, following the same processes they do for all other controlled substances. Pharmacies would order, track, store, and dispose of methadone through the same systems they have in place for other controlled substances. In this model, the client is under the care of a medical provider who determines the need for and conducts any necessary counseling, toxicology testing, or ancillary services and ensures compliance with any federal regulations that are promulgated. Changes to federal regulations (or the federal statute those regulations implement) would be required to make this model permissible along with an alignment of state laws. Clear regulations and protocols for providers and pharmacies who choose to serve their communities under this model would facilitate its success.

Figure 1. The Pharmacy-dispensed methadone model

A patient meets with their medical provider and is prescribed methadone. The doctor provides other services such as counseling and toxicology testing.

The prescription is sent to the pharmacy to be filled.

The patient picks up the prescription as they would any other prescription at the pharmacy.

Critical success factors:

- Federal statutory or regulatory changes (and possibly state harmonization) to make this model permissible.
- Pharmacies can obtain and store methadone in the same manner the pharmacy already uses for all other controlled substances to reduce costs.
- DEA-registered medical providers are available for the purpose of receiving new patients, prescribing methadone, and managing all treatment aspects.
- Pharmacists can confirm the methadone prescription validity with any qualified DEA-registered medical prescriber.
- DEA allows the use of all forms of methadone for OUD treatment (e.g., pills, liquid, and dissolvable diskettes).
- The pharmaceutical sector assures manufacturing and delivery pathways for methadone in diskette form to facilitate client needs (e.g., those who cannot swallow pills; diskettes dissolve in water before ingesting).
- Pharmacies obtain clarification from regulators on inclusion of and access to methadone dispensing information in state prescription drug monitoring databases

Anticipated clientele and visit intensity:

As of 2023, there were approximately 380,000 people receiving methadone treatment for OUD at 2074 OTPs. (13,29) The Pharmacy-dispensed methadone model is not for everyone. Based on interviews with community advisory board members, pharmacy leaders, and OTP leaders,[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 15% greater response to this model compared to a medication unit in the pharmacy model. That estimation led to a starting client base in year one of 6-17 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 one and four 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:

Startup costs included initial staff training by staff type to account for wage-level differences. Specifically, we included anti-stigma and methadone for OUD treatment training for pharmacist-level staff and anti-stigma training for technician-level staff. System start-up costs are included (e.g., formulating new relevant standard operating procedures).

Annual costs:

Annual costs derived from staff wages and reoccurring costs such as DEA licensing fees, medication, and alcohol wipes. A flat overhead percentage (12%) was charged to all costs, including the startup costs. See Technical Appendix for additional details.

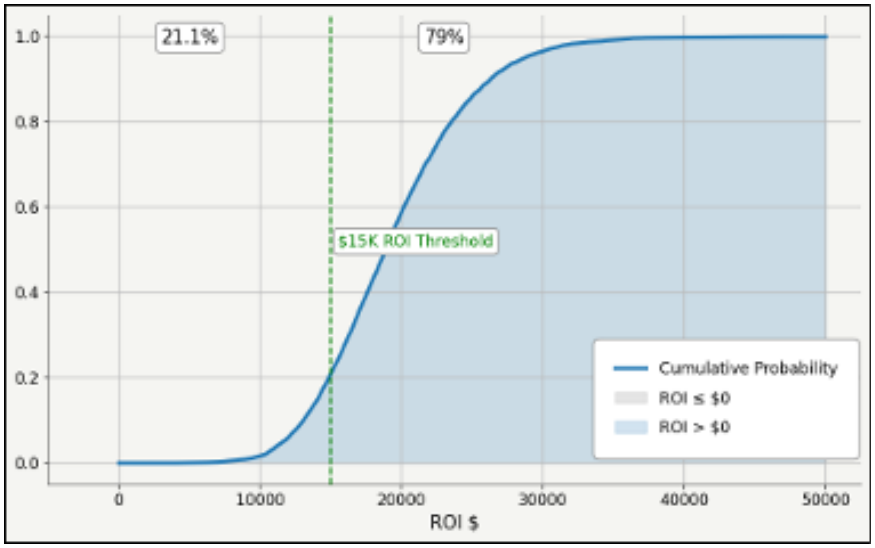
Income Sources:

In addition to a startup grant of $5,000 from state or local entities (especially where opioid settlement monies are available), the payment structure was a type of "enhanced fee for service," with a per-prescription income from the following:

- Profit on the medication.
- A standard dispensing fee.
- Added amount paid by the state to the pharmacy per prescription fill; such incentive payments are already in place for vaccines. (30,31)

Return on Investment:

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



We found that over three years, there would be $2.05 returned for every $1 spent (95% uncertainty interval, UI: $1.48-$2.75). Additionally, a participating pharmacy would have an 79.0% likelihood of netting $15,000 or more by year three.

Potential competitors:

We estimated an OTP would lose some income, with the loss of approximately 3-10 long-term clients per month; however, there are ways to compensate for these loses via practice changes. For example, a modest increase in the overall market size is expected due to the new "product" of dispensing methadone for OUD in the community pharmacy. By recruiting these patients as well as building relationships with pharmacies, OTPs could offset the initial loss of revenue. Finally, based on interviews with key informants, private equity OTP investors are expected to slow or pause new investment for a year or two until market shifts stabilize.

Key differentiators from the status quo:

- Increases patient access to methadone treatment
- Promotes patient-centered care, e.g., client traveling two hours or daily travel
- Increases clinician options for clients who need methadone access

Implementation Considerations:

If federal and state law or regulatory changes make the Pharmacy-dispensed methadone model permissible, successful implementation would require willingness of pharmacists and medical providers to engage with this delivery model, pharmacists' ability to ensure adequate stocking of methadone, and training for pharmacists. Policymakers and regulators at the DEA and SAMHSA could make this model more feasible by ensuring clear regulations from the inception of the new law. Payers could consider supplemental or incentive 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. For pharmacies, the Pharmacy-dispensed methadone model offers an opportunity to better serve their community, to differentiate themselves from other pharmacies for competitive advantage, and to generate additional revenue from dispensing methadone and companion incentive pay. For OTPs, while some new competition may be created, new business may also result by expanding the market for methadone treatment. For payers, expanded access to methadone treatment may yield cost savings if people remain on methadone for a longer period and decrease utilization of expensive emergency health services.

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

Pharmacies:

- Include training investment at startup for pharmacists and pharmacy techs (including procedures, methadone treatment training, privacy), as well as internal ongoing anti-stigma education.

OTPs:

- Take advantage of any increase in market size, i.e., more people seeking methadone maintenance treatment.

Policymakers:

- Either: (1) Congress amends the Controlled Substances Act (CSA) to more clearly allow methadone to be prescribed by DEA-registered medical providers and dispensed for OUD treatment at pharmacies; or (2) DEA changes its interpretation of the current CSA and issues adjusted regulations allowing the same.
- States lower regulatory barriers.
- States provide pharmacies incentive payment per methadone treatment prescription similar to vaccine or buprenorphine policies.
- State or local entities give one-time grants to cover startup costs and incentivize pharmacies to join the program, particularly from opioid settlement funds.

Payers:

- Insurers provide per prescription fill incentive pay to pharmacies.

Clients:

- Gain access to more locations for methadone treatment.
- Experience fewer barriers to methadone maintenance 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 medication treatment for OUD is an apparent and urgent national issue. This model offers bold and actionable regulatory changes that will provide a pathway for increased access to methadone for OUD, while simultaneously creating new business opportunities for pharmacies and fostering market growth. Expanding methadone access beyond the current limitations of addiction specialist-only prescribing and pharmacy dispensing is essential. Enabling a broader range of clinicians, including those in federally qualified health centers, to prescribe methadone would help address access gaps, particularly in rural communities. Please see associated policy briefs for other approaches to expand access to methadone through pharmacies.

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