



## Learning from COVID-19: How Pandemic-Era Policies for Methadone Prescribing Could Improve Opioid Treatment

**B**efore the COVID-19 pandemic, the United States was already seeing staggering numbers of drug overdose deaths, with over 70,000 people dying from an overdose in 2019. When the pandemic began in early 2020, in-person health care visits presented significant risk for COVID-19 infection and spread. Federal agencies took swift action to create sweeping, yet temporary, regulatory changes to opioid use disorder (OUD) treatment policy so that patients could maintain uninterrupted access to health care. Since the onset of the pandemic, racial disparities in overdose prevalence have widened in the state, with overdose deaths among Black people outpacing other racial groups in California.<sup>1</sup> Statewide, counties including San Francisco, Los Angeles, and San Diego are facing unprecedented increases in overdose-related morbidity and mortality, in part due to the rise of illicitly manufactured fentanyl.<sup>2</sup> Because both the COVID-19 pandemic and the overdose crisis have evolved in the past two years, re-examination of the role of addiction treatment in reducing opioid-associated morbidity and mortality and promoting health equity is needed.

### The History of Methadone Treatment Policies and Regulations in the US Is Highly Racialized

Methadone is a gold-standard medication effective in reducing mortality for people with OUD. In the US, patients can only access methadone treatment through outpatient treatment programs, or OTPs (colloquially, “methadone clinics”). Before the COVID-19 pandemic, federal and state restrictions required patients to visit clinics daily to receive their methadone

doses, ostensibly to guard against methadone overdose and misuse (defined as “the use of any drug in a manner other than how it is indicated or prescribed” including diverting prescriptions for nonmedical use and altering the route of administration).<sup>3</sup> Only people meeting strict criteria, including having stable housing and sufficient length of time in treatment, had access to methadone “take-home doses” or “take-homes.”<sup>4</sup>

Methadone was first studied in the 1960s and approved by the Food and Drug Administration in the 1970s for OUD treatment. The federal government established OTPs as a national network of clinics operating separately from all other aspects of health care.<sup>5</sup> OTPs offered methadone maintenance treatment in parallel to services designed to enhance recovery and social integration (e.g., in-person counseling, linkages to housing). OTPs were deliberately placed in impoverished, inner-city locations, and the dominant media narratives portrayed patients on methadone as criminal, heroin-using Black and Latinx people. These narratives allowed federal agencies, including the Substance Abuse and Mental Health Services Agency (SAMHSA) and the Drug Enforcement Agency, as the alcohol and drug law enforcement agency of the US Department of Justice, to create and regulate a methadone treatment system centered on surveillance and stigma.<sup>6</sup> This surveillance exists on the individual level by requiring patients to attend clinic daily and be directly observed taking their medication, and also at the OTP level with OTPs having to comply with strict reporting and regulatory requirements to state and federal agencies. For example, before the COVID-19 pandemic, if a patient receiving methadone needed

to travel out of state for any reason, any requests for additional take-home doses of methadone needed for travel required pre-approval from SAMHSA through State Opioid Treatment Authorities. No other controlled substance or medication in the US requires this level of regulation and restriction.

These treatment policies also have sociodemographic implications, where more than 90% of OTPs are concentrated in urban areas, in part due to state and federal regulations resulting in limited OTP expansion into rural areas.<sup>7</sup> Simultaneously, due to racial/ethnic segregation and other forms of structural racism across the US health system, Black and Latinx communities lack access to other, less restrictive OUD treatments like buprenorphine, which can be prescribed in any primary care doctor's office licensed to prescribe it.<sup>8</sup> These conditions make the highly surveilled system of methadone the only medication option for many communities of color. Experts have emphasized that loosening restrictions to methadone is essential to addressing these impacts of structural racism on both overdose deaths and treatment access.<sup>9</sup>

### **Risks Posed by Burgeoning Fentanyl Use Highlight Need for Expanded Methadone Access**

In recent years, illicitly manufactured fentanyl has come to quickly dominate the US drug supply and is now the most widely implicated opioid in overdose deaths.<sup>10</sup> Unlike its predecessors (heroin and prescription opioids), fentanyl has several unique pharmacologic properties, including being easier to illicitly manufacture and transport with higher potency and slower clearance from the body.<sup>11</sup> These properties led to both the proliferation of fentanyl in the US drug supply and a dramatically higher risk of overdose death compared to heroin and other opioids. Early studies demonstrate that among people using fentanyl, risk of severe precipitated withdrawal symptoms when initiating buprenorphine is higher compared to people

using heroin, which may make buprenorphine a less appealing medication treatment option in the era of fentanyl for patients.<sup>12</sup>

Buprenorphine and methadone are the only two medication treatments shown to reduce mortality from OUD.<sup>13</sup> For treatment of OUD from fentanyl, clinicians and patient advocates speculate that methadone may be the preferred medication for treatment initiation, but regulatory barriers to accessing methadone will be a significant challenge to effective long-term treatment.<sup>14</sup> There is an urgent need for state and federal governments to consider rapidly expanding methadone access as one way of reducing overdose deaths.

### **Prepandemic Restrictions on Methadone Treatment Are Unprecedented in Chronic Disease Care**

Methadone for OUD treatment is restricted and regulated in a manner singularly distinct from other chronic medical illnesses, including treatments with similar risk for misuse and significant associated harms. For example, many people with diabetes mellitus — a relapsing-remitting chronic condition like OUD — must take insulin to stay healthy. Insulin is an injectable medication that requires the use of syringes and needles, a strict schedule, and careful attention to dosing to avoid significant harms, including severe hypoglycemia, loss of consciousness, coma, and death. Even with these considerations, millions of Americans are routinely prescribed insulin and entrusted with self-administration of this medication at home.

In another chronic illness, attention deficit hyperactivity disorder (ADHD), standard first-line treatment includes use of stimulant prescription medications (i.e., amphetamines), which have similar potential for diversion and misuse to methadone. Yet there are no restrictions or regulations on prescribing or administering stimulants for treatment of ADHD comparable to those imposed on methadone.

Both scenarios are starkly different from the restrictions and regulations placed on methadone treatment for OUD, despite similar potential treatment harms and risks. Methadone restrictions thereby unintentionally generate stigma and barriers to care that impede OUD treatment engagement and stabilization.

When COVID-19 was declared a public health emergency, over 400,000 Americans were receiving methadone for OUD treatment.<sup>15</sup> In March 2020, SAMHSA enacted temporary exemptions to methadone-prescribing policies. One of these exemptions allowed OTPs individual discretion to initiate or extend take-homes for anyone receiving methadone, effectively removing the previous federal requirements for take-home eligibility.<sup>16</sup> This report reexamines the state of methadone dispensing in the US and evaluates the impact of less restrictive methadone-prescribing policies implemented due to the COVID-19 pandemic.

## COVID-19 Led to Sweeping National Changes in Take-Home Methadone Prescribing

Before the pandemic, for a patient receiving methadone to be eligible for take-homes, SAMHSA regulations required documentation that a patient is “responsible in handling narcotic medications” as demonstrated by meeting eight criteria (see sidebar).

In March 2020, SAMHSA issued emergency regulations that vastly expanded eligibility for take-home dosing, enabling OTPs to prescribe take-homes of:

- ▶ Up to 14 days for “less stable” patients
- ▶ Up to 28 days for “stable” patients

These emergency regulations gave OTP clinicians discretion in determining who might be eligible for take-homes, making it newly possible for patients who may not have otherwise qualified for take-homes to receive them. Additional federal exemptions included waivers related to urine toxicology testing, requirements for counseling, and allowances for billable telehealth visits, methadone home delivery, and surrogate methadone pickup. These changes were implemented immediately across OTPs nationwide, though implementation did vary.

### SAMHSA Criteria for Take-Home Eligibility Pre-Pandemic

1. Absence of recent abuse of drugs (opioid or nonnarcotic), including alcohol
2. Regularity of clinic attendance
3. Absence of serious behavioral problems at the clinic
4. Absence of known recent criminal activity (e.g., drug dealing)
5. Stability of the patient's home environment and social relationships
6. Length of time in comprehensive maintenance treatment
7. Assurance that take-home medication can be safely stored within the patient's home
8. Whether the rehabilitative benefit the patient derived from decreasing the frequency of clinic attendance outweighs the potential risks of diversion

Source: *Federal Guidelines for Opioid Treatment Programs*, Substance Abuse and Mental Health Services Administration, March 2015, 82.

## A Natural Experiment: Increased Access to Methadone Take-Home Doses During the Pandemic

Since March 2020, several early studies have been published examining the impact of regulatory changes. Findings include:

- ▶ **OTP approaches to implementing these regulatory changes have varied nationwide**, where some OTPs reported quickly making adaptations to their clinical practice to rapidly expand access to take-home doses, while others have described maintaining or reverting to prepandemic take-home criteria.<sup>17</sup>
- ▶ **Individual states have also made sweeping methadone policy changes in response to COVID-19.**<sup>18</sup> For instance, New York, with special approval from the Centers for Medicare & Medicaid Services, began delivering Medicaid reimbursement for OTP services in a weekly bundled rate. This was to help OTPs avoid financial loss, since they were no longer being reimbursed for daily in-person visits.<sup>19</sup>
- ▶ **Concerns about increased methadone diversion or overdose with increased take-home access have not borne out.** Early observational studies from OTPs in Connecticut, New York, North Carolina, Oregon, and Washington have not found significant increases in either adverse outcome in 2020 compared to prior years.<sup>20</sup>
- ▶ **Interviews with providers have highlighted increased clinician satisfaction and positive impacts on patient treatment experiences after implementing increased take-home access**, with the majority expressing desire for these changes to remain beyond the COVID-19 public health emergency.<sup>21</sup>

To explore these questions further, the authors' research group conducted a mixed-method study using qualitative and quantitative methods to assess the impact of the less restrictive methadone-prescribing policies at an OTP in a public safety-net community hospital in San Francisco.

In the qualitative component, stakeholder interviews were conducted with 10 providers (including two physicians, five social worker associates, and three nurse practitioners) and 20 patients receiving medication treatment for OUD. All interviews were transcribed, coded, and analyzed to identify emergent themes. Qualitative findings<sup>22</sup> include:

- ▶ Providers were cautious when implementing expanded take-home policies and reported making individualized decisions, using patient factors to decide if benefits outweighed risks of overdose and misuse (e.g., patient drug use, overdose risk, housing status, and vulnerability to COVID-19).

*"Instead of saying, everybody gets two weeks, right, like pushing it to the max, we've said, okay, everybody who has stimulant use disorder can get two take-homes per week, and if their attendance remains good, if they show no evidence of relapse to heroin or opioid [use], we can expand it from there and step up to three, four, up to six take-homes per week depending on their situation."*

— OTP provider

- ▶ New patient groups started receiving take-homes, and providers noted few adverse events.

*“We don’t have any data from the urine samples to look at whether there’s been a shift in what substances they’re using. But we also don’t have tons of people, either overdosing by mishandling them or even coming back early and saying, ‘Hey, I lost my take-homes,’ or, ‘Something happened with my take-homes.’”*

— OTP provider

- ▶ Patients who received take-homes appreciated increased autonomy and flexibility with take-home access, which in turn increased likelihood of treatment stabilization and engagement.

*“The whole thing was just a game changer for me. Because there is no way I could have done it [without take-homes]. I couldn’t go to school and carry a full load and be on methadone. It would just not work.”*

— OTP patient

- ▶ Patients who remained ineligible for take-homes (usually due to ongoing nonprescribed opioid or benzodiazepine use) desired greater transparency in understanding why they were not getting take-homes and shared decision-making with their providers.

In the quantitative component, a retrospective analysis was conducted using electronic health data from both the OTP (Methasoft) and the health network (Epic) from January 2019 to December 2020 for all established patients in OTP care, defined as having been in care for at least 90 days. Patients were categorized as having never received take-homes during the study period, being new to receiving take-homes,

and having been on take-homes and having had them increased. Clinic-level intake, retention, and take-home prescribing; acute care utilization; and mortality were assessed using pre-post analysis and chi-square testing.

- ▶ Clinic volume, intake, and retention were largely unchanged after implementation of the new regulations, though the average monthly proportion of patients receiving take-homes significantly increased from 31% to 47% ( $p < .001$ ).
- ▶ Among 506 established patients at the OTP:
  - ▶ There were no significant differences in 10-month mortality: Among those who never received take-homes, 10-month mortality was 2.7% compared to 3.2% among those who newly started take-homes ( $p = .79$ ) and 0.8% among those with increases in take-homes ( $p = .24$ ).
  - ▶ A higher number of patients who never received take-homes had emergency department (ED) visits (47.0%) compared to patients who newly received take-homes (ED visits 29.2%,  $p < .001$ ) or who had increases in take-homes (ED visits 17.5%,  $p < .001$ ) during the study period.
  - ▶ Patients who never received take-homes also had slightly higher hospitalizations (19.7%) than those who newly received take-homes (14.3%,  $p = .19$ ) or who had increases in take-homes (17.5%,  $p = .02$ ), though only the latter comparison was statistically significant.

## Key Policy Considerations

- ▶ Increasing access to methadone treatment is a key strategy to mediate the overdose crisis, especially in the context of increased fentanyl availability and use.
- ▶ Less restrictive methadone-prescribing regulations issued due to the COVID-19 public health emergency have increased access to methadone take-homes.

- ▶ Early studies have not found substantial evidence of increasing harms related to methadone overdose or diversion despite increased access to take-homes,<sup>23</sup> and patients and clinicians have desired these regulations to remain.<sup>24</sup>
- ▶ Keeping methadone regulatory changes in place after the COVID-19 public health emergency may reduce barriers to methadone access and is a key opportunity to improve equity in the care of people with OUD.
  - ▶ Specifically, regulatory changes have potential to improve the treatment experiences of patients by increasing autonomy and quality of care, facilitating progression toward treatment stability.
- ▶ Any post-emergency regulatory changes that limit already-established access to take-homes could potentially amplify pre-pandemic inequities in methadone treatment by undermining already-fragile trust in health systems among communities of color.
- ▶ More extensive research is needed in evaluating the long-term benefits and harms of expanding methadone access, in addition to exploring the impact of methadone treatment structures and settings on patient outcomes.<sup>25</sup>
- ▶ Public and private insurers should make certain that reimbursement practices for out-of-office OTP services such as take-homes align with incentives that facilitate treatment progression and stabilization.

## Opportunities for Long-Term Reform

- ▶ The current temporary flexibilities regarding methadone take-homes and OTPs have been long sought by advocates to minimize the burdens associated with recovery from OUD.
- ▶ SAMHSA has several legal pathways to ensure continuation of these regulatory changes indefinitely without needing congressional approval.<sup>26</sup> Congress is also considering alternative routes of

expanding methadone access, including enacting legislation that would expand dispensing of methadone to community pharmacies.<sup>27</sup>

- ▶ By reducing the number and frequency of required in-person interactions, policies such as telehealth assessments, telehealth counseling, and take-home dosing could help to increase enrollment in, and adherence to, medication for addiction treatment while reducing stigma.

## Conclusion

SAMHSA issued emergency regulations that expanded access to methadone take-homes to mitigate exposure risks for COVID-19 infection. During the COVID-19 pandemic, the US, and especially California, has experienced unprecedented increases in opioid-associated mortality due in part to increases in the availability of illicit fentanyl. What opioid deaths might have been without expanded methadone take-home access is unknowable, though available data evaluating SAMHSA's regulatory changes, including these study findings, indicate high acceptability among patients and providers, and few adverse events.

Policymakers could consider making the emergency regulations permanent. Permanently expanding increased access to take-homes could expand methadone access for patients who use fentanyl and increase autonomy, stabilization, and treatment satisfaction among current patients receiving methadone. Expanding methadone take-homes through permanent regulatory changes could provide remediation for the history of medical racism and treatment segregation that historically contributed to stigma and oversurveillance in methadone treatment, particularly for Black and Latinx people with opioid use disorder who face the highest risk for overdose mortality in California.

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CHCF informs policymakers and industry leaders, invests in ideas and innovations, and connects with changemakers to create a more responsive, patient-centered health care system.

## Endnotes

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