Expanding Access to Methadone for Opioid Use Disorder

Model 3: Enhanced 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 Substance Abuse and Mental Health Services Administration (SAMHSA) and Drug Enforcement Administration (DEA)- certified opioid treatment programs (OTPs) can dispense methadone for OUD treatment, with limited exceptions for hospitals providing 72-hour treatment while arranging OTP referral. (1,2) In this brief, we describe an approach that could be implemented if current federal laws and regulations were amended (and states matched federal policy). In this model, not only do pharmacists dispense methadone, but they may also serve as the patient's care provider, making appointments, ordering and interpreting laboratory tests, and referring patients to counseling and social services. In this model, the pharmacist can bill the patient's insurance for these services like other providers, while separately billing for the medication. Two companion policy briefs explore other models: one that is a simple Pharmacy-dispensed methadone model where pharmacists simply treat methadone for OUD as all other controlled substance prescriptions, and a second model that is 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, community pharmacists stocked and dispensed methadone for OUD. (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 only addiction medication in the US that is completely siloed from the rest of the healthcare system. (9,10) Although there are ~2,100 OTPs in the US, 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 an alternative 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 that there is less stigma associated with getting medications at a 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 – it is estimated approximately 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 orientation, training, and support to provide such services. (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 led to 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 so long as they complete their training of the Narcotic Control Regulations. (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)

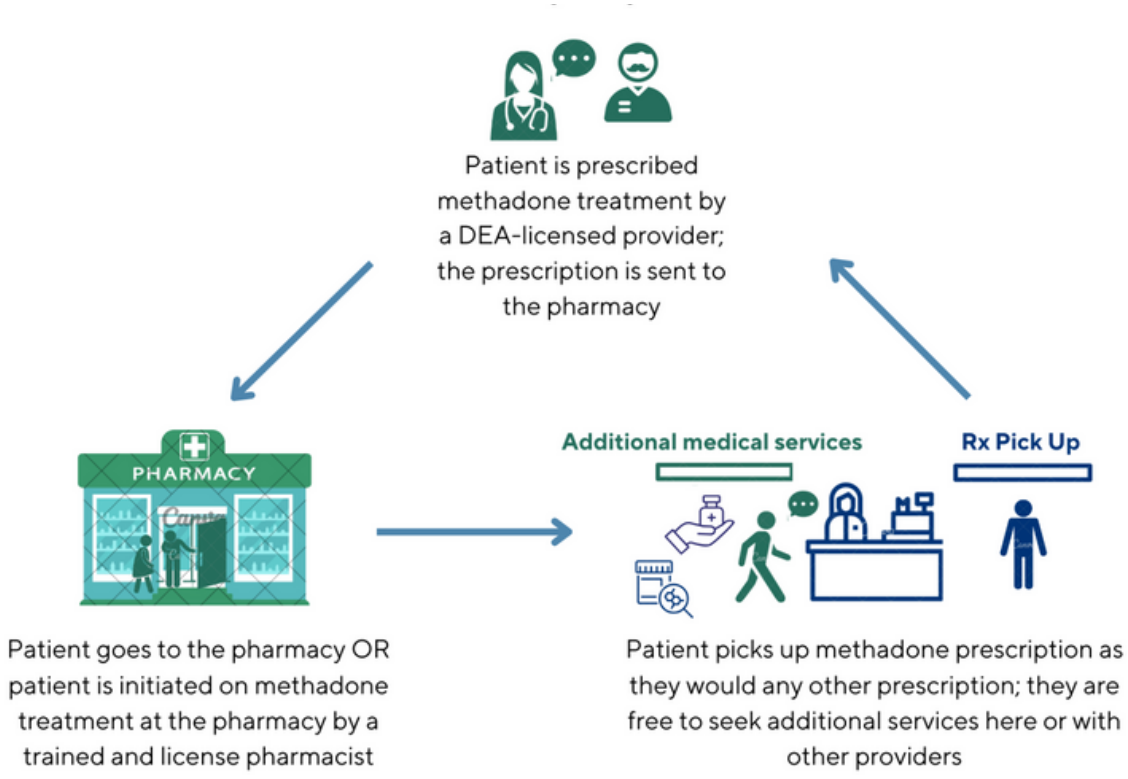
The Board of Directors of the American Society of Addiction Medicine (ASAM) adopted the following public policy statement on October 23, 2021: "SAMHSA [The Substance Abuse and Mental Health Services Administration] and DEA [Drug Enforcement Administration] regulations should allow pharmacy dispensing 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. (12,28)

While current regulations prohibit pharmacies from dispensing methadone for the treatment of OUD, a change to those regulations (or the federal statute 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 Enhanced 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. This model builds on the Pharmacy-dispensed methadone model by also incorporating pharmacists with provider status, receiving equitable reimbursement, and serving an expanded scope of practice. Thus, clients can choose to be initiated on methadone treatment, receive toxicology testing, and receive other supportive services at the pharmacy. Clients are also free to choose to receive those services at OTPs or with other providers. Changes to federal law and regulations (and possibly complementary state actions) would be required to make this model permissible.

Figure 1. The Enhanced pharmacy-dispensed methadone model



Critical success factors:

- Federal legislation and 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, which can reduce costs.
- Patients have more freedom to choose take-home dosing.
- DEA-registered medical providers are available for the purpose of receiving new patients, prescribing methadone, and managing all treatment aspects.
- 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 because diskettes dissolve in water before being ingested).
- 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. (11,29) The Enhanced pharmacy-dispensed methadone model is not for everyone. Based on interviews with community advisory board members, pharmacy leaders, and other key 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 25% 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 6-19 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 28 visits per month per client. 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 and security staff. A liquid methadone dispensing machine was the only equipment cost in the initial calculations. System startup costs were included (e.g., formulating new relevant standard operating procedures).

Annual costs:

Annual costs consisted of staff wages for all activities plus other reoccurring costs such as DEA licensing fees, medication, alcohol wipes, and oral toxicity swab tests. A flat overhead percentage (12%) was charged to all costs, including the startup costs. See Technical Appendix for additional details.

Additional costs added for sensitivity analyses:

- New durables such as a high security safe
- Equipment, e.g., telemedicine equipment and software
- Construction of a separate consult space
- Pharmacist training - Motivational interviewing and how to administer the Clinical Opioid Withdraw Scale (COWS) to support daily dosing and patient safety
- Pharmacy tech training - Telemedicine equipment, EKG device, third-party billing, and community-health worker (CHW) certification to support patient safety and care needs
- Social worker training - Telemedicine equipment, to allow the offering of counseling services at the pharmacy
- Certified security staff
- Home delivery service

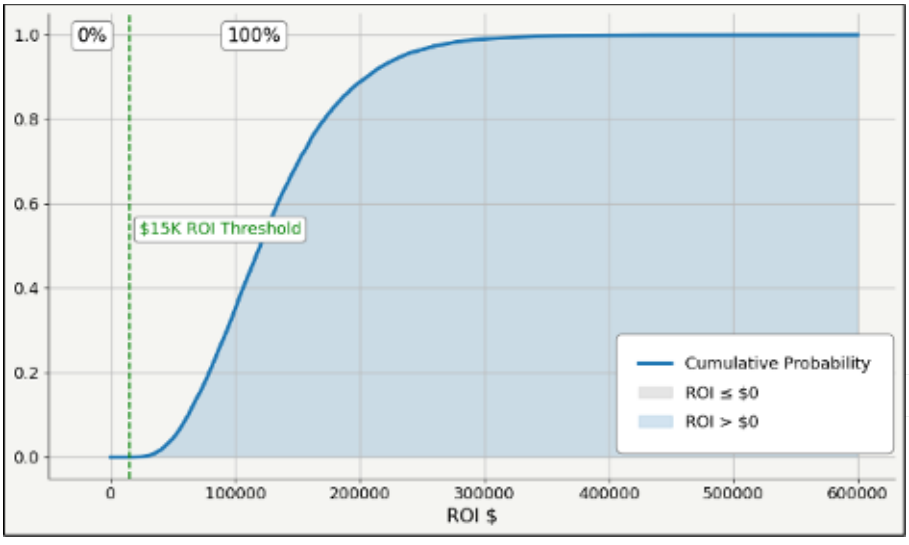
Income sources:

In addition to a startup grant from state or local entities (especially where opioid settlement monies are available), the payment structure was a combination of “enhanced fee for service” and expanded scope of work with billable services. Income sources were as follows:

- Per-prescription filled profit on the medication
- Per-prescription filled standard dispensing fee
- Added amount paid by the state to the pharmacy per prescription filled; such incentive payments are already in place for vaccines and for buprenorphine, another FDA-approved medication for treating OUD. (30,31)
- Medication therapy management (MTM) billing
- MTM includes a comprehensive review of all medications, medication-related education, and collaboration with other health care providers.
- Chronic care management billing (CCM)
- CCM is a primary care service for clients with two or more chronic conditions and includes comprehensive assessment, documentation, and coordination with other providers.
- Home delivery charge to clients (sensitivity analyses only)
- Third-party billing for pharmacy technician with community health worker certification, and social worker counseling sessions (sensitivity analyses only)

Return on Investment:

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



We found that over 3 years, there was $2.33 returned for every $1.00 spent (95% uncertainty interval, UI: $1.91-$2.85).We found that a participating pharmacy would have a 100.0% likelihood of netting $15,000 or more by year three and 95.5% likelihood of netting $50,000 or more by year three.

We conducted two sensitivity analyses. In the first, we added some services and related startup costs and revenue and found a return on investment (ROI) very like the base case, i.e., $2.15 earned for every $1:00 spent (95%UI $1.64-$2.69) and 99.9% likelihood of netting $15,000 or more by year three. Moreover, in a second sensitivity analysis we added all possible costs and removed the CCM revenue stream but still found and ROI of $1.60 earned for every $1.00 spent (95%UI $1.21-$1.98) and 97.4% likelihood of netting $15,000 or more by year three . See the Technical Appendix for more details.

Potential competitors:

We estimated an OTP would lose income equivalent to approximately 4-11 long-term clients per month; however, there are ways to compensate for those losses 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
- Allows highly trained pharmacists to practice at the top of their qualifications
- Increases patient choice

Implementation Considerations:

IIf federal and state statutory changes make the Enhanced pharmacy-dispensed methadone model becomes permissible, requirements for successfully implementing this model include willingness of pharmacists 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 laws. Payers could consider supplemental 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 Enhanced 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. Additionally, they can expand their scope of practice in a way that serves many other clients (e.g., MTM and CCM), potentially reducing the rate of pharmacy closures. For OTPs, while some new competition is created, new business may also result because of the increased market size. 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 technicians.
- Expand scope of practice.
- Enable technicians to expand scope, e.g., certification as community health workers.
- Set up private treatment space if not already available.
- Consider ongoing anti-stigma and trauma-informed trainings.

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.
- Federal officials grant provider status to pharmacists, including equal billing rates with doctors for clinical services.
- State officials allow pharmacists to expand scope of practice and to bill Medicaid.
- 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, particularly from opioid settlement funds, and incentivize pharmacies to join the program.

Payers:

- Insurers provide per prescription fill incentive pay to pharmacies.
- Insurers provide reimbursement for clinical services to pharmacists equal to that of doctors

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 and other services.
- 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. (3,15) 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 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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