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In Australia, Primary Care and Pharmacies Deliver Methadone

Model could inform U.S. practices, but some administrative rules raise concerns about access

Overview

Methadone is an effective medication, approved by the Food and Drug Administration, to treat opioid use disorder (OUD). Research shows that it can reduce overdose deaths and help people stay in treatment.[1] In the U.S., the medication is heavily regulated and available only at opioid treatment programs, health care facilities governed by federal and state laws. These programs subject patients to punitive rules—such as limits on take-home doses and frequent urine screens—borne of stigma surrounding addiction and the medication itself.[2]

Other countries approach methadone treatment differently, often making it easier for patients to access lifesaving care while still fulfilling their obligations under international drug control treaties.[3] These approaches can shed light on ways for policymakers to improve OUD treatment in the U.S.

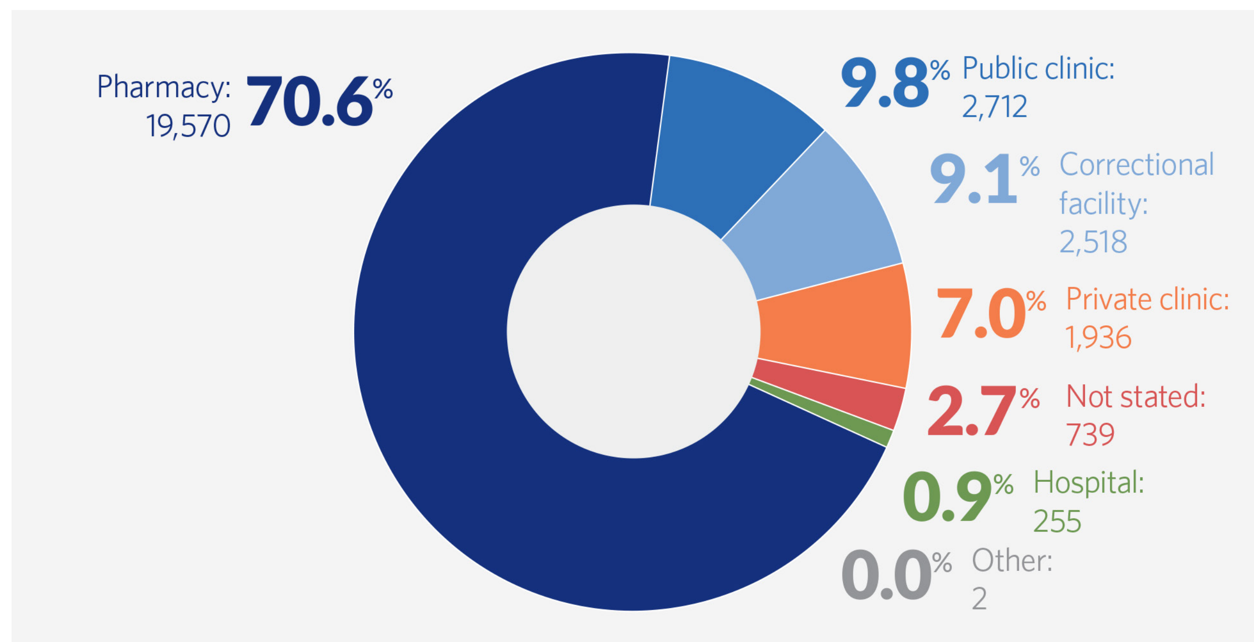
Australia's approach to methadone treatment

In Australia, most methadone prescriptions for treating OUD are written by general practitioners working in private practice, and retail or community pharmacies fill most prescriptions.[4] This kind of treatment is not available in the U.S., where the medication is provided only in tightly regulated clinics known as opioid treatment programs.[5]

Figure 1:

Most of the 47,500 Methadone Patients in Australia Receive the Medication at a Pharmacy

Patients served at various dosing points on a snapshot day in 2021



Notes: Data for 2021 excludes Queensland. Each state and territory reports data for a single "snapshot day," usually in June, although the exact date varies across jurisdictions.

Source: Australian Institute of Health and Welfare, National Opioid Pharmacotherapy Statistics Annual Data collection, https://www.aihw.gov.au/reports/alcohol-other-drug-treatment-services/national-opioid-pharmacotherapy-statistics/contents/about

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Australia's model was raised as one approach to consider during a National Academies of Sciences, Engineering, and Medicine meeting requested by the White House to inform the future of methadone regulation in the U.S. [6]

Treatment settings and guidance

Unlike in the United Kingdom, where any prescriber or pharmacy can offer methadone treatment for OUD, Australia regulates this medication at both the state and federal levels. This results in variations in the delivery of care, much like in the U.S. and Canada.[7]

In Australia, federal rules set general standards for treatment.[8] The standards state that agonist treatment (medication treatment with either methadone or buprenorphine) can be prescribed in primary care or a specialty

clinic, providers should consult with patients on the best medication for them, and counseling should be offered but participation in counseling should not be required to get treatment. This counseling recommendation aligns with the evidence, which shows that medication alone can be effective in treating OUD.[9]

When it comes to setting standards for who can prescribe methadone, and which pharmacies can provide it, the federal rules defer to the states and territories.

All jurisdictions require the prescriber to obtain a permit or other approval from a government authority, but the specific rules that apply can vary.[10] For example, in Victoria, providers are initially allowed to treat up to five patients and can undergo training for permission to treat more; these guidelines do not specify a maximum number of patients.[11] In Western Australia, on the other hand, the guidelines state that providers can treat no more than 50 patients, though that number drops to 25 when a prescriber is the only one in the region, due to concerns about the number of patients who would be affected if the prescriber were to stop practicing.[12] In both states, prescribers need special training to receive a permit.[13]

Similar permitting rules apply to pharmacies that dispense methadone. New South Wales is one example. There, permitted pharmacies can serve up to 65 patients, though patients considered "stable" who have to go to the pharmacy only once a week or less for their doses do not count toward this limit.[14] And in a few states and territories, like Victoria and Western Australia, pharmacists who dispense methadone are required to take additional training.[15]

States and territories also set rules about supervised consumption—when the pharmacist watches as the patient takes methadone—and eligibility for and amounts of unobserved take-home doses. These rules are influenced by federal guidelines, which, in contrast to the United Kingdom's rules, emphasize supervised consumption, stating that "In general, treatment of opioid dependence with methadone or buprenorphine is based on daily, supervised dosing at a pharmacy or clinic."[16] These rules discourage providing more than four take-home doses per week.[17]

Across Australia, the specific take-home amounts available to patients vary, as illustrated by the comparison of rules in Victoria and Western Australia below.

Table 1

Take-Home Policies Vary Across Australian States

Amounts provided in Victoria and Western Australia based on time in treatment

Victoria	Western Australia
First three months of treatment: No take-home doses **Three to six months:** Up to two take-home doses per week **Over six months:** Up to four take-home doses per week, no more than three supplied at one time	**First six months of treatment:** No take-home doses **Six to 12 months:** One take-home dose per week **12 to 24 months:** Two take-home doses per week, only one supplied at a time **Over 24 months:** Three take-home doses per week, no more than two supplied at one time

Sources: Victoria State Government Department of Health and Human Services, "Policy for Maintenance Pharmacotherapy for Opioid Dependence" (2016), https://www.health.vic.gov.au/sites/default/files/migrated/files/collections/policies-and-guidelines/p/pharmacotherapy-policy-opioid-dependence.docx; Western Australian Community Program for Opioid Pharmacotherapy (CPOP), "Clinical Policies and Procedures for the Use of Methadone and Buprenorphine in the Treatment of Opioid Dependence" (2014), https://www.mhc.wa.gov.au/media/1614/wa-clinical-policies-and-procedures-for-the-use-of-methadone.pdf

These rules not only dictate how often a patient in treatment must go to a pharmacy to get medication, they also affect a patient's financial well-being: While the medication itself is covered by Australian Medicare—the country's universal health insurance—the pharmacist's services aren't.[18] Patients pay out of pocket for these costs, estimated in one study to be a median AU$110 for 28 days of care.[19] As a result, care is more expensive for those in the early stages of treatment, when they have to go to the pharmacy most frequently.[20] These costs have led some patients to discontinue treatment, either voluntarily or because their provider refused to continue offering treatment without payment.[21]

Changes in treatment due to COVID-19

Like the U.S., Australian states and territories relaxed methadone take-home rules during the COVID-19 pandemic.[22] For example, rather than relying on total time in treatment, Victoria recommended that prescribers assess each patient's risk of overdose using a standardized framework.[23] Patients deemed "low risk" were eligible for up to six take-home doses a week. This policy change coincided with a decrease in methadone overdoses.[24] The U.S. had a similar experience: Increased take-home doses were not associated with increased methadone overdoses.[25] In New South Wales, which also relaxed the rules on supervised consumption, a study of patients attending three clinics found that providing additional take-home doses was not associated with a statistically significant increase in substance use.[26]

Treatment outcomes

Consistent with a large body of evidence, research conducted in Australia—primarily New South Wales—has found that pharmacy-based opioid agonist treatment is associated with reduced heroin use, mortality, criminal charges, and hospitalizations due to injection-related infections.[27] Among people who use syringe services programs (which distribute free, new, sterile syringes to people who inject drugs), clients who are prescribed methadone are less likely to discontinue treatment than people taking buprenorphine.[28]

Studies of patient perspectives also indicate that methadone treatment is successful: patient satisfaction is high, and it helps improve lives:[29]

> "Now I'm on the methadone I think a lot straighter. I go fishing, I can go camping. When I was on the other gear [illicit drugs] I didn't want to do any of that sort of stuff."[30]
>
> Patient in rural Australia

However, some patients express a wish for more privacy at the pharmacy and find burdensome the frequent pharmacy visits required by state regulations, particularly in rural areas where patients must travel long distances to reach a dosing pharmacy.[31]

Indeed, researchers and treatment advocates have raised concerns about the treatment system's capacity to meet the need.[32] A New South Wales study found that 87% of all clients receiving methadone or buprenorphine were served by just 20% of registered prescribers—meaning treatment is concentrated in a small subset of the workforce.[33] Further, the authors found that for each year in the study, more providers stopped offering medications for OUD than started.[34]

Findings like these have led to calls, similar to ones in the U.S., for reducing the administrative burden on prescribers and providing routine training on the use of medications so that treating OUD becomes an accepted part of general clinical practice.[35]

Conclusion

The Australian approach to methadone delivery allows people with OUD to access high quality, effective care in doctors' offices and community pharmacies. However, treatment is constrained by state and territorial regulations that limit which providers and pharmacies can offer the medication and also require frequent observed doses. These rules also vary across jurisdictions, meaning that access to methadone providers and take-home doses is determined in large part by where patients live rather than their individual needs.

Australia's approach is similar to that of the U.S., which also has a federal system of methadone regulation that allows states to impose additional rules on providers and patients beyond those required by federal law.[36] As federal policymakers in the U.S. contemplate changes to methadone rules, to maximize access to treatment they can carefully consider how states will implement these changes and encourage them to draft rules that emphasize access and flexibility. Without coordinated action from both levels of government, access to this lifesaving medication is likely to remain limited.

Endnotes

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