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Changes in Methadone Regulation During COVID-19

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I INTRODUCTION

The COVID-19 pandemic has created a natural experiment for the treatment of opioid use disorder (OUD) that decades of advocacy could not achieve. Evidence-based treatment for OUD currently exists in the form of medications for opioid use disorder (MOUD), including buprenorphine, naltrexone, and methadone. Methadone, a long-acting, synthetic opioid used to treat OUD that is approved by the Food and Drug Administration (FDA), is the oldest MOUD and has a significant body of evidence to demonstrate its safety and efficacy. Despite this, access to methadone is significantly limited in the United States due to federal regulations that place unique restrictions on its use to treat OUD. Unlike any other medication in the United States, patients must initially report to an opioid treatment program (OTP) *daily* to receive their methadone dose. It takes at least one year for a patient to receive a fourteen-day supply of take-home doses (THDs) and two years for a twenty-eight-day supply.[1] The justifications for these stringent regulations have included fears that the medication would be diverted for recreational use; however, as we demonstrate in this chapter, much of the motivation for such strict regulation also derived from racist sentiment by regulators.

Since the federal regulations governing methadone were introduced in 1972, advocates of methadone treatment for OUD have suggested that THD policies should be relaxed to increase access to it.[2] Until the COVID-19 pandemic,

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1 42 C.F.R. § 8.12(i)-(j) (2021).

2 Jerome H. Jaffe & Charles O'Keeffe, From Morphine Clinics to Buprenorphine: Regulating Opioid Agonist Treatment of Addiction in the United States, 70 Drug & Alcohol Dependence S3, S5, S7 (2003); Inst. of Med. et al., Federal Regulation of Methadone Treatment 12 (Richard A. Rettig & Adam Yarmolinksy eds., 1995).

however, methadone continued to be more strenuously regulated due to the lack of political power among those prescribed methadone (a higher proportion of Black, Indigenous, and People of Color);[3] competing financial incentives of OTPs, where THDs can minimize financial return;[4] and the lack of pharmaceutical lobbying efforts to support the deregulation of this generic medication.

During the pandemic, the Substance (Ab)use and Mental Health Services Administration (SAMHSA) relaxed regulations surrounding THDs, along with the Drug Enforcement Agency (DEA), which authorized OTP employees, law enforcement, and the National Guard to allow for methadone doorstep delivery to limit viral spread. Prior to the pandemic, people were required to attend OTPs in person to obtain their medication up to six times a week taking one to two years to be deemed eligible for fourteen- or twenty-eight-day THDs, respectively; this was widely viewed as a major barrier to methadone access.[5] We focus on the federal SAMHSA waiver, released in March 2020, which allowed "clinically stable" patients enrolled in OTPs to immediately receive either fourteen or twenty-eight days of THDs, regardless of time enrolled in treatment.[6] This chapter tells a larger story about methadone regulations in the United States and how COVID-19 prompted a historic change in the way the medication is dispensed. We begin with a history of the 1972 federal methadone regulations and the sociopolitical context that informed this legislation, paying specific attention to what motivated the initial restrictions on THDs. We next describe SAMHSA's March 2020 waiver and pertinent results from research studies conducted in the United States and internationally on how increases in THDs during COVID-19 affected overdose rates, diversion, and patient preferences. We then conclude with our preliminary survey data, contextualized within this growing body of scholarship, which assess patient experiences with increased THDs due to COVID-19 at a for-profit OTP located in Nashville, Tennessee.

II BACKGROUND

A *The Base of Evidence for Methadone*

Methadone has been shown to decrease opioid overdose deaths and all-cause mortality, while also increasing adherence to substance use disorder treatment and

[3] Anne Schneider & Helen Ingram, Social Construction of Target Populations: Implications for Politics and Policy, 87 *Am. Pol. Sci. Rev.* 334, 338 (1993).

[4] Giliane Joseph et al., Reimagining Patient-Centered Care in Opioid Treatment Programs: Lessons from the Bronx During COVID-19, 122 *J. Subst. Abuse Treat.* art. 108219, at 3 (2020).

[5] COVID-19 FAQ, US Dep't of Just. Drug Enf't Admin. Diversion Control Div., www.deadiversion.usdoj.gov/faq/coronavirus_faq.htm (last visited Oct. 6, 2021).

[6] Substance Abuse & Mental Health Serv. Admin., Opioid Treatment Program (OTP) Guidance (2020), www.samhsa.gov/sites/default/files/otp-guidance-20200316.pdf (hereinafter, Opioid Treatment Program).

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decreasing the rates of infectious diseases associated with intravenous substance use.[7] It is correlated with improved health-related quality of life, physical, and mental health outcomes,[8] as well as with higher rates of employment and metrics of "social stability."[9] Methadone is more effective than readily available behavioral health treatment modalities that emphasize an abstinence-only approach.[10]

Notwithstanding these benefits, THDs of methadone have been stringently regulated. Accidental overdose or co-ingestion – particularly in patients who are unable to store their medication in a locked box – as well as non-prescribed and illicit use of opioids are ongoing fears that currently guide the strict regulation of methadone. However, while diversion exists, there is evidence to support the conclusion that increasing access to this medication reduces hospital admissions and otherwise promotes recovery.[11] Countries with more flexible THD guidelines do not report increased levels of overdose deaths,[12] and several randomized controlled trials have found no difference in treatment retention or diversion in patients receiving daily supervised dosing versus THDs with contingency management.[13] Thus, allowing for more flexible THDs would permit easier access to this lifesaving medication, yet such reforms are hindered by the sociopolitical history of methadone regulation.

B *The Sociopolitical History of Methadone Regulations*

The sociopolitical history of methadone regulation in the United States is rooted in racist theories of criminality and social deviance that motivated early regulation of narcotics, and these same racialized constructions continue to inform *where* and *how* methadone is dispensed.[14] During the mid-1960s, methadone maintenance treatment began to be accepted as effective medical treatment. Physician-researchers began framing methadone as a treatment geared toward criminals who

[7] Luis Sordo et al., Mortality Risk During and After Opioid Substitution Treatment: Systematic Review and Meta-Analysis of Cohort Studies, BMJ, at 1, 4 (Apr. 26, 2017).

[8] Icro Maremmani et al., Substance Use and Quality of Life Over 12 Months Among Buprenorphine Maintenance-Treated and Methadone Maintenance-Treated Heroin-Addicted Patients, 33 *J. Subst. Abuse Treat.* 91, 93 (2007).

[9] Gavin Bart, Maintenance Medication for Opiate Addiction: The Foundation of Recovery, 31 *J. Addict. Dis.* 207, 217 (2012).

[10] Barbara Andraka-Christou, The Opioid Fix: America's Addiction Crisis and The Solution They Don't Want You to Have 10 (1st ed. 2020).

[11] Einat Peles et al., Earning "Take-Home" Privileges and Long-Term Outcome in a Methadone Maintenance Treatment Program, 5 *J. Addict. Med.* 92, 94–96 (2011); Alexander Y. Walley et al., Methadone Dose, Take Home Status and Hospital Admission Among Methadone Maintenance Patients, 6 *J. Addict. Med.* 186, 190 (2012).

[12] Open Soc'y Inst., Lowering the Threshold: Models of Accessible Methadone and Buprenorphine Treatment, 12, 27 (2010).

[13] Rosella Saulle et al., Supervised Dosing with a Long-Acting Opioid Medication in the Management of Opioid Dependence 2 (Cochrane Drugs & Alcohol Grp. eds., 2017).

[14] Mical Raz, Treating Addiction or Reducing Crime?: Methadone Maintenance and Drug Policy Under the Nixon Administration, 29 *J. Pol'y Hist.* 58, 60–61 (2017).

used drugs, namely young Black men.[15] Black people who used drugs in the early 1970s were depicted as threats to "community" safety, rather than people suffering from the sequelae of structural violence.[16] This fit squarely with President Nixon's desire to disrupt Black communities, by associating Black persons with heroin and then heavily criminalizing it. By expanding methadone, President Nixon could also make good on his campaign promise to be "tough on crime." By the early 1970s, he began a nationwide expansion of methadone maintenance treatment and created the Special Action Office of Drug Abuse and Prevention, which was instrumental in the establishment of the FDA's 1972 regulations.

Many private, for-profit methadone clinics closed because they no longer met the FDA's standards and were soon replaced by federal, state, and city-funded methadone clinics that served growing Black and Latinx populations who could now afford this treatment. Many rapidly gentrifying neighborhoods in urban cities did not want methadone maintenance treatment programs on their city blocks, which pushed methadone clinics into what physician-anthropologist Helena Hansen and historian Samuel Roberts have called "geographically marginalized" spaces where "local opposition is less organized, such as low income and Black or Latinx neighborhoods."[17] In line with the narrative that methadone was being used to treat criminals, the 1972 regulations required urine reports and mandated behavioral therapy, mimicking carceral procedures and solidifying methadone's place in a larger structure of racialized surveillance.[18] This history continues to fuel structural inequalities in opioid treatment access, where methadone is dispensed in OTPs and remains highly regulated.

In contrast, the pharmaceutical company that originally developed buprenorphine – Reckitt and Colman – played a significant role in paving the way for new legislation that would make that medication increasingly accessible and profitable. In the 1990s, company representatives used their lobbying power to convince members of Congress to allow physicians to prescribe "certain FDA[-]approved opioids without being subject to the current regulations," in other words, the regulations surrounding methadone.[19] Reckitt and Colman also founded a non-profit organization that launched advertising campaigns casting buprenorphine as a solution to the opioid addiction experienced by White suburban communities.[20] These lobbying efforts, coupled with Reckitt and Colman's racialized framing,[21] resulted in

[15] Id. at 65.
[16] Keturah James & Ayana Jordan, The Opioid Crisis in Black Communities, 46 *J. L. Med. Ethics* 404, 412 (2018).
[17] Helena Hansen & Samuel K. Roberts, Two Tiers of Biomedicalization: Methadone, Buprenorphine, and the Racial Politics of Addiction Treatment, 14 *Critical Persps. on Addiction* 79, 91 (2012).
[18] Federal Regulation of Methadone Treatment, supra note 2, at 6.
[19] Jaffe & O'Keeffe, supra note 2, at S9.
[20] Julie Netherland & Helena Hansen, White Opioids: Pharmaceutical Race and the War on Drugs that Wasn't, 12 *Biosocieties* 217, 232–33 (2017).
[21] Id. at 229.

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the Drug Addiction Treatment Act of 2000, which allows buprenorphine to be prescribed in office-based settings by physicians who have undergone an eight-hour course,[22] and leaves the methadone regulations unchanged. Governmental agencies justified the continued and much more stringent regulation of methadone because they considered the medication, when compared to buprenorphine, to be a more potent opioid agonist with higher "abuse" potential. Access to buprenorphine is concentrated in predominantly White neighborhoods, and Black patients are less likely to receive this less regulated MOUD compared to White patients.[23] Rooted in racialized understandings of criminality, methadone has been regulated for the protection of "the public," rather than for the safety, efficacy, and treatment of people with OUD.

C *OTPs and Restrictions on Take-Home Methadone*

At present, methadone is regulated by three federal agencies – the FDA, DEA, and SAMHSA – making methadone the most regulated pharmaceutical medication in the United States.[24] The FDA monitors the safety and efficacy of methadone and has approved the medication for specific medical uses, including the treatment of chronic pain and OUD. Because methadone is considered a controlled substance, it is also regulated by the DEA. The 1971 Controlled Substances Act gives the DEA and the FDA joint authority over the scheduling of drugs that have potential for misuse. However, unlike other controlled prescription medications, methadone is subject to a *third* layer of regulatory control by SAMHSA if it is being prescribed to treat OUD. Only OTPs are permitted to dispense methadone for the treatment of OUD, and methadone is subjected to restriction on THDs.[25]

SAMHSA sets the accreditation standards for OTPs and promulgates guidelines that govern the frequency, dosage, and dispensing of methadone by OTPs.[26] If methadone is being prescribed for pain management, it can be prescribed by office-based practices, and offices need not comply with the SAMHSA regulations.[27] There is no base of evidence to justify this distinction.

Perhaps the defining features of methadone regulations are the location limitations, namely that patients are not allowed to take the medication home with them and that it must be dispensed in an OTP. Since 1972, federal regulations surrounding

[22] Andraka-Christou, supra note 10, at 46. As of April 28, 2021, medical providers are no longer required to take an eight-hour (for physicians) or twenty-four-hour (for advanced practice providers) course before prescribing buprenorphine to fewer than thirty patients.

[23] William C. Goedel et al., Association of Racial/Ethnic Segregation with Treatment Capacity for Opioid Use Disorder in Counties in the United States 2–3 (2020).

[24] Andraka-Christou, above note 10, at 125.

[25] Medication Assisted Treatment for Opioid Use Disorders, 42 C.F.R. § 8.1 (2001).

[26] Accreditation of Opioid Treatment Programs, 42 C.F.R. § 8.3 (2001).

[27] Andraka-Christou, supra note 10, at 125.

THDs have mandated that patients receiving methadone for the treatment of OUD must *travel* to OTPs *almost daily* to receive their medication under directly observed therapy for at least the first ninety days of treatment, and often for longer periods of time.[28] Directly observed therapy means that health care providers must, according to SAMHSA, watch patients "drink and speak after dosing" to ensure medication adherence and diversion control, treating patients as if they have "done something wrong" and are involved in the carceral system.[29]

Per SAMHSA guidelines, OTPs may gradually increase the number of THDs by one THD per week every ninety days until one year, when patients are eligible to receive a fourteen-day supply, or two years, when patients may receive a twenty-eight-day supply.[30] Even though the guidelines allow for a twenty-eight-day supply after two years of treatment, many OTPs across the country continue to require that patients come in more frequently. The laws of individual states also vary widely in terms of when patients are able to qualify for increased THDs. Some states do not even allow *any* THDs to be given to patients.[31]

SAMHSA's current regulatory scheme actively disincentivizes OTPs from issuing THDs based on varying types of reimbursement.[32] For instance, some private, for-profit OTPs can bill for the number of times patients physically present to the clinic – a major source of financial revenue. In some instances, even if a patient is "clinically stable," financial incentives are prioritized over maximizing quality of life and patient care for people with OUD.[33] Furthermore, patients who are allowed a twenty-eight-day supply continue to be scrutinized by OTPs. For instance, despite attaining the maximum number of THDs, many patients are still required to present to a clinic weekly for urine toxicology screens and random bottle counts, often traveling long distances with little notice.[34]

Under the SAMHSA guidelines, OTP leadership can evaluate a patient's eligibility for THD privileges based on "regularity of clinic attendance," absence of recent substance use and criminal activity, and the "stability of the patient's home environment."[35] Such subjective determinations invite bias, particularly against Black, Indigenous, and People of Color, and against persons living in rural or economically disadvantaged communities. Many OTPs also establish their own internal guidelines, including prohibiting patients from receiving increased THDs

[28] Id. at 126.
[29] Substance Abuse and Mental Health Serv. Admin., Federal Guidelines for Opioid Treatment Programs 18 (2015).
[30] 42 C.F.R. § 8.12 (2001).
[31] Jaffe & O'Keeffe, supra note 2, at S5.
[32] Corey S. Davis & Derek H. Carr, Legal and Policy Changes Urgently Needed to Increase Access to Opioid Agonist Therapy in the United States, 73 *Int'l J. Drug Pol'y* 42, 44 (2019).
[33] Joseph et al., supra note 4, at 1.
[34] Andraka-Christou, supra note 10, at 126.
[35] Federal Guidelines for Opioid Treatment Programs, supra note 29, at 53.

for cannabis-positive urine toxicology reports, even if they have been consistently adherent to methadone treatment.[36]

D *The Disruptive Nature of Daily Methadone Dosing*

Traveling to an OTP daily to receive methadone is extremely disruptive to the lives of people with OUD. The SAMHSA regulations about THDs prior to COVID-19 require patients to take time away from childcare, school, and work to access methadone. Employment security, which promotes treatment adherence, has also been shown to be compromised, given the need to accommodate the demand of daily medical appointments.[37] Moreover, the cost and time of travel to OTPs, particularly for rural populations, can be prohibitive.[38] Further, there are privacy and stigma concerns for patients at OTPs, which often require patients to line up outside to receive medication. This contrasts with buprenorphine, which can be prescribed inside providers' offices and does not require directly observed therapy. Many grassroots organizations, including the Drug Policy Alliance, medical societies such as the National Academy of Medicine and the American Society of Addiction Medicine, and directly-impacted groups, like the Urban Survivors Union, have called for sweeping changes in the regulations surrounding methadone and the provision of THDs.[39]

III A WAIVER FOR TAKE-HOME METHADONE DURING COVID-19

SAMHSA's federal waiver during COVID-19 addressed some of these barriers. In line with social distancing protocols put in place to reduce the spread of COVID-19, SAMHSA's March 2020 waiver granted exemptions to the regulations on THDs.[40] Under the waiver, which remained in effect in some states through 2021, patients deemed "clinically stable" by OTP leadership can receive a fourteen- or twenty-eight-day supply regardless of their time at the OTP. As a result, thousands of patients have received increased THDs, a historic shift in care for people with OUD.[41] However, OTPs are not uniformly funded (e.g., for-profit, city-funded, or state-funded). Coupled with variable clinical discretion about which patients

[36] Andraka-Christou, supra note 10, at 128.

[37] Lindsey Richardson et al., Addiction Treatment-Related Employment Barriers: The Impact of Methadone Maintenance, 43 *J. Subst. Abuse Treat.* 276, 281–82 (2012).

[38] Paul J. Joudrey et al., Drive Times to Opioid Treatment Programs in Urban and Rural Counties in 5 US States, 322 *JAMA* 1310, 1310 (2019).

[39] Jaffe & O'Keeffe, supra note 2, at S7; Corey S. Davis & Elizabeth A. Samuels, Opioid Policy Changes During the COVID-19 Pandemic – and Beyond, *J. Addict. Med.*, May 2020, at 1, 2; Brendan Saloner et al., A Public Health Strategy for the Opioid Crisis, 133 *Pub. Health Rep.* 24S, 29S (2018).

[40] Opioid Treatment Program, supra note 6.

[41] Editorial Bd., Post-Coronavirus Pandemic, Methadone Should be Just as Easy to Get, Bos. Globe (May 24, 2020), www.bostonglobe.com/2020/05/24/opinion/post-coronavirus-pandemic-keep-methadone-easy-obtain/.

receive increases in THDs, there has been immense heterogeneity in how OTPs enforced the SAMHSA waiver. Furthermore, there is no centralized data collection system that tracks how many OTPs across the United States adopted SAMHSA's waiver and how many patients received increases in THD after March 2020.

Since SAMHSA issued the waiver, research groups across the United States, Europe, and Asia have examined the effect of increased THDs during COVID-19 on patient preferences and experiences with treatment, diversion, and fatal and non-fatal overdose rates. To further substantiate our survey results in the context of other studies conducted during COVID-19, our team conducted a literature search. On September 9, 2021, a search on the following databases was conducted: MEDLINE, Embase, and APA PsycInfo on the Ovid platform and Web of Science Core Collection (Clarivate). Search terms included both controlled vocabulary terms and keywords for the concepts of "opioid treatment" and "take-home medication." The search was limited to articles published between March 2020 and September 9, 2021 on the effects of COVID-19 on take-home medication use for opioid treatment. The database search was supplemented by a focused Google search for unpublished literature.

Most studies had multiple outcomes related to changes in OTP services during COVID-19, but we only included measures related to methadone THDs. A summary of key findings is included in Table 19A.1, which can be found in the Appendix (published online).[42] Overall, these findings demonstrate three key points: (1) most OTPs in the United States and internationally significantly increased the number of THDs in response to COVID-19;[43] (2) diversion and overdose rates did not significantly increase as a result of increased THDs;[44] and (3) most OTP providers wanted increases in THDs to become a permanent fixture of methadone dispensing.[45]

A *Patients' Lived Experiences with Increased THD During COVID-19: Lessons from an OTP in Nashville, Tennessee*

Contextualized by findings from other studies in Table 19A.1, our survey data sought to understand how THDs during COVID-19 impacted patients' quality of life, perceived stigma, lived experience, and OUD treatment outcomes at a for-profit OTP in Nashville, Tennessee.

1 Methods

To understand the impact of these changes on patients with OUD, our research team obtained informed consent and conducted telephone surveys of eligible patients at

[42] For further explanation of the methodologies used in this chapter, please see the Appendix at https://petrieflom.law.harvard.edu/assets/publications/Chapter_19_-_Adams_Appendix_-_Final_Version.pdf.

[43] See Appendix, notes 1–4, 6–9, 13.

[44] See Appendix, notes 2, 4, 6–9, 13.

[45] See Appendix, notes 5, 10–11, 13–14.

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TABLE 19.1 *Demographics of research participants from Nashville OTP*
The second column indicates gender and race/ethnicity options read aloud to patients. The third column indicates the number of participants with the corresponding percentages that chose each option.

Demographics (n = 22)*		
Gender	Woman	11 (50%)
	Man	11 (50%)
	Non-Binary	0
	Other	0
Race/ethnicity	American Indian or Alaska Native	1 (4.5%)
	Asian or Asian American	0
	Black, African, or African American	1 (4.5%)
	Caucasian	19 (86.4%)
	Hawaiian Native or Pacific Islander	0
	Non-Caucasian Hispanic or Latinx	0
	Other: Caucasian/American Indian	1 (4.5%)

* Demographic questions were incorporated into the survey at a later date and therefore represent 22 of the 34 total participants.

a for-profit OTP in Nashville about their experiences receiving increased THDs during COVID-19. The survey instrument consists of twenty-four questions, with free text boxes to capture patients' direct comments. The survey was administered from June to August 2020, with demographic questions (including race and gender) incorporated in July, after seven participants had already completed the survey. Due to the negative impact that THDs had on this for-profit OTP's financial status, this OTP decided to no longer provide twenty-eight-day supplies of THDs, thus ending our data collection prematurely. After collection, the open-ended responses were analyzed to identify common themes and narratives using qualitative methods. Because of the small sample size, this chapter presents the results of the qualitative analysis, with frequency statistics provided only for context. Note that this is one partner site in an ongoing multi-site (six nationwide OTP) trial.

Light gray points indicate the number of THDs per week given to an individual participant prior to the exemption, and the corresponding dark gray points represent the number of THDs per week given to the same participant after the exemption was issued.

2 Results

Demographic data are available for twenty-two of the thirty-four participants. Eleven identified as women and eleven identified as men (n = 22). One identified as American Indian or Alaska Native, one as Black, African, or African American, nineteen as Caucasian, and one as Other: Caucasian/American Indian (n = 22) (Table 19.1). Prior to COVID-19, more than half, eighteen of thirty-four participants

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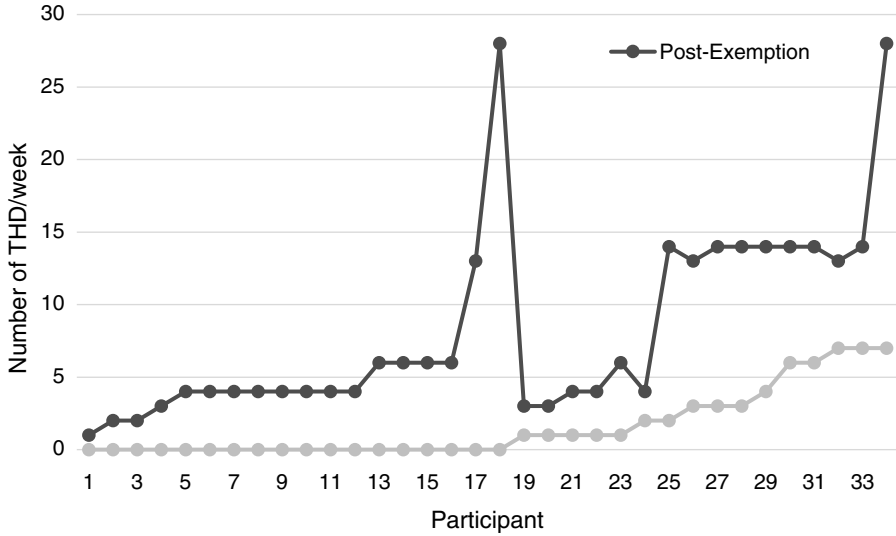

FIGURE 19.1 Number of THDs per participant pre- and post-COVID-19 exemption

(52.9 percent), were not receiving THDs, five were receiving one THD per week (14.7 percent), and two were receiving two THDs per week (5.9 percent). After the COVID-19 exemption, THDs ranged from one to twenty-eight THDs per week among this population (Figure 19.1). The following is a summary of the salient themes that emerged from the analysis.

Participants reported taking great care with storing their THDs to prevent diversion. All participants indicated their THDs were locked (n = 34), with thirty-one out of thirty-four participants (91.2 percent) storing THDs in a lockbox, two out of thirty-four participants (5.9 percent) storing THDs in a cupboard or cabinet, and one out of thirty-four participants (2.9 percent) storing THDs under the bed (Table 19.2). Furthermore, no participants stated that they had shared, given away, or sold their THDs or had any THDs stolen since the change in their THDs during COVID-19.

Three out of thirty-four participants (8.8 percent) took THDs in greater amounts than prescribed, citing under-dosing or the need to self-medicate to manage symptoms as motivating factors (Table 19.2). For example, one participant stated: "One time because my dosage wasn't enough, … I needed to take more to make myself not be sick, and therefore I needed to take more. Now that I'm on the right dosage I do not need to." Another participant identified "stress" and "anxiety" specifically related to his health during the pandemic as his reason for taking more than prescribed. No participants reported they had overdosed on opioids since their recent increase. Barriers to treatment adherence prior to the COVID-19 regulation, which

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TABLE 19.2 *Safety measure quantitative responses*
The first column represents an abbreviated description of the question asked to each participant (see Section III.A.1 for full-length survey questions). The second column indicates the options read aloud for participants. The third column indicates the number of participants who chose each option.

Safety Measures (n = 34)		
Storage location of THD	Lockbox	31 (91.2%)
	Bookbag/purse	0
	Cupboard/cabinet	2 (5.9%)
	Other: under bed	1 (2.9%)
Locked	Yes	34 (100%)
	No	0
Missed THD	Yes	3 (8.8%)
	No	31 (91.2%)
Taken more THD than prescribed	Yes	3 (8.8%)
	No	31 (91.2%)
Overdosed from opioids	Yes	0
	No	34 (100%)
Shared, given away, or hold THD or had THD stolen	Yes	0
	No	34 (100%)

allowed for increased THDs, were related to transportation difficulties, causing missed OTP appointments. For example, one participant said that "[it was] hard getting back and forth," because he lived an hour away from the clinic. Similarly, another participant said that he lived forty minutes away from the clinic and did not have enough money for gas to make it to his appointment.

Thirty-two out of thirty-four participants (94.1 percent) overwhelmingly preferred THDs to dosing at the OTP in part because the burden caused by frequent commuting to an OTP to receive a dose was at least partially relieved (Table 19.3). Participants reported living 35 to 120 minutes away from their OTP and described travel to the OTP as a "huge inconvenience" and "burden … [as there is] no other closer clinic." Some participants reported that, prior to the increase in THDs, the frequent commute to the OTP ***interfered with their work duties*** and cited the ***child-care difficulties*** that commuting created. One woman stated, "it's better to have take homes just because of work and I have a daughter and am starting to work again, so it's inconvenient to come [to the clinic] multiple times a week." One participant described her new dosing schedule as "a lot easier and less stressful" because previously she was often "running late to work." Another stated that they had "been able to hold down a job" due to the increase in THDs. Other participants explained that the ***financial difficulties*** of travel were barriers to treatment. For example, one participant stated "sometimes [I] would miss going to clinic due to financial reasons" such as not having enough gas money or bus fare.

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TABLE 19.3 *Patient preference quantitative responses*
The first column represents an abbreviated description of the question asked to each participant (see methods for full-length survey questions). The second column indicates the options read aloud for participants. The third column indicates the number of participants who chose each option.

Patient Preferences (n = 34)		
Dosing preference	Taking it with me	32 (94.1%)
	Coming into clinic	0
	No preference	2 (5.9%)
	Positive	31 (91.2%)
Impact on quality of life	Negative	1 (2.9%)
	No Impact	2 (5.9%)

Thirty-one out of thirty-four participants (91.2 percent) reported that THDs contributed to improvements in their overall well-being. "It's been life changing to have my medicine with me," confided one participant. Another stated, "I wake up … my first thought is that I don't have to wake up and worry about feeling bad. I can wake up clear minded. I can live a full happy life, and not be stuck chasing dope or feeling sick." One participant stated that due to the need to frequently report to the OTP, he "wasn't able to travel for six years, missing family vacations and stuff. It was a whole lot. Mentally." Some participants said that increased ***THDs provided more time for family obligations***. One woman stated, "I help take care of my in-laws and not having to run to the clinic every day is quite helpful." Another reported, "because I have 2 kids, and I have to get them ready for school, but [now] I don't have to run out there every day to get my dose. Anything is better than every day." Other participants reported ***reduced stress and hassle of presenting to the clinic as frequently***. "I mean it's less stressful, I live in [town] so it's far to drive all the way to the clinic just to get a dose and come all the way back." Another participant said that she doesn't "freak out if there is an accident and doesn't make it" to the clinic, resulting in a missed dose. Another reported, "It's [THDs] helping me tremendously … and I'm not so stressed."

Participants stated that increased THDs contributed to a ***greater sense of stability and accomplishment in treatment***. "[It] feels like you've accomplished a lot more not having to go as often. Before it was so long to get increased take-homes," one participant explained. She further expressed feeling more "successful" with the program now compared to before when she had to come in every day. Another participant described his increase in THDs as: "Definitely a positive reinforcement to stay clean."

Participants also reported that THDs ***decreased the stigma*** they felt from being in methadone treatment. One participant described daily dosing as a "dehumanizing process" as the strict guidelines often make patients feel as though they are being

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"treated like criminals." Another participant commented that since an increase in THDs, he felt like he was "living a more normal life" and that he was "no longer concerned about how friends at work feel about [him] going to a methadone clinic every day."

Some participants reported that the increase in THDs provided a ***sense of safety during the pandemic***. One stated, "I've got a two-year-old who is immunocompromised and an 88-year-old father who is at risk. [I] cannot afford to come in during COVID." No participants felt the increase in THDs had a negative impact on their quality of life. "I would definitely be on board with take-homes after this," one participant concluded. "It has been a definite improvement in my life, and I hope it continues."

IV DISCUSSION AND RECOMMENDATIONS FOR FUTURE POLICYMAKING

COVID-19 produced a natural experiment to study how increased THDs impact patient experiences, preferences, diversion, and overdose rates. As found in studies conducted during COVID-19 across the United States,[46] as well as internationally,[47] none of our participants reported diversion or overdoses since the increase in THDs, and approximately 94 percent of our participants stated they preferred increased THDs, saying that being able to take their medication home with them improved their quality of life. Our findings add to the growing body of evidence demonstrating that increased THDs can eliminate unnecessary barriers to methadone treatment, while simultaneously decreasing the burdens shouldered by patients in treatment. Our study and others provide the data needed to aid policymakers in creating more patient-centered, evidence-informed substance use disorder policies that counter unfounded narratives that have prevented access to more just methadone treatment.

Our study does have limitations that must be taken into consideration. First, we are presenting one site of a larger trial, thereby resulting in a smaller sample size, with a majority White cohort, and a lack of experimental design. These findings will need to be validated by a larger sample size, one more representative of the diverse population of people in methadone treatment. Nevertheless, the narratives that emerged from the data remain useful as a testament to how increased THDs had a positive impact on employment, family life, and feelings of self-worth, bolstering the case for regulatory reform. Moreover, because of institutional racism, which fueled the heavy regulation of methadone, such stringent methadone policies disproportionately affect Black and Latinx communities,

[46] See Appendix, notes 4, 7–9, 12.
[47] See Appendix, notes 2, 4.

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who are also less likely to have access to less heavily regulated medications for OUD, such as buprenorphine.[48] Therefore, policies that decrease access to THDs are not only an issue of access to care, but also a racial justice issue that involves health equity. As such, methadone THD policy reform requires immediate action.

Given our results, in concert with other domestic and international studies (Table 19A.1) showing an overall positive trend with increased THDs, SAMHSA's COVID-19 waiver, should be extended indefinitely. However, there must be additional federal support and legislation, as individual states currently have the authority to not enforce the exemptions on THDs. For instance, even though increases in THDs have not been shown to increase overdoses or diversion, on September 30, 2021, OTPs in Pennsylvania were ordered to scale back their increases in THDs and reverted to the pre-COVID-19 restrictions.[49] With a record 93,000 overdose deaths in 2020, removing barriers to methadone access is paramount: increased THDs must be prioritized in order to prevent unnecessary deaths.[50]

Furthermore, as written, the relaxed guidelines give OTPs permission to increase THDs when certain treatment milestones are met, but OTPs are not incentivized financially to do so. Like other health care providers, some OTPs are financed through fee-for-service arrangements, which allow them to bill for daily medication provision and drug testing. If OTPs provide THDs, they can no longer bill for the daily clinic visit, thus resulting in decreases in financial revenue for the clinic. Therefore, the increase in THDs must be accompanied by payment reforms that incentivize THDs. Such reforms can take many forms, including bundled payments and quality-based payments. Second, the language in SAMHSA's waiver regarding "clinical stability" is problematic and invites OTP clinicians to make subjective determinations that are likely informed by bias, particularly against racial and ethnic minorities and persons living in rural and/or economically disadvantaged communities. As such, SAMHSA should commission a taskforce to assist it in defining "clinical stability" and issue guidelines based on their findings.

COVID-19 has demonstrated that federal regulatory agencies must be proactive about increasing access to methadone treatment. Participants in our study frequently reported that the distances they had to travel to reach an OTP were a major barrier to care. Increasing the number of THDs permitted helps address the barriers to showing up daily to the facility, but it does not address the number of OTPs, which

[48] Goedel et al., supra note 23, at 1.

[49] Governor Tom Wolf, Gov. Wolf Signs Bill Extending COVID-19 Emergency Regulation Suspensions, Expanding Family Caregiver Supports (June 11, 2021), www.abc27.com/news/health/coronavirus/gov-wolf-signs-bills-extending-covid-19-regulation-suspensions-and-to-support-family-caregivers/.

[50] Josh Katz & Margot Sanger-Katz, "It's Huge, It's Historic, It's Unheard-of": Drug Overdose Deaths Spike, NY Times (July 14, 2021), www.nytimes.com/interactive/2021/07/14/upshot/drug-overdose-deaths.html.

has remained largely stagnant over the past fifteen years.[51] Studies such as ours, and others in Table 19.A.1,[52] have demonstrated that there is little risk of diversion or overdose deaths due to increases in THDs, suggesting that fears of diversion are likely exaggerated. Thus, the United States should revisit new models of methadone dispensing, such as pharmacist-administered dosing or prescriptions by primary care providers, as in Canada, the United Kingdom, and Australia.[53] Integrating methadone treatment into our health care system would decrease the carceral overtones of addiction treatment, and patients would likely feel less stigma toward their OUD diagnosis.

[51] Nicholas Chadi & Paxton Bach, Methadone Matters, Pub. Health Post (Mar. 8, 2019), www.publichealthpost.org/viewpoints/methadone-matters/.

[52] See Appendix, notes 2, 4, 7–9, 12.

[53] Susan L. Calcaterra et al., Methadone Matters: What the United States Can Learn from the Global Effort to Treat Opioid Addiction, 34 *J. Gen. Intern. Med.* 1039, 1041 (2019).