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Title

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Permalink

<https://escholarship.org/uc/item/6hd662ht>

Journal

American Journal of Public Health, 112(S2)

ISSN

0090-0036

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Publication Date

2022-04-01

DOI

10.2105/ajph.2022.306806

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Peer reviewed

Federal and State Regulatory Changes to Methadone Take-Home Doses: Impact of Sociostructural Factors

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Methadone is an effective medication to treat opioid use disorder.¹ Access to methadone take-home doses (THDs) is restricted by federal and state guidelines. Before the COVID-19 pandemic, patients were obligated to attend opioid treatment programs (OTPs) daily because of concerns about the safety of THDs. Eligibility for 14- or 28-day THDs required daily visits over one or two years, respectively. Federal regulations for THDs changed during the COVID-19 pandemic, allowing OTPs to initiate or extend THDs.² Emerging data suggest increasing access to THDs does not increase adverse events.³⁻⁵

In March 2020, the Substance Abuse and Mental Health Services Administration (SAMHSA) enacted exemptions allowing increased THDs to mitigate severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection risk by decongregating OTP settings. Patients were allowed 14- or 28-day THDs, on provider discretion, regardless of treatment length. However, implementation varied across OTPs. We conducted three independent studies on the expanded THD exemptions to assess implementation and impact on patients and providers in three geographically diverse OTP settings. We report on lessons learned from the implementation of the THD exemptions in three vulnerable population groups in Tennessee, California, and Puerto Rico exposed to differing sociostructural factors that influence treatment access: OTP financial structure, housing status, and incarceration.

FINANCIAL STRUCTURE IMPACT

In a multisite, mixed methods study examining the experiences and outcomes of individuals with opioid use disorder who received increased THDs (study 1), we noted that the financial structuring of one OTP influenced the implementation of regulations during COVID-19. We provide observations from October 2020 to March 2021 and comments from a medical director of a for-profit OTP in Tennessee. Without daily dosing, some for-profit OTPs faced financial loss from decreased overall reimbursements because of reduced clinic visits.

Several months into the COVID-19 pandemic, some OTPs rolled back THD exemptions despite public health and social-distancing guidelines. One medical director stated, “They [the OTP] are rolling back the COVID-19 exemption even though the state hasn’t directed OTPs to do so.” The director noted that the return to pre-COVID-19 guidelines was primarily attributable to financial loss and that it negatively affected patient safety: “We weren’t able to limit the volume of patients in the clinic or keep them socially distanced due to [staff] shortages and patients not being given take-homes.” Many clinicians resigned, some out of frustration with the OTP leadership in limiting THDs. “They [clinicians] felt it was unconscionable to have a long line of patients waiting out the door, down the block, not socially distanced in the midst of a pandemic.”

INCREASED AVAILABILITY OF HOUSING IMPACT

We conducted a qualitative study in California to assess the impact of COVID-19–initiated housing interventions on THD expansion with 20 patients and 10 clinicians at a single OTP in San Francisco from August to November 2020 (study 2). Patients reported previously experiencing homelessness and received housing through COVID-19 hotel placements offered by the city, affording the opportunity for THDs. One patient had been stable in methadone maintenance treatment (MMT) for 17 years but had never received THDs because of unstable housing. Another patient emphasized the importance of housing to her recovery and how COVID-19–related housing interventions were helpful. Patients new to THDs also faced challenges. One participant described being expelled from residential treatment for not immediately notifying staff about her new THDs (Box 1). Hotel placement was available only to those who met strict eligibility criteria; those who were younger and without health conditions still could not access THDs because of lack of stable housing. Additionally, OTP providers discussed how providing THDs for those living in COVID-19 hotels offered safer storage compared with shelters (Box 1). Providers said THDs also offered patients more flexibility and autonomy in treatment. Providers reported that without housing, success in treatment was difficult; patients with stable housing were better able to engage in care. Although providers were initially concerned about potential adverse events associated with expanded access to THDs, these had not occurred.

INCARCERATION STATUS IMPACT

In a study in Puerto Rico, we examined COVID-19 methadone regulations in a prison setting (study 3). We report on MMT program adjustments to avoid pre- and postrelease disruptions in care. Before the COVID-19 pandemic, daily methadone doses were transported from the OTP to the prison MMT program. At release, participants register in the corresponding community-based OTP to receive services. In February 2020, 88 incarcerated men were enrolled in the MMT program. Because of COVID-19, admissions were postponed until October 2020. Participants were provided

with guidance on COVID-19 prevention measures, and daily delivery and dispensing of methadone by the OTP staff was discontinued. One week's worth of THDs was supplied to the prison MMT programs and dispensed by a prison nurse. Other health services were sustained through telemedicine. As of September 2020, 33 participants had been released after sentence completion. To assist with reentry, THDs were prescribed at release to facilitate service connection to community-based OTPs. All participants attended the OTP within several days. At a 30-day follow-up, participants continued to engage with community OTPs and did not experience adverse outcomes from THDs.

SUSTAINABILITY

Across all three studies, we observed how expanded access to THDs affected patient access to care. Furthermore, our notes and observations underscore the influence of structural factors in implementing exemptions across various treatment settings, geographical location, and patient populations. As we continue to face an ongoing public health crisis with both COVID-19 and increasing rates of drug overdose deaths, there is a need to maintain exemptions for THDs. Although SAMHSA recently announced a continuation of the THD exemption policy,⁶ it is unclear whether these will remain indefinitely. Our three studies highlight the need for more research to assess the role of OTP financial structures on THD policies, housing as a barrier to MMT stabilization with THDs, and treatment access and transitions to community-based OTPs for persons released from incarceration. Future research should explore financial support initiatives for private, for-profit MMT programs because of dependence on billing for patient encounters given that they constitute nearly half of OTPs in the United States. Policy recommendations include expanding coverage, addressing out-of-pocket costs, increasing provider reimbursement, and incentivizing system integration.^{7,8} Housing requirements should be reconsidered, as this may challenge, instead of facilitating, treatment stabilization. Furthermore, efforts to minimize housing disruptions, including permanent extensions of housing access made available during COVID-19 and medical-legal partnerships that prevent evictions, play critical roles in accessing THDs. Finally, further research is needed to understand the impact of varied state OTP regulations among persons released from prison on MMT. This could inform best policy recommendations to ensure treatment connection to community OTPs for THDs among an often neglected population.⁹

PUBLIC HEALTH SIGNIFICANCE

The COVID-19 pandemic allowed us to explore the impact of increasing THDs for persons with opioid use disorder. We also observed factors that influence provider decisions on THDs, such as OTP financial structures and housing. Housing requirements for THDs are a barrier to treatment stabilization for patients experiencing homelessness who may otherwise not engage in treatment.

The pandemic's unique circumstances facilitated practices enabling uninterrupted care and coordinated transition to community services for incarcerated populations. These challenges and opportunities inform a public health agenda to better understand how THD exemptions affect patient outcomes, safety from overdose, and client-centered care.

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PUBLICATION INFORMATION

Full Citation: Wyatt JP, Suen LW, Coe WH, et al. Federal and state regulatory changes to methadone take-home doses: impact of sociostructural factors. *Am J Public Health*. 2022;112(S2):S143–S146. Acceptance Date: February 23, 2022. DOI: <https://doi.org/10.2105/AJPH.2022.306806>

CONTRIBUTORS

J. P. Wyatt wrote the initial draft of the editorial. J. P. Wyatt, L. W. Suen, C. E. Albizu-Garcia, K. R. Knight, and A. Jordan conceptualized the editorial. C. E. Albizu-Garcia, K. R. Knight, and A. Jordan critically reviewed the editorial and approved the final version. C. E. Albizu-Garcia, K. R. Knight, and A. Jordan are co-senior authors. All authors contributed to revisions of the editorial.

ACKNOWLEDGMENTS

J. P. Wyatt, W. H. Coe, Z. M. Adams, M. Gandhi, H. M. Batchelor, and A. Jordan received funding from the Foundation for Opioid Response Efforts (FORE). L. W. Suen receives funding from the University of California, San Francisco (UCSF), the National Clinical Scholars Program, and the San Francisco Veterans Affairs Medical Center. S. Castellanos, N. Joshi, and K.R. Knight conducted work funded by the California Health Care Foundation (grant G-31069). S. Satterwhite received funding from the National Institute of General Medical Sciences through the UCSF Medical Scientist Training Program (grant T32GM007618). C. E. Albizu-Garcia receives funding from the National Institute on Drug Abuse (grant 5TR21DA048394). A. Jordan is supported through the National Institute on Alcohol Abuse and Alcoholism (grant R01 AA028778).

Note. The views and conclusions contained in this document are those of the authors and should not be interpreted as representing the official policies or stance, either expressed or implied, of FORE.

CONFLICTS OF INTEREST

The authors have no conflicts of interest to declare.

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BOX 1—Patient and Provider Quotes on the Intersection of COVID-19 Housing Interventions and Methadone Treatment at an Opioid Treatment Program in San Francisco, CA

Patients who received housing through the shelter-in-place hotels found housing favorable. Housing allowed stability, which increased the likelihood of methadone treatment stabilization.

Participant A: "Very much [like the Shelter in Place Hotel]. If I had to pay rent I'd pay rent. . . . I leave every day, about 12:30, go dose, and then I stay outside until dark. . . . I'm even thinking of maybe going to work at Amazon."

Participant B: "[The Isolation and Quarantine Site is] very respectful and [has] no noise. The reason I like it there: it's small. The space is small but I like that I don't have to buy toilet paper. They supply the toilet paper. They give us dinner. . . . It's nice, the rooms are nice; you got your own bathroom, a sink, a closet. It's nice."

Participant C: "I think the biggest thing is housing stability. A lot of people have unstable housing. I had unstable housing at that point, so the fact that I have a place to live, that's like—I've been in it for a while, I'm gonna be in it for a while. I'm not worried about next month's rent, that kind of thing."

Patients new to methadone take-homes also faced challenges.

Participant D: "I got kicked out of the other transitional housing [because of not reporting my take-home doses], which was something that really upset me too. Because they knew that even though the pandemic was happening, I was one of the only residents there that was really making an active effort to look for a job. And I found one. . . . Like I'm actually trying to make a contribution here around the household and you're going to get rid of me because of one mistake. And it was just very heartbreaking."

Providers perceived how providing COVID-19–related housing through hotels for patients experiencing homelessness could offer new opportunities for methadone take-home doses.

Provider A: "[Patients in shelter-in-place hotels] are now in a secure location. They're not in a place where, like in the shelters, where they could get rolled for their methadone as easily. They can store methadone in their room, pull the door closed and it's locked. . . . People who are using methadone are using it to support and maintain their own opioid use disorder. And if you have it set up so that people have the opportunity to do what's best for themselves, they usually do take advantage of it, so that part's good. So we have been able to [give] people [methadone] who were placed in SIP [shelter-in-place] hotels who otherwise would never have met the criteria for take-homes."

Provider B: "These are people who maybe didn't have [take-homes] before, and so you want to just make sure it's gonna work. . . . And if they do okay, then you feel really good. Like, okay I can give you more. . . . You have empiric evidence that they have handled take-homes safely. . . . So we have felt very comfortable taking those people and then giving them [take-homes] afterwards."

Providers witnessed how COVID-19–related housing through hotels could lead to periods of treatment stabilization and increase recovery for patients.

Provider C: "They have time to reflect, stop using, and come out and really not want to go back to it. There is one client in particular who, she was drinking consistently and using [drugs]. She was COVID positive and went into a quarantine hotel. She stopped drinking [alcohol] and stopped using [drugs]. . . . It's something she wanted to do but [getting quarantined in the hotel] really forced her into it, and now she's doing really well."

Provider D: "Minus all of the sickness and death that this pandemic has caused, it has pointed out a lot of things that I think a lot of people in our field have known for a long time. Like if people don't have food and housing, they can't possibly focus on higher level needs, and it's happening now in practice."
