AND MOUD FOR ALL: A PROPOSAL TO INCREASE ACCESS TO METHADONE FOR THE TREATMENT OF OPIOID USE DISORDER (OUD) IN THE FEDERAL PRISON SYSTEM

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I. INTRODUCTION

In 2022, the United States hit a grim milestone when over 109,000 lives were lost to overdose-related deaths, with approximately 80% of those

deaths attributable to opioid use.[1] Since 2013, opioid-related overdose deaths have skyrocketed over 1,000%, prompting a Public Health Emergency declaration in 2017.[2] Opioid use disorder (OUD) is especially prevalent in correctional facilities,[3] with an estimated 25% of all incarcerated persons meeting OUD diagnostic criteria, compared to less than 5% of the general population.[4] Since 1982, the incarcerated population in the United States has risen steeply, with over two million people currently in federal, state, tribal, and local custody.[5] Of those two million,

[1] Brian Mann, *U.S. Drug Overdose Deaths Hit a Record in 2022 as Some States See a Surge*, NPR (May 18, 2023, 4:29 PM), https://www.npr.org/2023/05/18/1176830906/overdose-death-2022-record.

[2] Christine L. Mattson et al., *Trends and Geographic Patterns in Drug and Synthetic Opioid Overdose Deaths — United States, 2013–2019*, CTRS. FOR DISEASE CONTROL & PREVENTION (Feb. 12, 2021), https://www.cdc.gov/mmwr/volumes/70/wr/mm7006a4.htm?s_cid=mm7006a4_w; *Determination that a Public Health Emergency Exists*, U.S. DEP'T. OF HEALTH & HUM. SERVS. (Oct. 26, 2017), https://www.phe.gov/emergency/news/healthactions/phe/Pages/opioids.aspx.

[3] Joseph Longley et al., *A National Snapshot Update: Access to Medications for Opioid Use Disorder in U.S. Jails and Prisons (2023)*, O'NEILL INST. FOR NAT'L & GLOB. HEALTH L. AT GEO. L. CTR. 1–2 (Feb. 7, 2023), https://oneill.law.georgetown.edu/wp-content/uploads/2023/02/ONL_Revised_50_State_P5-Updated.pdf. Substance use disorder (SUD) touches upon numerous, disconnected systems across different levels of government, most notably the criminal justice system. Shelly Weizman et al., *Transcending MET (Money, Ego, Turf): A Whole Person, Whole Government Approach to Addressing Substance Use Disorder Through Aligned Funding Streams and Coordinated Outcomes*, O'NEILL INST. FOR NAT'L & GLOB. HEALTH L. AT GEO. L. CTR. 3–4 (June 6, 2023), https://oneill.law.georgetown.edu/wp-content/uploads/2023/06/ONL_Whole_Person_Government_P6r1.pdf.

[4] Christine Vestal, *New Momentum for Addiction Treatment Behind Bars*, STATELINE (Apr. 4, 2018, 12:00 AM), https://stateline.org/2018/04/04/new-momentum-for-addiction-treatment-behind-bars/; *Opioid Use Disorder Treatment in Jails and Prisons*, PEW CHARITABLE TRS. (Apr. 23, 2020), https://www.pewtrusts.org/en/research-and-analysis/issue-briefs/2020/04/opioid-use-disorder-treatment-in-jails-and-prisons; Katherine M. Keyes et al., *What Is the Prevalence of and Trend in Opioid Use Disorder in the United States from 2010 to 2019? Using Multiplier Approaches to Estimate Prevalence for an Unknown Population Size*, 3 DRUG & ALCOHOL DEPENDENCE REPS. 1, 3 (Apr. 25, 2022), https://www.sciencedirect.com/science/article/pii/S2772724622000300.

[5] Wendy Sawyer & Peter Wagner, *Mass Incarceration: The Whole Pie 2023*, PRISON POL'Y INITIATIVE (Mar. 14, 2023), https://www.prisonpolicy.org/reports/pie2023.html.

over 300,000 persons, or 16.7% of all prisoners,[6] are incarcerated on drug-related charges.[7]

Methadone is a "life-saving medication"[8] approved by the Food and Drug Administration (FDA) for the treatment of OUD and has consistently been shown to be both safe and effective.[9] Despite its efficacy, methadone for the treatment of OUD remains one of, if not the most, tightly regulated medications in the United States.[10] Addiction policy advocates agree that federal reforms are needed "to address the longstanding issue of inadequate access to [methadone] . . . and to develop strategies to finally address [this] longstanding and pernicious health and social disparity."[11] Arguably, the population that could benefit most from federal reforms surrounding methadone access is the prisoner population.

This article proposes reforms to federal regulations surrounding methadone for the treatment of OUD, with the goal of increasing access for those incarcerated within the federal correctional system. Section II discusses methadone as an effective treatment for OUD. Section III details the disproportionate impact that the opioid crisis has had on the prisoner population. Section IV describes the federal regulations surrounding methadone for the treatment of OUD and how these regulations have impeded access for the prisoner population. Section V proposes two paths

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[6] There is much debate on the most respectful term to refer to persons incarcerated in correctional facilities. For purposes of this Article, the terms "prisoner" or "incarcerated person(s)" will be used. Blair Hickman, *Inmate. Prisoner. Other. Discussed.*, MARSHALL PROJECT (Apr. 3, 2015, 7:15 AM), https://www.themarshallproject.org/2015/04/03/inmate-prisoner-other-discussed.

[7] Sawyer & Wagner, *supra* note 5; *see generally* Taylor Pendergrass, *The War on Drugs Failed – Lawmakers Must Meet the Fentanyl Crisis with New Solutions*, AM. C.L. UNION (Mar. 11, 2022), https://www.aclu.org/news/smart-justice/the-war-on-drugs-failed-lawmakers-must-meet-the-fentanyl-crisis-with-new-solutions.

[8] *See WHO Model Lists of Essential Medicines*, WORLD HEALTH ORG. (July 2023), https://www.who.int/groups/expert-committee-on-selection-and-use-of-essential-medicines/essential-medicines-lists.

[9] *See infra* Section II.

[10] Bridget C.E. Dooling & Laura E. Stanley, *A Vast and Discretionary Regime: Federal Regulation of Methadone as a Treatment for Opioid Use Disorder*, GEO. WASH. UNIV. 2, 4 (Aug. 11, 2022), https://regulatorystudies.columbian.gwu.edu/sites/g/files/zaxdzs4751/files/2022-08/gw-reg-studies_report_federal-methadone-regulations_bdooling-and-lstanley.pdf.

[11] NAT'L ACADS. OF SCIS., ENG'G, & MED., METHADONE TREATMENT FOR OPIOID USE DISORDER: IMPROVING ACCESS THROUGH REGULATORY AND LEGAL CHANGE: PROCEEDINGS OF A WORKSHOP 3 (2022).

forward – one broad[12] and one targeted to federal correctional facilities[13] – that will increase accessibility to methadone for the treatment of OUD. Section VI concludes and suggest further innovations to be explored.

II. METHADONE IS THE "GOLD STANDARD" FOR THE TREATMENT OF OPIOID USE DISORDER

Experts in addiction science and public policy advocate for a whole-person approach to OUD recovery that is evidence-based, culturally competent, and patient-centered.[14] Methadone, one of the three medications[15] currently approved by the Food and Drug Administration (FDA) for the treatment of opioid use disorder (OUD),[16] is considered to be the "gold standard."[17]

Methadone is a full opioid agonist[18] and has been approved by the FDA for use as a medication for opioid use disorder (MOUD) since 1973.[19] In 2021, approximately 630,000 OUD patients received

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[12] *See infra* Section V.B.2.i.

[13] *See infra* Section V.B.2.ii.

[14] Weizman et al., *supra* note 3, at 4–7.

[15] *Information About Medication-Assisted Treatment (MAT)*, U.S. FOOD & DRUG ADMIN. (May 23, 2023), https://www.fda.gov/drugs/information-drug-class/information-about-medication-assisted-treatment-mat. While a vital tool in fight against the opioid crisis, this Article does not discuss naloxone (Narcan®), an opioid antagonist used to prevent opioid-related overdose deaths. *Naloxone*, SUBSTANCE ABUSE & MENTAL HEALTH SERVS. ADMIN., https://www.samhsa.gov/medications-substance-use-disorders/medications-counseling-related-conditions/naloxone (last visited Dec. 29, 2023). Recognizing naloxone's role in harm reduction and overdose prevention, the Food and Drug Administration (FDA) approved naloxone as an over-the-counter medication in 2023. *FDA Approves First Over-the-Counter Naloxone Nasal Spray*, U.S. FOOD & DRUG ADMIN. (Mar. 29, 2023), https://www.fda.gov/news-events/press-announcements/fda-approves-first-over-counter-naloxone-nasal-spray.

[16] *Information about Medication-Assisted Treatment (MAT)*, U.S. FOOD & DRUG ADMIN. (May 23, 2023), https://www.fda.gov/drugs/information-drug-class/information-about-medication-assisted-treatment-mat; 42 C.F.R. § 8.12(h)(2)(i)(2023).

[17] Hilary Smith Connery, *Medication-Assisted Treatment of Opioid Use Disorder: Review of the Evidence and Future Directions*, 23 HARV. REV. PSYCHIATRY 63, 64 (Mar.–Apr. 2015).

[18] Full agonists bind tightly to receptors to trigger cellular signaling pathways with maximal effect. Partial agonists do not bind receptors as tightly and have a reduced effect. Antagonists bind receptors to stop cellular signaling pathways. Jeffrey Fudin, *Opioid Agonists, Partial Agonists, Antagonists: Oh My!*, PHARMACY TIMES (Jan. 6, 2018), https://www.pharmacytimes.com/view/opioid-agonists-partial-agonists-antagonists-oh-my.

[19] In 1966, researchers from Rockefeller University published a study demonstrating that methadone alleviated many of the cravings and withdrawal symptoms, such as constipation, anxiety, muscle aches, sweating, and nausea, experienced by OUD patients. *Fifty Years After Landmark Methadone Discovery, Stigmas and Misunderstandings Persist*, ROCKEFELLER UNIV.

methadone as part of their treatment plan.[20] Methadone has consistently been shown to be both safe[21] and effective, as it is most highly associated with long-term recovery,[22] reduced risk of overdose,[23] and reduced risk of infectious disease transmission,[24] compared to other MOUD.

The second MOUD approved by the FDA is buprenorphine (Suboxone® or Subulex®), a partial opioid agonist.[25] Compared to non-MOUD treatment, buprenorphine, at higher doses, has shown some efficacy in suppressing illicit opioid use.[26] However, buprenorphine is less effective than methadone, in terms of promoting treatment retention and long-term recovery.[27]

The final FDA-approved MOUD is naltrexone (Vivitrol®), an opioid antagonist[28] typically administered as a monthly, extended-release, injectable medication.[29] Use of naltrexone, however, requires that a patient experience complete withdrawal from opioids, a brutal process that can include insomnia, excessive sweats, muscle aches, nausea, vomiting,

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(Dec. 9, 2016), https://www.rockefeller.edu/news/12410-fifty-years-after-landmark-methadone-discovery-stigmas-and-misunderstandings-persist/ [hereinafter *Fifty Years*].

[20] *2021 National Survey of Drug Use and Health (NSDUH) Annual Report*, SUBSTANCE ABUSE & MENTAL HEALTH SERVS. ADMIN. (Dec. 2022), https://www.samhsa.gov/data/release/2021-national-survey-drug-use-and-health-nsduh-releases#annual-national-report [hereinafter *2021 NSDUH Report*].

[21] *Methadone*, SUBSTANCE ABUSE & MENTAL HEALTH SERVS. ADMIN. (June 20, 2023), https://www.samhsa.gov/medications-substance-use-disorders/medications-counseling-related-conditions/methadone.

[22] *See* Pengyue Zhang et al., *Examining Differences in Retention on Medication for Opioid Use Disorder: An Analysis of Ohio Medicaid Data*, 136 J. OF SUBSTANCE ABUSE TREATMENT 4–8 (Mar. 17, 2022), https://www.jsatjournal.com/article/S0740-5472(21)00412-8/fulltext.

[23] Sarah E. Wakeman et al., *Comparative Effectiveness of Different Treatment Pathways for Opioid Use Disorder*, 3 J. OF AM. MED. ASS'N NETWORK OPEN 4–8 (Feb. 5, 2020), https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2760032.

[24] Katelyn F. McNamara et al., *A Systematic Review and Meta-Analysis of Studies Evaluating the Effect of Medication Treatment for Opioid Use Disorder on Infectious Disease Outcomes*, 8 OPEN F. INFECTIOUS DISEASES 4–6 (May 30, 2021), https://academic.oup.com/ofid/article/8/8/ofab289/6291088.

[25] Fudin, *supra* note 18.

[26] *Tried-and-True Methadone Shows Superiority over Buprenorphine*, RECOVERY RSCH. INST., https://www.recoveryanswers.org/research-post/tried-true-methadone-shows-superiority-buprenorphine/ (last visited Dec. 29, 2023).

[27] *Id.*

[28] Fudin, *supra* note 18.

[29] *Naltrexone*, SUBSTANCE ABUSE & MENTAL HEALTH SERVS. ADMIN. (June 9, 2023), https://www.samhsa.gov/medications-substance-use-disorders/medications-counseling-related-conditions/naltrexone.

diarrhea, and even death.[30] Further, naltrexone is not considered to be an effective part of long-term recovery.[31]

While methadone is considered by the World Health Organization to be an "essential medicine,"[32] federal regulations,[33] racially motivated healthy inequities,[34] and stigma[35] represent significant barriers to methadone access in the United States. These barriers disproportionately impact one particularly vulnerable population dependent on the government for health care – the prisoner population.

III. ACCESS TO METHADONE IN PRISONS IS LIMITED, DESPITE THE DISPARATE EFFECT THAT OPIOID USE DISORDER HAS HAD ON THE PRISONER POPULATION

The strong correlation between opioid use disorder (OUD) and incarceration means that correctional facilities are on the frontline of the overdose epidemic.[36] In the face of heightened need, though, incarcerated individuals have historically been deprived of access to methadone[37], the most effective[38] medication of opioid use disorder (MOUD). Burdensome federal regulations, drug diversion concerns, and outdated perceptions of

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[30] Mansi Shah & Martin R. Huecker, *Opioid Withdrawal*, STATPEARLS (July 21, 2023), https://www.ncbi.nlm.nih.gov/books/NBK526012/.

[31] Zhang et al., *supra* note 22, at 2; Wakeman et al., *supra* note 23, at 4; Longley et al., *supra* note 3, at 1–2.

[32] *WHO Model Lists of Essential Medicines*, *supra* note 8, at 2.

[33] *See infra* Section IV.

[34] *See* Weizman et al., *supra* note 3, at 8–12. Access to and use of these MOUD splits sharply when examined by race. Approximately 50% of Black patients receive no follow-up SUD treatment after a non-fatal overdose, and on average, it takes Black OUD patients five years longer to receive any treatment, compared to White patients. In light of these disparities, overdose deaths in Black communities exponentially increase. *Id.*

[35] Stigma – among medical professionals, policymakers, and the general public – remains a major barrier to OUD treatment. Regina M. LaBelle, *Opinion: Reduce the Stigma to Help People with Substance Use Disorder*, WASH. POST (July 11, 2022, 5:28 PM), https://www.washingtonpost.com/opinions/2022/07/11/reduce-stigma-help-people-with-substance-abuse-disorder/.

[36] *See* Jaclyn S. Tayabji, *Rehabilitation Under the Rehabilitation Act: The Case for Medication Assisted Treatment in Federal Correctional Facilities*, 101 B.U. L. REV. 79, 87 (2021).

[37] *See id.* at 88–94.

[38] *See supra* Section II.

methadone have resulted in sparse and inconsistent implementation of MOUD in correctional treatment programs.[39]

These barriers have had a devastating effect on prisoners with OUD. Deaths associated with overdose or withdrawal have nearly quadrupled in correctional facilities since 2000[40] and account for approximately 19% of all deaths in custody.[41] Individuals recently released from incarceration are between 56- and 129-times more likely to die from overdose, compared to those who have never been incarcerated.[42]

These bleak statistics do not have to be our reality, nor should they be. Treatment with any MOUD reduces a prisoner's risk of overdose by 85%[43] and risk of any death by 75%.[44] Methadone has been shown to be especially efficacious for the incarcerated population and has been shown to significantly reduce rates of recidivism – more than buprenorphine, naltrexone, or any other non-MOUD behavioral therapy.[45]

Despite these promising results, it is estimated that only approximately 12% of U.S. prisons and jails provided any MOUD in 2021.[46] However, the number of correctional facilities providing methadone *specifically* is likely substantially lower,[47] as the federal

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[39] Longley et al., *supra* note 3, at 2; *Opioid Use Disorder Treatment in Jails and Prisons*, *supra* note 4, at 1; *Over-Jailed and Un-Treated*, AM. C.L. UNION 10–11 (2021), https://www.aclu.org/sites/default/files/field_document/20210625-mat-prison_1.pdf.

[40] *See* Shelly Weizman et al., *Dying Inside: To End Deaths of Despair, Address the Crisis in Local Jails*, O'NEILL INST. FOR NAT'L & GLOB. HEALTH L. AT GEO. L. CTR. 1 (Dec. 2022), https://oneill.law.georgetown.edu/wp-content/uploads/2022/12/ONL_Big_Ideas_Dying_Inside_P5.pdf.

[41] *Id.* Overdose and withdrawal deaths most commonly occur within twenty-fours after intake, and the average settlement for an overdose- or withdrawal-associated death in custody is approximately $1 million. *Id.* at 4.

[42] Longley et al., *supra* note 3, at 1.

[43] *Over-Jailed and Un-Treated*, *supra* note 39, at 4.

[44] *Id.*

[45] *See generally* Verner S. Westerberg et al., *Community-Based Methadone Maintenance in a Large Detention Center is Associated with Decreases in Inmate Recidivism*, 70 J. OF SUBSTANCE ABUSE TREATMENT 1 (July 17, 2016), https://www.jsatjournal.com/article/S0740-5472(15)30064-7/fulltext#secst0010.

[46] Josh Rising et al., *How the Drug Enforcement Administration Can Improve Access to Methadone in Correctional Facilities and Save Lives*, JOHNS HOPKINS BLOOMBERG SCH. OF PUB. HEALTH 3 (May 31, 2022), https://americanhealth.jhu.edu/sites/default/files/JHU-026%20Methadone%20White%20Paper-r1.pdf.

[47] *Id.*

regulatory framework governing methadone administration and dispensing represent significant hurdles for prisons and jails.[48]

While recent efforts have sought to deregulate MOUD in general,[49] federal regulations and correctional facility policies still place substantial limitations on what type of MOUD can be administered,[50] who can receive MOUD,[51] and how long treatment can last.[52] For example, some prisons only provide a single form of MOUD, the most common being naltrexone.[53] However, naltrexone can only be administered once a patient has completely withdrawn from opioids and is not associated with long-term recovery.[54] MOUD is not a "one size fits all" therapy, and providing only a limited selection of FDA-approved MOUD restricts the patient's ability to find the most effective treatment for them.[55]

Similarly, many correctional facilities only permit long-term methadone administration to pregnant persons with OUD, as methadone exposure *in utero* is significantly safer than illicit opioid use.[56] Short-term methadone administration is sometimes permitted for incarcerated persons undergoing acute withdrawal, but this treatment can only last three days.[57] Finally, some correctional facilities will only allow a person who was receiving MOUD prior to incarceration to continue with their care (a process called "maintenance"), while denying incarcerated persons the opportunity to begin MOUD treatment (a process called "initiation" or

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[48] *See infra* Section IV.C.

[49] *See infra* Section IV.B.2.ii.

[50] *See generally* Shelly Weizman et al., *National Snapshot: Access to Medications for Opioid Use Disorder in U.S. Jails and Prisons*, O'NEILL INST. FOR NAT'L & GLOB. HEALTH L. AT GEO. L. CTR. 1 (July 2021), https://oneill.law.georgetown.edu/wp-content/uploads/2021/07/National-Snapshot-Access-to-Medications-for-Opioid-Use-Disorder-in-U.S.-Jails-and-Prisons.pdf.

[51] *See infra* Section IV.C.

[52] *Over-Jailed and Un-Treated*, *supra* note 37, at 20–22.

[53] Longley et al., *supra* note 3, at 1.

[54] *See Naltrexone*, *supra* note 29.

[55] *See generally* Jennifer J. Carroll et al., *Linking People with Opioid Use Disorder to Medication Treatment: A Technical Package of Policy, Programs, and Practices*, CTRS. FOR DISEASE CONTROL & PREVENTION 22 (2022), https://www.cdc.gov/drugoverdose/pdf/pubs/linkage-to-care_edited-pdf_508-3-15-2022.pdf.

[56] *See generally* Jonathan M. Davis et al., *Comparison of Safety and Efficacy of Methadone vs Morphine for Treatment of Neonatal Abstinence Syndrome: A Randomized Clinical Trial*, 172 J. OF AM. MED. ASS'N PEDIATRICS 741 (June 18, 2018), https://jamanetwork.com/journals/jamapediatrics/fullarticle/2685283.

[57] *Program Statement 6360.01, Pharmacy Services*, FED. BUREAU OF PRISONS 38 (Jan. 1, 2005), https://www.bop.gov/policy/progstat/6360_001.pdf.

"induction").[58] In sum, incarcerated individuals are often left without adequate care.[59]

IV. FEDERAL REGULATIONS SURROUNDING METHADONE SIGNIFICANTLY IMPEDE ACCESS TO THIS LIFE-SAVING MEDICATION

While methadone is highly associated with treatment retention, long-term recovery, and other positive outcomes,[60] it is also the most highly regulated medication for opioid use disorder (MOUD) at the federal level.[61] First, the scheduling[62] of methadone by the Drug Enforcement Agency (DEA)[63] is more restrictive than all other MOUD.[64] Second, methadone is the only DEA-controlled medication subject to two distinct regulatory frameworks based solely on the medical condition for which it is being used to treat.[65] Finally, federal prisons—home to a population that has been disproportionately affected by the opioid crisis and are dependent on the government for care—must also abide by these federal regulations, significantly impacting this population's accessibility to methadone.

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[58] Longley et al., *supra* note 3, at 1.

[59] Lisa B. Puglisi & Emily A. Wang, *Health Care for People Who Are Incarcerated*, 7 NATURE REVS. DISEASE PRIMER 1, 1–2 (July 8, 2021), https://www.nature.com/articles/s41572-021-00288-9.

[60] *See supra* Section II.

[61] Dooling & Stanley, *supra* note 10, at 4.

[62] 21 U.S.C. § 812(b).

[63] Of note, the DEA has the authority to schedule, reschedule, or de-schedule substances. 21 U.S.C. § 811(a).

[64] Noa Krawczyk et al., *Recent Modifications to the US Methadone Treatment System are a Band-Aid—Not a Solution—to the Nation's Broken Opioid Use Disorder Treatment System*, 1 OXFORD ACAD. 1, 1 (2023), https://academic.oup.com/healthaffairsscholar/advance-article-pdf/doi/10.1093/haschl/qxad018/50654144/qxad018.pdf.

[65] INST. OF MED. (U.S.) COMM. ON FED. REGUL. OF METHADONE TREATMENT, FEDERAL REGULATION OF METHADONE TREATMENT (Richard A. Rettig & Adam Yarmolinsky eds. 1995), https://www.ncbi.nlm.nih.gov/books/NBK232114/ [hereinafter FEDERAL REGULATION OF METHADONE TREATMENT].

A. Methadone is classified as a Schedule II substance by the Drug Enforcement Agency

Pursuant to the Controlled Substances Act of 1970 (CSA), methadone is classified by the DEA as a Schedule II substance,[66] meaning that its prescribing, storing, recordkeeping, administering, and dispensing is subject to more federal restrictions, compared to Schedule III (buprenorphine[67]) or unscheduled (naltrexone[68]) MOUD.

Schedule II substances are the most highly regulated medications permitted to be prescribed.[69] For example, a prescription for a Schedule II substance must be in written form and may not be refilled,[70] whereas a prescription for a Schedule III substance can be conveyed verbally and may be refilled up to five times.[71]

Schedule II substances are recognized as having both a legitimate medical use and a "high[er] potential for abuse, with use potentially leading to severe psychological or physical dependence."[72] Other Schedule II substances include hydrocodone (Vicodin®), amphetamine (Adderall®), methylphenidate (Ritalin®), morphine, and oxycodone (OxyContin®).[73]

Despite its scheduling, however, methadone misuse is significantly lower[74] at 3.7% than misuse of other Schedule II opioids, such as

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[66] Comprehensive Drug Abuse Prevention and Control Act (or Controlled Substances Act) of 1970, 21 U.S.C. § 812(Schedule II)(b)(11).

[67] 21 C.F.R. § 1308.13(e)(2)(i) (2023). The Drug Addiction Treatment Act of 2000 (DATA 2000) required physicians to obtain a DATA waiver (or X waiver) from the Substance Abuse and Mental Health Services Administration (SAMHSA) to prescribe buprenorphine in an office setting. Buprenorphine Practice Guidelines, 85 Fed. Reg. 22439, 22439–40 (Apr. 28, 2021). In February 2023, the DEA rescinded the DATA waiver requirement, paving the way for increased buprenorphine prescribing from office-based practices – as encouraged by SAMSHA. *See Buprenorphine*, SUBSTANCE ABUSE & MENTAL HEALTH SERVS. ADMIN. (July 18, 2023), https://www.samhsa.gov/medications-substance-use-disorders/medications-counseling-related-conditions/buprenorphine; *see also Waiver Elimination Act (MAT Act)*, SUBSTANCE ABUSE & MENTAL HEALTH SERVS. ADMIN. (June 7, 2023), https://www.samhsa.gov/medications-substance-use-disorders/waiver-elimination-mat-act.

[68] *See Naltrexone*, *supra* note 29 and accompanying text.

[69] Dooling & Stanley, *supra* note 10, at 19–22.

[70] 21 C.F.R. §§ 1306.11(a), 1306.12(a) (2023).

[71] 21 C.F.R. §§ 1306.21(c), 1306.22(a), (e).

[72] 21 U.S.C. § 812(b)(2).

[73] 21 C.F.R. § 1308.12.

[74] *See infra* Section IV.B.2.ii. While proponents of the status quo may argue that stringent federal regulations surrounding methadone have contributed to its lower rate of misuse, recent

hydrocodone (46.9%) and oxycodone (30.4%), or the misuse of other MOUD, buprenorphine (8.9%).[75] Similarly, methadone is associated with significantly fewer overdose deaths than other opioids. Natural or semi-synthetic, Schedule II opioids, such as oxycodone, are responsible for approximately four overdose deaths per 100,000 people.[76] Synthetic opioids, such as fentanyl, are responsible for 17.8 overdose deaths per 100,000 people.[77] Methadone, however, is only associated with 1.06 overdose deaths per 100,000 people.[78]

Thus, methadone, as a Schedule II substance, is more restricted than all other MOUD, and superfluous federal regulations surrounding methadone for the treatment of OUD specifically represent an additional barrier for prisoners seeking effective treatment.[79]

B. Methadone is subject to a bifurcated regulatory landscape based on the medical condition for which it is being used to treat

While methadone is primarily known as a MOUD, it is also prescribed for the management of severe pain.[80] Out of all Schedule II substances, including methadone for pain management, ***only methadone prescribed for the treatment of OUD*** is restricted by additional federal regulations.[81] Thus, despite being a single medication, methadone is the only medication subject to two distinct regulatory frameworks based solely on the indication for which it is being prescribed.[82]

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increases in methadone access due to the COVID-19 pandemic have not born this out. Christopher M. Jones et al., *Methadone-Involved Overdose Deaths in the US Before and After Federal Policy Changes Expanding Take-Home Methadone Doses from Opioid Treatment Programs*, 79 J. OF AM. MED. ASS'N PSYCHIATRY 932, 932–34 (July 13, 2022), https://jamanetwork.com/journals/jamapsychiatry/fullarticle/2793744.

[75] *2021 NSDUH Report*, *supra* note 20, at A-7.

[76] *Opioid-Related and Other Drug Poisoning Deaths per 100,000 People*, STATE HEALTH COMPARE, https://statehealthcompare.shadac.org/map/197/opioidrelated-and-other-drug-poisoning-deaths-per-100000-people-by-drug-type#162/37/233 (last visited Dec. 29, 2023).

[77] *Id.*

[78] *Reduce Overdose Deaths Involving Methadone – IVP-24*, HEALTHY PEOPLE 2030, U.S. DEP'T OF HEALTH & HUMAN SERVS., https://health.gov/healthypeople/objectives-and-data/browse-objectives/injury-prevention/reduce-overdose-deaths-involving-methadone-ivp-24 (last visited Dec. 29, 2022).

[79] *See infra* Section IV.C.

[80] *See* FEDERAL REGULATION OF METHADONE TREATMENT, *supra* note 65, at 210–14.

[81] *Id.* at 133.

[82] *Id.* at 120.

1. Methadone for pain management

Since 1947,[83] methadone has been approved by the Food and Drug Administration (FDA) for pain management and is considered an effective analgesic for cancer patients with uncontrolled pain.[84] The prescribing, dispensing, and administering of methadone for the management of severe pain is governed solely by its Schedule II classification.[85] A practitioner[86] who prescribes any Schedule II drug – including methadone for the treatment of pain – must be a registered with the DEA and complete annual continued medical education (CME) classes to remain compliant.[87]

Pharmacies must also register with the DEA to "dispense, or conduct research with, controlled substances in Schedule II, III, IV, or V,"[88] using Form DEA-224,[89] with renewal every three years.[90] In determining whether to approve the registration, the DEA considers a number of factors, including recommendations from state licensing boards or other authorities, the applicant's experience in dispensing such medications, the applicant's conviction record regarding controlled substances, and the applicant's compliance with laws and regulations governing controlled substances.[91]

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[83] *See Fifty Years*, *supra* note 19.

[84] Sebastiano Mercadante et al., *Morphine Versus Methadone in the Pain Treatment of Advanced-Cancer Patients Followed Up at Home*, 16 J. OF CLINICAL ONCOLOGY 3658–60 (1998), http://citeseerx.ist.psu.edu/document?repid=rep1&type=pdf&doi=5a671779e4e158687be52014595d470c3165b203; *see also* FEDERAL REGULATION OF METHADONE TREATMENT, *supra* note 65, at 18.

[85] Dooling & Stanley, *supra* note 10, at 19–20.

[86] *See infra* Section V.B.1.

[87] Phillip Zhang & Preeti Patel, *Practitioners and Prescriptive Authority*, STATPEARLS (Sept. 19, 2022, 11:59 AM), https://www.statpearls.com/point-of-care/131545; 21 N.C.A.C. § .0101 (2020).

[88] 21 U.S.C. § 823(g)(1).

[89] *See infra* note 246.

[90] 21 N.C.A.C. § .0101 (2020); After registration with the DEA, pharmacies must create an initial inventory record of their Schedule II controlled substances and then update this inventory record on a biennial basis. Records of Schedule II controlled substances are to be maintained separately from all other records and must be kept and available for review by relevant authorities for two years. Diversion Control Div., Drug Enf't Agency, *Pharmacist's Manual: An Informational Outline of the Controlled Substances Act*, U.S. DEP'T OF JUST. 34–35 (2022), https://www.deadiversion.usdoj.gov/GDP/%28DEA-DC-046R1%29%28EO-DEA154R1%29_Pharmacist%27s_Manual_DEA.pdf.

[91] 21 U.S.C. §§ 823(g)(1)(A)–(E).

2. Methadone for OUD

The above regulations allow practitioners to prescribe and pharmacists to dispense all Schedule II drugs for all indications, ***with the exception of methadone for the treatment of OUD.***[92] Methadone for the treatment of OUD can only be administered or dispensed, ***but not prescribed***, by a practitioner "registered to conduct a narcotics treatment program"[93] or opioid treatment program, or OTP.[94]

The establishment and operation of OTPs are largely governed by the Narcotic Addict Treatment Act of 1974 (NATA).[95] This legislation, with the Controlled Substances Act of 1973 (CSA), represents the cornerstone of the American "War on Drugs," a policy that directly contributed to mass incarceration in the United States, with negligible, if not negative, effects on substance use, long-term recovery, or overdose deaths.[96] These regulations, which require a unique registration for providers of OUD treatment,[97] have not been substantially revised since their enactment,[98] and are a significant barrier for people seeking methadone as part of their recovery.[99]

These OTPs, which require approval from the Substance Abuse and Mental Health Services Administration (SAMHSA), **are the only** clinical practices certified to provide long-term methadone treatment for people diagnosed with OUD.[100] While pharmacies dispense approximately 1.9 million methadone prescriptions for pain management each year, they are **not allowed** to administer or dispense methadone for the treatment of

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[92] *See generally* Dooling & Stanley, *supra* note 10.

[93] 21 C.F.R. § 1306.07(a) (2023).

[94] The terms opioid treatment program (OTP) and narcotic treatment program (NTP) are interchangeable. However, this Note will use OTP exclusively. *Opioid (Narcotic) Treatment Program Services (OTP/NTP Sample Clauses)*, LAW INSIDER, https://www.lawinsider.com/clause/opioid-narcotic-treatment-program-services-otp-ntp (last visited Dec. 29, 2023).

[95] Narcotic Addict Treatment Act of 1974 (NATA), 21 U.S.C. §§ 801–904.

[96] Pendergrass, *supra* note 7.

[97] 21 U.S.C. § 823(h).

[98] *See generally* FEDERAL REGULATION OF METHADONE TREATMENT, *supra* note 65.

[99] Alaina McBournie et al., *Methadone Barriers Persist, Despite Decades of Evidence*, HEALTH AFFS. (Sept. 23, 2019), https://www.healthaffairs.org/content/forefront/methadone-barriers-persist-despite-decades-evidence.

[100] *Certification of Opioid Treatment Programs (OTPs)*, SUBSTANCE ABUSE & MENTAL HEALTH SERVS. ADMIN. (July 24, 2023), https://www.samhsa.gov/medications-substance-use-disorders/become-accredited-opioid-treatment-program.

OUD.[101] Thus, the current regulatory framework surrounding the establishment and the operation of OTPs results in a closed system that imposes prohibitive restrictions on the establishment of OTPs, while simultaneously requiring OUD patients seeking methadone to engage with OTPs exclusively.

i. Federal regulations surrounding the establishment of OTPs

OTPs become approved to administer or dispense methadone via a two-step approval process requiring both accreditation and certification. First, an OTP must be accredited via a SAMHSA-authorized accreditation body, of which there are only six nationwide.[102] Accreditation is a peer-review process to determine whether a potential OTP is complying with the accreditation body's OTP standards, as well as SAMHSA's OTP standards.[103] In addition to initial and renewal surveys every three years, accreditation bodies are tasked with responding to reports of noncompliance, performing "for cause" inspections, and reporting their findings to SAMHSA.[104] The process of accreditation can also be associated with high fees, depending on an OTP's volume and services provided.[105]

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[101] *See* Mark Faul et al., *Methadone Prescribing and Overdose and the Association with Medicaid Preferred Drug List Policies — United States, 2007–2014*, CTRS. FOR DISEASE CONTROL & PREVENTION (Mar. 31, 2017), https://www.cdc.gov/mmwr/volumes/66/wr/mm6612a2.htm; *U.S. Opioid Dispensing Rate Maps*, CTRS. FOR DISEASE CONTROL & PREVENTION (Nov. 10, 2021), https://www.cdc.gov/drugoverdose/rxrate-maps/index.html.

[102] *Certification of Opioid Treatment Programs (OTPs)*, *supra* note 100; *Approved Accreditation Bodies*, SUBSTANCE ABUSE & MENTAL HEALTH SERVS. ADMIN. (Apr. 25, 2023), https://www.samhsa.gov/medications-substance-use-disorders/become-accredited-opioid-treatment-program/approved-accreditation-bodies.

[103] *Certification of Opioid Treatment Programs (OTPs)*, *supra* note 100; 42 C.F.R. §§ 8.3–8.6 (2023).

[104] 42 C.F.R. § 8.4.

[105] *See, e.g.*, *2021 Behavioral Health Care and Human Services Pricing Worksheet*, JOINT COMM'N 2 (2021), https://pages.jointcommission.org/rs/433-HWV-508/images/Price%20worksheet.pdf. The cost of accreditation can range from under $30,000 to almost $130,000 for non-residential OTPs. *Id.*

After accreditation, certification by SAMHSA[106] goes beyond "ensuring that OTPs are meeting regulatory criteria"[107] and focuses on treatment oversight.[108] Like accreditation, certification must be renewed every three years.[109] Additionally, state[110] and local authorities can and do impose additional regulations and restrictions on OTPs, further affecting accessibility.[111] For example, West Virginia has placed a moratorium on the establishment of all new OTPs, and Pennsylvania does not allow OTPs to provide services through medication units,[112] geographically separate components of an OTP, either mobile or brick-and-mortar, that can be added to an existing OTP's registration.[113]

These regulations have resulted in a scarcity of OTPs. There are only approximately 1800 OTPs[114] in the United States, leaving almost 77.5 million people without accessible methadone treatment.[115] Over 80% of U.S. counties do not have an OTP,[116] and the state of Wyoming has no OTPs at all.[117] These "treatment deserts" significantly impact residents of

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[106] In 2015, SAMHSA released the *Federal Guidelines for Opioid Treatment Programs* to aid accreditation, certification, and operation of OTPs. *See generally Federal Guidelines for Opioid Treatment Programs*, SUBSTANCE ABUSE & MENTAL HEALTH SERVS. ADMIN. (Jan. 2015), https://store.samhsa.gov/sites/default/files/d7/priv/pep15-fedguideotp.pdf.

[107] *Certification of Opioid Treatment Programs (OTPs)*, *supra* note 100.

[108] *Id.*

[109] 42 C.F.R. § 8.4(a)(1) (2023).

[110] In 2022, nearly 100% of states imposed additional regulations on the establishment and/or operation of OTPs. *Overview of Opioid Treatment Program Regulations by State*, PEW CHARITABLE TRS. (Sept. 19, 2022), https://www.pewtrusts.org/en/research-and-analysis/issue-briefs/2022/09/overview-of-opioid-treatment-program-regulations-by-state.

[111] *Id.*

[112] 42 C.F.R. § 8.2; *Overview of Opioid Treatment Program Regulations by State*, *supra* note 110.

[113] Letter from Substance Abuse & Mental Health Servs. Admin. to OTP Directors, SOTAs and State Directors on Mobile Component, SUBSTANCE ABUSE & MENTAL HEALTH SERVS. ADMIN. 1 (Sept. 29, 2021), https://www.samhsa.gov/sites/default/files/2021-letter-mobile-component.pdf.

[114] Sugy Choi et al., *Clinics Optimizing MEthadone Take-Homes for Opioid Use Disorder (COMET): Protocol for a Stepped-Wedge Randomized Trial to Facilitate Clinic Level Changes*, 18 PLOS ONE 1, 2 (June 9, 2023), https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0286859.

[115] JOHNATHAN H. DUFF & JAMESON A. CARTER, CONG. RSCH. SERV. R45782, LOCATION OF MEDICATION-ASSISTED TREATMENT FOR OPIOID ADDICTION: IN BRIEF 9 (2019).

[116] *Overview of Opioid Treatment Program Regulations by State*, *supra* note 110.

[117] *Id.*

rural communities, whose average distance to an OTP is 55.5 miles.[118] Geographic inaccessibility of OTPs is a major factor in treatment retention and survival.[119] Longer travel times to an OTP correlate to both a reduced likelihood of completing a treatment program and higher rates of opioid-related overdoses.[120] Therefore, the burden imposed by federal regulations on establishing OTPs has negatively impacted long-term recovery efforts by OUD patients.

ii. Federal regulations surrounding the operation of OTPs

Federal regulations for OTPs extend to its operations as well. Under the current guidelines, the majority of OUD patients must visit an OTP daily to receive methadone, to be ingested under direct observation of OTP staff.[121] While take-home doses of methadone can be dispensed from the OTP based on certain restrictive criteria,[122] only a maximum of fourteen take-home doses can be dispensed for those who have been stable and compliant for one year.[123] A recent survey in North Carolina revealed that almost 60% of patients with take-home privileges still had to attend an OTP five to six days per week because they were only dispensed one to

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[118] Robert A. Kleinman, *Comparison of Driving Times to Opioid Treatment Programs and Pharmacies in the US*, 77 J. OF AM. MED. ASS'N PSYCHIATRY 1163, 1165–71 (July 15, 2020), https://jamanetwork.com/journals/jamapsychiatry/fullarticle/2768026.

[119] Dooling & Stanley, *supra* note 10, at 9, 16.

[120] *See generally* Kyle Beardsley et al., *Distance Traveled to Outpatient Drug Treatment and Client Retention*, 25 J. OF SUBSTANCE ABUSE TREATMENT 279 (Dec. 2003), https://www.jsatjournal.com/article/S0740-5472(03)00188-0/fulltext; Solmaz Amiri et al., *Increased Distance Was Associated with Lower Daily Attendance to an Opioid Treatment Program in Spokane County Washington*, 93 J. OF SUBSTANCE ABUSE TREATMENT 26 (Oct. 2008), https://www.sciencedirect.com/science/article/pii/S0740547218301879; Paul J. Joudrey et al., *Drive Times to Opioid Treatment Programs in Urban and Rural Counties in 5 US States*, 322 J. OF AM. MED. ASS'N 1310 (Oct. 1, 2019), https://jamanetwork.com/journals/jama/fullarticle/2752051.

[121] 42 C.F.R. §§ 8.12(h)–(i) (2023); David Frank et al., *"It's Like 'Liquid Handcuffs'": The Effects of Take-Home Dosing Policies on Methadone Maintenance Treatment (MMT) Patients' Lives*, 18 HARM REDUCTION J. 1 (Aug. 14, 2021), https://harmreductionjournal.biomedcentral.com/articles/10.1186/s12954-021-00535-y.

[122] 42 C.F.R. §§ 8.12(i)(2)–(4) (including but not limited to, length of time in treatment, regularity of attendance, absence of drug or alcohol "abuse," absence of "drug dealing," and homelife stability).

[123] 42 C.F.R. §§ 8.12(i)(3)(v). After 2 years of compliance, a patient can receive a maximum one-month supply of methadone, but they are required to make monthly visits to their OTP. 42 C.F.R. § 8.12(i)(3)(vi).

two take-home doses weekly.[124] Thus, these regulations have resulted in a system that restricts the establishment of these OTPs yet requires most patients receiving methadone to visit OTPs daily.

There has been recent momentum to re-examine the federal regulations governing OTP operations.[125] The COVID-19 pandemic[126] necessitated increased flexibility in take-home dose requirements, which allowed OTPs to meet the public health challenge while patients continued treatment with methadone safely.[127] Ultimately, the flexibilities shined an unexpected light on the efficacy and safety of increased access to methadone for OUD patients.[128] Despite a dramatic increase in overdose deaths involving opioids during the pandemic generally, overdose deaths involving methadone remained constant.[129] In light of these results,[130] SAMHSA has proposed to make these temporary flexibilities permanent.[131]

While revisions that increase access to methadone in the community are indeed a positive step, they fail to provide much-needed relief to prisoners with OUD. The unique, controlled environment of a correctional facility means that take-home doses of methadone are not an option for

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[124] Mary C. Figgatt et al., *Take-Home Dosing Experiences Among Persons Receiving Methadone Maintenance Treatment During COVID-19*, 123 J OF SUBSTANCE ABUSE TREATMENT 1, 2–3 (2021), https://www.jsatjournal.com/article/S0740-5472(21)00002-7/fulltext.

[125] *See* Medications for the Treatment of Opioid Use Disorder, 87 Fed. Reg. 77330, 77330–31 (Dec. 16, 2022) (to be codified at 42 C.F.R. pt. 8).

[126] Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID-19) Outbreak, 85 Fed. Reg. 15337, 15337 (Mar. 13, 2020).

[127] Under these COVID-19 special rules, practitioners were allowed to dispense up to 28 days of take-home doses for "stable" patients, and up to 14 days of take-home doses for "less stable" patients. *Opioid Treatment Program (OTP) Guidance*, SUBSTANCE ABUSE & MENTAL HEALTH SERVS. ADMIN. 1, https://www.samhsa.gov/sites/default/files/otp-guidance-20200316.pdf (Mar. 19, 2020); *Methadone Take-Home Flexibilities Extension Guidance*, SUBSTANCE ABUSE & MENTAL HEALTH SERVS. ADMIN., https://www.samhsa.gov/medications-substance-use-disorders/statutes-regulations-guidelines/methadone-guidance (Dec. 21, 2023).

[128] Noa Krawczyk et al., *Synthesising Evidence of the Effects of COVID-19 Regulatory Changes on Methadone Treatment for Opioid Use Disorder: Implications for Policy*, 8 LANCET PUB. HEALTH e238, e243 (Mar. 2023), https://www.thelancet.com/journals/lanpub/article/PIIS2468-2667(23)00023-3/fulltext.

[129] Merianne Rose Spencer, et al., *Drug Overdose Deaths in the United States, 2001–2021*, CTRS. FOR DISEASE CONTROL & PREVENTION 4 (Dec. 22, 2022), https://www.cdc.gov/nchs/data/databriefs/db457.pdf.

[130] *See id.*; Medications for the Treatment of Opioid Use Disorder, 87 Fed. Reg. at 77330, 77334.

[131] Medications for the Treatment of Opioid Use Disorder, 87 Fed. Reg. at 77331.

those incarcerated. However, procedures for medication dispensing are currently established in federal correctional facilities, meaning that methadone can be delivered on a daily basis to prisoners diagnosed with OUD,[132] without the same diversion concerns that exist in the community. Despite a general trend toward increased access to methadone, correctional facilities remain shackled by onerous regulations.

C. Federal prisons, which house a vulnerable population with a heightened need for care, must adhere to onerous federal regulations surrounding methadone, while complying with the First Step Act of 2018

The effect of these regulatory barriers surrounding methadone is even more dire for prisoners. Approximately 25% of prisoners struggle with opioid use disorder (OUD),[133] and those recently released from incarceration are significantly more likely to die of an overdose than the non-incarcerated population.[134] Despite this documented need, access to effective medications for opioid use disorder (MOUD) is severely restricted in correctional facilities because *prisons must also comply with opioid treatment program (OTP) requirements to dispense methadone*.[135] The federal correctional system, operated by the Bureau of Prisons (BOP), represents a logistically "simpler" opportunity to increase this vulnerable population's access to the "gold standard" of care – a change that has been mandated by the First Step Act of 2018 (FSA).[136]

1. The Bureau of Prisons (BOP) is an exemplary candidate for

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[132] *National Formulary Part 1*, HEALTH SERVS., FED. BUREAU OF PRISONS 7 (May 2, 2022), https://www.bop.gov/resources/pdfs/2022_winter_formulary_part_1.pdf; *Review of the Federal Bureau of Prisons' Pharmaceutical Drug Costs and Procurement*, U.S. DEP'T OF JUST. 11 (Feb. 20, 2020), https://oig.justice.gov/sites/default/files/reports/e20027_1.pdf.

[133] Vestal et al., *supra* note 4.

[134] Weizman et al., *supra* note 50, at 1.

[135] *See* Sachini Bandara et. al, *Medications for Opioid Use Disorder in Jails and Prisons: Moving Toward Universal Access*, JOHN HOPKINS 7, https://americanhealth.jhu.edu/sites/default/files/2021-08/JHU-014%20OUD%20in%20Jail%20Report%20FINAL%202.pdf (July 2021).

[136] *See infra* Section IV.C.3.

methadone reform because it is only required to comply with federal OTP regulations

The Bureau of Prisons (BOP) is the federal agency responsible for the care, custody, and control of prisoners incarcerated for committing federal offenses.[137] Federal prisoners represent only 8% of the total U.S. prison population,[138] but the BOP alone houses more prisoners than the countries of South Africa, Vietnam, or Colombia.[139] If the BOP were a sovereign nation, it would rank 12th in a list of countries with the highest prisoner populations.[140] Currently, 44.4% of all federal prisoners are incarcerated for drug-related crimes.[141] It is estimated that 25% of federal prisoners meet the criteria for OUD diagnosis,[142] meaning that there are currently over 39,000 prisoners in need of OUD treatment.[143]

The BOP also represents a unique opportunity to trailblaze flexibility for methadone access. While state prisons and local jails must adhere to both federal[144] and state[145] regulations, the BOP, as a federal agency, are only required to follow federal regulations regarding methadone for the treatment of OUD,[146] thus representing a more manageable path for change.

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[137] *About Us*, FED. BUREAU OF PRISONS, https://www.bop.gov/about/ (last visited Dec. 29, 2023). As of July 29, 2023, the BOP housed 157,890 federal prisoners in 122 institutions across 37 states. Approximately 93% of BOP prisoners are male, and 57.3% of the BOP prisoner population is White, while 38.6% is Black. *Inmate Gender*, FED. BUREAU OF PRISONS, https://www.bop.gov/about/statistics/statistics_inmate_gender.jsp (Sept. 16, 2023); *Inmate Race*, FED. BUREAU OF PRISONS, https://www.bop.gov/about/statistics/statistics_inmate_race.jsp (Sept. 16, 2023).

[138] *See* Sawyer & Wagner, *supra* note 5, at 1–2.

[139] *Compare Statistics*, FED. BUREAU OF PRISONS, https://www.bop.gov/about/statistics/population_statistics.jsp (Sept. 7, 2023) (finding that there are 157,919 prisoners in federal custody) *with Countries with the largest number of prisoners as of December 2022*, STATISTA (Aug. 23, 2023), https://www.statista.com/statistics/262961/countries-with-the-most-prisoners/ (finding that there are 144,938 prisoners in South Africa, 125,697 prisoners in Vietnam, and 98,242 prisoners in Colombia).

[140] *See Countries with the largest number of prisoners as of December 2022*, *supra* note 139.

[141] *Offenses*, FED. BUREAU OF PRISONS (Sept. 9, 2023), https://www.bop.gov/about/statistics/statistics_inmate_offenses.jsp.

[142] Vestal et al., *supra* note 4, at 1.

[143] *See Statistics*, *supra* note 139.

[144] *See supra* Section IV.

[145] *Overview of Opioid Treatment Program Regulations by State*, *supra* note 110, at 2.

[146] 42 C.F.R. § 8.11(f)(1) (2016). It should be noted that "while federal agencies operating OTPs have agreed to cooperate voluntarily with State agencies . . . . on an informal basis for

2. Current BOP policy requires all federal correctional facilities to adhere to federal OTP requirements to administer methadone for the treatment of OUD

Federal prisons that wish to provide methadone to prisoners with OUD must adhere to the federal regulations surrounding OTPs, meaning that the correction facility must either become accredited and certified to be an OTP or partner with an existing, community OTP to provide services through a medication unit.[147] The first option requires the federal correctional facilities to be accredited by an accreditation body and certified by SAMSHSA, with renewal every three years.[148] The second option allows federal correctional facilities to contract with an established OTP in the community, where OTP staff members either bring in and administer methadone to prisoners daily, or prisoners are transported to the community OTP every day to receive their methadone.[149] The current scarcity of OTPs in the United States, however, means that partnering with an existing OTP may not be an option for federal prisons located in the 80% of counties without an OTP.[150] Further, increased traffic in or out of the correctional facility represents a substantial safety concern.[151] Due to these restrictive policies, only 268 prisoners in BOP custody were receiving any form of MOUD in 2021.[152]

BOP facilities that are not registered as OTPs allow only three patient populations to receive methadone: pregnant/post-partum persons with OUD; prisoners experiencing acute withdrawal from opioids; and prisoners prescribed methadone for pain.[153] This guidance reveals two

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designated State representatives to visit Federal OTPs . . . ," the consequences of "informal" non-compliance remain unknown. *Id.*

147 *Opioid Use Disorder: Diagnosis, Evaluation, and Treatment*, FED. BUREAU OF PRISONS 20 (Aug. 2021), https://www.bop.gov/resources/pdfs/opioid_use_disorder_cg.pdf.

148 *See Certification of Opioid Treatment Programs (OTPs)*, *supra* note 100.

149 *Jails and Methadone Provision*, COMPREHENSIVE OPIOID, STIMULANT, & SUBSTANCE ABUSE PROGRAM 2 (Apr. 2020), https://www.cossapresources.org/Content/Documents/Articles/Jails_and_Methadone_Provision.pdf.

150 *Overview of Opioid Treatment Program Regulations by State*, *supra* note 110, at 2.

151 *Medications for Opioid Use Disorder Implementation Toolkit*, HEALTH MGMT. ASSOCS. 2, https://www.healthmanagement.com/wp-content/uploads/HMA-Concept-Brief-Options-to-Assure-Access-to-Methadone-for-Treatment-of-OUD-in-Jails.pdf (last visited Dec. 29, 2023).

152 Beth Schwartzapfel, *These Meds Prevent Overdoses. Few Federal Prisoners Are Getting Them*, MARSHALL PROJECT (Aug. 10, 2021, 6:00 AM), https://www.themarshallproject.org/2021/08/10/these-meds-prevent-overdoses-few-federal-prisoners-are-getting-them.

153 *Program Statement 6360.01, Pharmacy Services*, *supra* note 57, at 37.

things. First, BOP pharmacies are currently storing, recording, and dispensing methadone to prisoners.[154] Second, in some instances, BOP Health Services are utilizing methadone for the treatment of OUD.[155] The BOP is already complying with federal regulations surrounding methadone and has established protocols to handle the administration and dispensing of controlled substances within prison.[156] Because of the regimented nature of the federal correctional facility, methadone can be safely dispensed to prisoners on a daily basis, without triggering the same purported diversion concerns[157] associated with take-home doses in the community.

While the BOP has acted in recognition of the need for OUD care, the majority of patient-prisoners are receiving treatment that does not include MOUD. Since 1990,[158] the BOP has invested in multiple substance use disorder (SUD) treatment programs within their correctional facilities.[159] The most intensive SUD treatment program offered by the BOP is the Residential Drug Abuse Program (RDAP), a voluntary, 500-hour, residential treatment program for federal prisoners with a verifiable SUD diagnosis,[160] have at least two years left on their sentence, and be eligible for placement in a federal residential reentry center (or "halfway house") upon release.[161] Currently, there are seventy-six RDAPs at seventy federal correctional facility locations.[162] In 2023, almost 15,000 federal prisoners participated in the RDAP, and the wait list to join this program

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[154] *Id.* at 37–39.

[155] *Id.* at 37.

[156] *Opioid Use Disorder: Diagnosis, Evaluation, and Treatment*, *supra* note 147, at 20–23.

[157] Frank et al., *supra* note 121; *Use of Medication-Assisted Treatment for Opioid Use Disorder in Criminal Justice Settings*, SUBSTANCE ABUSE & MENTAL HEALTH SERVS. ADMIN. 12, https://store.samhsa.gov/sites/default/files/d7/priv/pep19-matusecjs.pdf (last visited Dec. 29, 2023).

[158] Crime Control Act of 1990, Pub. L. 101-647, § 2903, 104 Stat. 4789, 4913 (1990) (codified at 18 U.S.C. § 3621(b)).

[159] *See Substance Abuse Treatment*, FED. BUREAU OF PRISONS https://www.bop.gov/inmates/custody_and_care/substance_abuse_treatment.jsp (last visited Dec. 29, 2023).

[160] *DSM-5 Criteria for Diagnosis of Opioid Use Disorder*, AM. SOC'Y OF ADDICTION MED., https://www.asam.org/docs/default-source/education-docs/dsm-5-dx-oud-8-28-2017.pdf (last visited Dec. 29, 2023).

[161] *Residential Reentry Centers*, FED. BUREAU OF PRISONS, https://www.bop.gov/about/facilities/residential_reentry_management_centers.jsp (last visited Dec. 29, 2023).

[162] *Residential Drug Abuse Programs (RDAP) and Location*, FED. BUREAU OF PRISONS, https://www.bop.gov/inmates/custody_and_care/docs/rdap_locations.pdf?v=2.0.0 (last visited Dec. 29, 2023).

is in the thousands.[163] However, RDAPs do not offer methadone, or any other type of MOUD.[164]

3. The First Step Act of 2018 mandates increased access to medications for opioid use disorder (MOUD), including methadone, in BOP facilities

The First Step Act of 2018 (FSA), a bi-partisan criminal justice bill, was enacted to both reduce federal prison sentences[165] and improve conditions within BOP correctional facilities.[166] Importantly, the FSA mandated that federal prisons expand and promote rehabilitative, rather than punitive, programming.[167] One major component of that mandate was to expand access to all FDA-approved MOUD, including methadone, for prisoners with OUD.[168]

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[163] *Residential Drug Abuse Program (RDAP) Information*, FED. PRISON TIME, https://www.federalprisontime.com/rdap-information (last visited Dec. 29, 2023); *Frequently Asked Questions About the Residential Drug Abuse Program (RDAP)*, FAMS. AGAINST MANDATORY MINIMUMS 2, https://famm.org/wp-content/uploads/FAQ-Residential-Drug-Abuse-Program-5.3.pdf (last visited Dec. 29, 2023).

[164] Both Psychology Services and Health Services Division of the BOP play a role in the administration and dispensing of methadone in BOP facilities. Health Services Division personnel are tasked with the actual provision of methadone. *See* U.S. GOV'T ACCOUNTABILITY OFF., GAO-20-423, BUREAU OF PRISONS: IMPROVED PLANNING WOULD HELP BOP EVALUATE AND MANAGE ITS PORTFOLIO OF DRUG EDUCATION AND TREATMENT PROGRAMS (2020), https://www.gao.gov/assets/gao-20-423.pdf.

[165] The FSA also granted judges the discretion to impose reduced sentences for non-violent drug offenders with limited criminal background and converted the infamous "three strikes" rule to a twenty-five-year sentence, rather than a life sentence. Jesselyn McCurdy, *The First Step is Actually the Next Step After Fifteen Years of Successful Reforms to the Federal Criminal Justice System*, 41 CARDOZO L. REV. 189, 226, 234 (2019).

[166] Examples include retroactive application of reduced sentencing for crack cocaine in the Fair Sentencing Act of 2010 and the prohibition on the shackling of pregnant federal prisoners. Justin George, *What's Really in the First Step Act?*, MARSHALL PROJECT (Nov. 16, 2018, 12:45 PM), https://www.themarshallproject.org/2018/11/16/what-s-really-in-the-first-step-act?psafe_param=1&gclid=EAIaIQobChMIlYHekuDN_wIVZTLUAR3X_wqxEAAYAyAAEgJqHvD_BwE; Ames Grawert, *What Is the First Step Act – And What's Happening with It?*, BRENNAN CTR. FOR JUST. (June 23, 2020), https://www.brennancenter.org/our-work/research-reports/what-first-step-act-and-whats-happening-it.

[167] Grawert, *supra* note 166.

[168] *First Step Act Annual Report April 2023*, U.S. DEP'T OF JUST. 36–38 (Apr. 2023), https://www.ojp.gov/first-step-act-annual-report-april-2023.

In response, the BOP issued interim technical guidance in 2020 to expand[169] access to all MOUD in federal prisons, including screening all inmates for eligibility[170] and providing access to all three FDA-approved MOUD.[171] In 2022, over 3,000 federal inmates received some form MOUD – an eleven-fold increase over 2021.[172] However, these participants only represent 1.9% of the federal prison population, significantly less than the estimated 25% (or approximately 39,000) of federal prisoners in need of OUD treatment.[173]

Bureaucratic barriers continue to hold progress back. As of April 2023, all BOP-operated Medical Referral Centers (MRCS) are certified as OTPs[174], but these MRCs – of which they are only six nationwide – provide "Care Level 4" or "significantly enhanced medical services [, including] 24-hour skilled nursing care or nursing assistance."[175] Because MRCs house less than 1% of the federal prisoner population,[176] access to methadone for the treatment of OUD is far from universal.

In sum, federal correctional facilities represent a logistically "simpler" opportunity to implement an expansion of OUD care considered the "gold standard," and the First Step Act invites the DEA to re-examine its regulations surrounding access to methadone for the treatment of OUD in all BOP-operated correctional facilities.

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[169] *See generally Memorandum for Clinical Directors Health Services Administrator, Re: Medication Assisted Treatment (MAT) Interim Technical Guidance*, FED. BUREAU OF PRISONS (Aug. 26, 2020), https://www.documentcloud.org/documents/21016594-mat-interim-technical-guidance-november-2020 [hereinafter *MAT Interim Technical Guidance*]. Neither the BOP National Formulary nor the Program Statement for Pharmacy Services reflect this expanded access to methadone. To be consistent with the FSA and BOP clinical guidance, these policies should be amended to allow universal access to methadone, as clinically appropriate, for the prisoners who satisfy the DSM-V criteria for "clinically significant impairment or distress" resulting from opioid use. *See National Formulary Part I*, *supra* note 132, at 116–21; *Program Statement 6360.01, Pharmacy Services*, *supra* note 57, at 37.

[170] *Opioid Use Disorder: Diagnosis, Evaluation, and Treatment*, *supra* note 147, at 8–10.

[171] *See generally MAT Interim Technical Guidance*, *supra* note 169.

[172] *First Step Act Annual Report April 2023*, *supra* note 168, at 35.

[173] *See supra* Section III.

[174] *Id.*

[175] *See infra* Section V.B.2.ii; *see also* Alan Ellis, *BOP Health Care: What You (and Your Clients) Need to Know*, L. OFFS. OF ALAN ELLIS, https://alanellis.com/bop-health-care-what-you-and-your-clients-need-to-know/ (last visited Dec. 29, 2023).

[176] *Program Fact Sheet*, FED. BUREAU OF PRISONS 1 (Mar. 31, 2020), https://www.bop.gov/about/statistics/docs/program_fact_sheet_20200501.pdf.

V. THE DRUG ENFORCEMENT AGENCY (DEA) MUST ACT TO INCREASE ACCESSIBILITY TO METHADONE IN FEDERAL CORRECTIONAL FACILITIES

Federal courts across the United States have intervened on behalf of prisoners when correctional facilities deny them access to adequate MOUD care during incarceration.[177] Removing the regulatory barriers that restrict prisoners' access to methadone in federal correctional facilities can and must be accomplished. While there are multiple avenues available for reform, *none of these paths require congressional intervention*.[178] First, the Drug Enforcement Agency (DEA) must adopt the broader definition of "practitioner" promulgated by the Controlled Substances Act of 1973 (CSA). Second, this Note proposes two alternatives that will increase access to methadone in federal prisons. Under the first option, the DEA has the authority[179] to permit all practitioners to prescribe and all pharmacies to dispense methadone for the treatment of OUD. Recognizing that this is a broad option, this Note also proposes a DEA-promulgated exemption for federal prisons specifically, waiving their requirement to accredited and certified as opioid treatment programs (OTPs).

A. Providing methadone is consistent with the prisoner's constitutional and statutory rights

[177] Weizman et al., *supra* note 40, at 2–4.

[178] 21 U.S.C § 821 (authorizing the Attorney General to promulgate rules pursuant to the "registration and control of the manufacture, distribution, and dispensing of controlled substances"); 28 C.F.R. § 0.100(b) (2023) (allowing Attorney General to "delegate[] authority to another Department of Justice official to exercise such function").

[179] 21 U.S.C § 821; 28 C.F.R. § 0.100(b).

Not only is increasing access to methadone supported by physicians,[180] pharmacists,[181] researchers,[182] and recovery experts,[183] it is supported by the prisoner's constitutional and statutory rights. Where federal regulations have erected barriers, prisoner-initiated litigation has increased momentum for expanded access to methadone in correctional facilities.[184] In *Estelle v. Gamble*, the Supreme Court found that incarcerated individuals have a constitutional right to medical care, and deprivation of this right constitutes "cruel and unusual punishment:"[185]

> We therefore conclude that deliberate indifference to serious medical needs of prisoners constitutes the "unnecessary and wanton infliction of pain," proscribed by the Eighth Amendment. This is true whether the indifference is manifested by prison doctors in their response to the prisoner's needs or by prison guards in intentionally denying or delaying access to medical care or intentionally interfering with the treatment once prescribed.[186]

Prisoners have leveraged this unique constitutional right to medical care[187] to advocate for increased MOUD access. In 2019, the Eleventh Circuit held that correctional officers who denied methadone maintenance treatment to a prisoner and observed her experience a withdrawal-induced stroke without intervention were not entitled to qualified immunity against the prisoner's subsequent Eighth Amendment claims.[188] Similarly, the Seventh Circuit allowed litigation to proceed because a jury[189] could conclude that the Cook County Jail in Illinois had a "widespread practice

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[180] Tanya Albert Henry, *AMA to Push for Better Access to Opioid-Use Disorder Treatments*, AM. MED. ASS'N (Nov. 18, 2020), https://www.ama-assn.org/delivering-care/overdose-epidemic/ama-push-better-access-opioid-use-disorder-treatments.

[181] *See generally* Jeffrey Bratburg et al., *Opioid Overdose Prevention*, J. OF AM. PHARMACISTS ASS'N (Sept./Oct. 2015), https://aphanet.pharmacist.com/sites/default/files/files/APPM%20APhA%202015%20Naloxone%20Review.pdf.

[182] *See* NAT'L ACADS. OF SCIS., ENG'G, & MED., *supra* note 11, at 51.

[183] Longley et al., *supra* note 3, at 3–4.

[184] *See, e.g.*, Estelle v. Gamble, 429 U.S. 97, 103 (1976).

[185] *Id.* at 104.

[186] *See Estelle*, 429 U.S. at 104–05; *see also* Carlson v. Green, 446 U.S. 14 (1980) (holding that the family of a federal prisoner who died in custody could initiate an action against the federal government and the individual official responsible).

[187] Puglisi & Wang, *supra* note 59 (stating that the only other American population with a constitutional right to health care are Native Americans).

[188] Foster v. Maloney, 785 F. App'x 810, 816–19 (11th Cir. 2019).

[189] Davis v. Carter, 452 F.3d 686, 695–97 (7th Cir. 2006).

or custom of inordinate delay in providing methadone treatment to inmates, which caused proximate harm."[190]

Prisoners have also challenged prison policies denying access to MOUD using the Americans with Disabilities Act (ADA).[191] The ADA prohibits discrimination against people with disabilities in a wide array of activities, from voting to employment to consumerism.[192] Under the ADA, OUD is a disability because "it is a drug addiction that substantially limits a major life activity."[193] While the ADA does not protect a person who engages in illegal drug use, it does protect people being treated with methadone and other MOUD.[194] In 2018, Maine Department of Corrections agreed to provide buprenorphine to a prisoner with five years of sobriety after the prisoner filed suit alleging an ADA violation.[195] The Department of Justice, which houses the BOP,[196] has likewise issued guidance stating that ADA protections indeed extend to prisoners with OUD who do not engage in illicit drug use.[197]

Prisoners have also utilized Section 504 of the Rehabilitation Act of 1973 (The Rehab Act) in their fight for MOUD access during incarceration.[198] The application of The Rehab Act largely mirrors that of

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[190] *Id.* at 692.

[191] American with Disabilities Act of 1990, §§ 42 U.S.C. 12101–12213 [hereinafter ADA]. Of note, the ADA has been held to apply to prisoners. *Know Your Rights: Legal Rights of Disabled Prisoners*, AM. C.L. UNION 1 (Nov. 2005), https://www.aclu.org/sites/default/files/images/asset_upload_file735_25737.pdf.

[192] *See Opioid Use Disorder*, ADA, https://www.ada.gov/topics/opioid-use-disorder/ (last visited Dec. 29, 2023).

[193] *Id.*

[194] *The Americans with Disabilities Act and the Opioid Crisis: Combating Discrimination Against People in Treatment or Recovery*, C.R. DIV., U.S. DEP'T OF JUST. 2 (Apr. 5, 2022), https://archive.ada.gov/opioid_guidance.pdf. Of note, the ADA protects those with alcohol use disorder who still consume alcohol. Madison Fields et al., *Recovery Ready Workplaces: A Key Strategy for Reducing Overdoses and Sustaining Recovery from Substance Use Disorder*, J. OF OPIOID MGMT. (Oct. 18, 2023), https://wmpllc.org/ojs/index.php/jom/article/view/3499.

[195] Complaint, Smith v. Fitzpatrick, No. 18-cv-00288 (Mass. Dist. Ct. 2019); Smith v. Fitzpatrick, No. 18-cv-00288, 2019 WL 1387682, at *1 (D. Me. Mar. 27, 2019).

[196] *Agencies*, U.S. DEP'T OF JUST., https://www.justice.gov/agencies/chart/grid (last visited Dec. 29, 2023).

[197] *Justice Department Issues Guidance on Protections for People with Opioid Use Disorder under the Americans with Disabilities Act*, U.S. DEP'T OF JUST. (Apr. 5, 2022), https://www.justice.gov/opa/pr/justice-department-issues-guidance-protections-people-opioid-use-disorder-under-americans.

[198] *See generally* Tayabji, *supra* note 36 (for a tremendous resource on the prisoner's right to MOUD under The Rehab Act).

the ADA, because it also disallows illegal drug use but not methadone for the treatment of OUD.[199] In 2019, a prisoner in a federal correctional facility alleged that the BOP policy denying access to methadone violated The Rehab Act, as well as the Eighth Amendment.[200] Here, the BOP reversed course and agreed to provide methadone for the entirety of her sentence, making her the first prisoner to win methadone maintenance treatment in federal prison.[201] As prisoners are entitled to health care and dependent on the government for that health care, litigation driven by prisoners with OUD has instigated change in access to methadone and other MOUD.

B. The DEA must take action to increase access to methadone for those incarcerated in federal correctional facilities

The requirement that BOP facilities be accredited and certified as an OTP or partner with an existing OTP in the community[202] to dispense methadone represents a substantial barrier to methadone access for prisoners.[203] Removing this requirement would alleviate this burden and allow the BOP to fulfill their obligation to expand access to this life-saving medication.[204]

Under the Controlled Substances Act of 1973 (CSA), the Attorney General "is authorized to promulgate rules and regulations and to charge reasonable fees relating to the registration and control of the manufacture, distribution, and dispensing of controlled substances. . . ."[205] The Attorney General has delegated this authority to the DEA.[206] Further, the DEA has the statutory authority to "waive the requirement for registration of certain manufacturers, distributors, or dispensers if [they] find[] it consistent with

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[199] 29 U.S.C. § 705(20)(C)(i).

[200] Complaint and Request for Emergency Injunctive Relief, DiPierro v. Hurwitz, No. 19-cv-10495 (Mass. Dist. Ct. 2019); *see also Federal Prison to Provide Medication for Addiction Treatment to Massachusetts Woman*, AM. C.L. UNION (June 5, 2019, 12:00 PM), https://www.aclum.org/en/news/federal-prison-provide-medication-addiction-treatment-massachusetts-woman.

[201] *Federal Prison to Provide Medication for Addiction Treatment to Massachusetts Woman*, AM. C.L. UNION (June 5, 2019, 12:00 PM), https://www.aclum.org/en/news/federal-prison-provide-medication-addiction-treatment-massachusetts-woman.

[202] *Opioid Use Disorder: Diagnosis, Evaluation, and Treatment*, *supra* note 147, at 8–10.

[203] *See infra* Section IV.C.

[204] *WHO Model Lists of Essential Medicines*, *supra* note 8.

[205] 21 U.S.C. § 821.

[206] 28 C.F.R. § 0/100(b) (2023).

the public health and safety."[207] Thus, the DEA, through the process of rulemaking, may amend regulations without congressional action.[208]

In their current form, regulations surrounding methadone for the treatment of opioid use disorder (OUD) state, in relevant part:

> (a) A practitioner may administer or dispense directly (but not prescribe) a narcotic drug listed in any schedule to a narcotic dependent person for the purpose of maintenance or detoxification treatment if the practitioner meets both of the following conditions:
>
> (1) The practitioner is separately registered with DEA as a narcotic treatment program.
>
> (2) The practitioner is in compliance with DEA regulations regarding treatment qualifications, security, records, and unsupervised use of the drugs pursuant to the Act.
>
> (b) Nothing in this section shall prohibit a physician who is not specifically registered to conduct a narcotic treatment program from administering (but not prescribing) narcotic drugs to a person for the purpose of relieving acute withdrawal symptoms when necessary while arrangements are being made for referral for treatment. Not more than one day's medication may be administered to the person or for the person's use at one time. Such emergency treatment may be carried out for not more than three days and may not be renewed or extended.
>
> (c) This section is not intended to impose any limitations on a physician or authorized hospital staff to administer or dispense narcotic drugs in a hospital to maintain or detoxify a person as an incidental adjunct to medical or surgical treatment of conditions other than addiction, or to administer or dispense narcotic drugs to persons with intractable pain in which no relief or cure is possible or none has been found after reasonable efforts.[209]

These regulations create three barriers. First, the term "practitioner" is defined narrowly by the DEA, thus limiting the types of practitioners

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[207] 21 U.S.C. § 822(d). The DEA recently exercised this authority in May 2023, when it proposed to continue COVID-19-precipitated flexibility for telehealth services to prescribe controlled substances. Temporary Extension of COVID-19 Telemedicine Flexibilities for Prescription of Controlled Medications, 88 Fed. Reg. 30037 (May 10, 2023) (to be codified at 21 C.F.R. pt. 1307, 42 C.F.R. pt. 12).

[208] Administrative Procedure Act, 5 U.S.C. §§ 551–559. Once an agency decides that a regulatory action is necessary or appropriate, it develops and typically publishes a proposed rule in the Federal Register, soliciting comments from the public on the regulatory proposal. After the agency considers this public feedback and makes changes where appropriate, it then publishes a final rule in the Federal Register with a specific date upon which the rule becomes effective and enforceable. In issuing a final rule, the agency must describe and respond to the public comments it received. *Learn About the Regulatory Process*, REGULATIONS.GOV, https://www.regulations.gov/learn (last visited Dec. 29, 2023).

[209] 21 C.F.R. §§ 1306.07(a)–(c) (2023).

that may utilize methadone for the treatment of OUD.[210] Second, practitioners are prohibited from prescribing methadone for the treatment of OUD.[211] Third, practitioners can only administer or dispense methadone for the treatment of OUD if they are accredited and certified as an OTP.[212] Here, the DEA has the authority[213] to amend their regulations to allow practitioner prescribing and pharmacy dispensing of methadone for the treatment of OUD at a community-wide[214] or BOP-specific[215] level.

1. The DEA must adopt the broad definition of "practitioner" from the Narcotic Addict Treatment Act of 1974 (NATA)

Section (a) of 21 C.F.R. § 1306.7 only permits practitioners separately registered with the DEA as an OTP to administer or dispense (but not prescribe) methadone for the treatment of OUD.[216] However, the DEA definition for "practitioner" is significantly narrower than the definition of "practitioner" adopted by Congress.[217] The NATA definition of "practitioner" includes "pharmac[ists] . . . or other person licensed, registered, or otherwise permitted . . . to distribute, dispense, [or] administer a controlled substance in the course of professional practice or research."[218] The DEA, on the other hand, explicitly excludes pharmacists or pharmacies from dispensing methadone for the treatment of OUD.[219]

The DEA should adopt the broader, more inclusive definition of "practitioner," thereby allowing pharmacists to dispense methadone for the treatment of OUD. This revision is consistent with both Congressional intent[220] and the more inclusive definition of "practitioner" proposed by SAMHSA in January 2023.[221]

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[210] *See id.* § 1306.07(a); *see also* 21 C.F.R. § 1300.01(b).

[211] Dooling & Stanley, *supra* note 10, at 16.

[212] 21 C.F.R. § 1306.07(a).

[213] 21 U.S.C. § 821; 28 C.F.R. §0.100(b) (2023); Reorganization Plan of 1970 No. 2 of 1973, 87 Stat. 1091, 1092, 1093 (1973).

[214] *See infra* Section V.B.2.i.

[215] *See infra* Section V.B.2.ii.

[216] 21 C.F.R. § 1306.07(a).

[217] *Compare id.* § 1306.07(a), *with* 21 U.S.C. § 802(21).

[218] 21 U.S.C. § 802(21).

[219] 21 C.F.R. § 1300.01(b).

[220] Dooling & Stanley, *supra* note 10, at 17–18.

[221] Medications for the Treatment of Opioid Use Disorder, 87 Fed. Reg. 87 Fed. Reg. 77330, 77338, 77351 (Dec. 16, 2022) (to be codified at 42 C.F.R. pt. 8) (expanding the definition of "practitioner" to include multiple types of health care professionals who are "appropriately

2. The DEA should grant exemptions that address the opioid crisis in the federal prison system

In their current form, federal regulations surrounding access to methadone are inconsistent with addiction science,[222] judicial interpretation of an inmates' constitutional right to health care,[223] and the First Step Act of 2018 (FSA)[224] mandate to expand access to all FDA-approved MOUD, including methadone. Here, the DEA has the authority[225] to amend its regulations surrounding methadone on a community-wide[226] or a federal prison-wide level.[227]

i. A broad approach: community-wide dispensing of methadone for the treatment of OUD by pharmacies

The DEA should revise Section (a) of 21 C.F.R. § 1306.7 to grant practitioners the power to "administer, dispense, or prescribe" methadone to OUD patients.[228] Under the current statutory language, only practitioners registered as an OTP with the DEA and in compliance with all administrative requirements can administer or dispense (but not prescribe) methadone for the treatment of OUD.[229] In light of the heightened need for OUD treatment in correctional facilities,[230] the constitutional obligation to provide health care to prisoners,[231] and the lack of methadone diversion issues posed by take-home doses in the correctional setting,[232] the DEA should proactively amend Section (a) as follows:

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licensed by a State to prescribe and/or dispense medications for opioid use disorder within an OTP").

[222] *See* Weizman et al., *supra* note 3, at 5–9.

[223] *See supra* Section V.A.

[224] *See supra* Section IV.C.3.

[225] 21 U.S.C § 821; 28 C.F.R. § 0.100(b) (2023); Reorganization Plan of 1970 No. 2 of 1973, 87 Stat. 1091, 1092, 1093 (1973).

[226] *See infra* Section V.B.2.i.

[227] *See infra* Section V.B.2.ii.

[228] 21 C.F.R. § 1306.07(a) (2023).

[229] *Id.*

[230] *See supra* Section IV.C.

[231] *See* Estelle v. Gamble, 429 U.S. 97, 104–05 (1976).

[232] *What Is the Treatment Need Versus the Diversion Risk for Opioid Use Disorder Treatment?*, NAT'L INST. ON DRUG ABUSE (Dec. 2021), https://nida.nih.gov/publications/research-reports/medications-to-treat-opioid-addiction/what-treatment-need-versus-diversion-risk-opioid-use-disorder-treatment.

(a) A practitioner[233] may ~~administer or dispense directly (but not prescribe)~~ administer, dispense, or prescribe a narcotic drug listed in any schedule to a narcotic dependent person for the purpose of maintenance or detoxification treatment if the practitioner is meets both of the following conditions:

The administering or prescribing practitioner is separately registered with DEA as a narcotic treatment program and is in compliance with DEA regulations regarding treatment qualifications, security, records, and unsupervised use pursuant to the Act, and

~~(2) The practitioner is in compliance with DEA regulations regarding treatment qualifications, security, records, and unsupervised use of the drugs pursuant to the Act.~~

The dispensing practitioner is authorized by the DEA to administer Schedule II controlled substances and is in compliance with DEA regulations regarding security, records, and unsupervised use pursuant to 21 C.F.R. §§ 1306.11–15.[234]

This proposal, in conjunction with the broader definition of "practitioner,"[235] would significantly increase federal prisoners' access to methadone. All BOP correctional facilities "maintain a pharmacy directed by a professionally and legally qualified pharmacist and staffed by a sufficient number of trained personnel, in keeping with the size of the institution and the scope of medical services provided."[236] BOP pharmacies are already storing and dispensing methadone to the treatment of pain or, in the case of pregnant persons, for the treatment of OUD.[237] Thus, federal correctional facilities are equipped to dispense methadone to OUD patients through the pharmacy pill line system[238] currently in place. If anything, the implementation of these proposed revisions would be logistically simpler, as BOP practitioners and BOP pharmacies are both contained with the same closed system.[239]

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[233] *See supra* Section V.B.1.

[234] *See* 21 C.F.R. § 1306.07(a); *see also* 21 C.F.R. §§ 1306.11–15 (describing prescription requirements for Schedule II controlled substances).

[235] *See supra* Section V.B.1.

[236] *Program Statement 6360.01, Pharmacy Services*, *supra* note 57, at 2.

[237] *Id.* at 37.

[238] *See Opioid Use Disorder: Diagnosis, Evaluation, and Treatment*, *supra* note 147, at 2.

[239] *Pharmacist*, FED. BUREAU OF PRISONS, https://www.bop.gov/jobs/positions/index.jsp?p=Pharmacist (last visited Dec. 29, 2023) (stating

This proposal is the most far-reaching in terms of expanded access to methadone. These revisions would allow practitioner prescribing and pharmacy dispensing of methadone for OUD *universally* – for prisoners and those in the community alike. In 2023, the Modernizing Opioid Treatment Access Act was introduced in the 118th Congress to allow pharmacies to dispense methadone to OUD patients, similar to the recommendations above.[240] Previous bills proposing these revisions had widespread support from the American Pharmacists Association and CVS Health, a worldwide retail pharmacy chain.[241]

While advocates of the current regulatory framework worry that pharmacy-based dispensing of methadone to OUD patients will significantly increase methadone-associated overdose deaths and diversion, studies have not supported this concern. Data from the COVID-19 pandemic have shown that methadone diversion and methadone-induced overdose deaths are significantly associated with methadone prescribed for pain management, not for treatment of OUD.[242] Further, these revisions would only allow practitioners the discretion to opt for pharmacy-based dispensing, based on the relevant factors.[243] In light of the ongoing opioid crisis across the United States and our constitutional obligation to prisoners health care, a broad increase in methadone access is an appropriate, if not necessary, response.

ii. A targeted approach: an exemption from OTP requirements for federal correctional facilities operated under the Bureau of Prisons

While there is a strong argument for allowing pharmacies across the country to dispense methadone for the treatment of OUD, the DEA can also amend its regulations surrounding administering, dispensing, and prescribing of methadone to provide a targeted exemption from the OTP

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that pharmacists and other practitioners "work as part of an interdisciplinary team . . . within a correctional facility").

[240] Modernizing Opioid Treatment Access Act, S. 644, 118th Cong. (2023–2024).

[241] Alison Knopf, *Bill to Allow Pharmacy Dispensing of Methadone Introduced in the Senate*, ADDICTION TREATMENT F. (Feb. 16, 2022), https://atforum.com/2022/02/bill-pharmacy-dispensing-methadone-senate/; *see, e.g.*, Fred Gebhart, *Pharmacists Fight to Take on Opioid Use Disorder*, DRUG TOPICS (Aug. 5, 2022), https://www.drugtopics.com/view/pharmacists-fight-to-take-on-opioid-use-disorder.

[242] *See What Is the Treatment Need Versus the Diversion Risk for Opioid Use Disorder Treatment?*, *supra* note 232; *see also* Jones et al., *supra* note 74.

[243] Medications for the Treatment of Opioid Use Disorder, 87 Fed. Reg. 77330, 77338, 77359 (proposed Dec. 16, 2022) (to be codified at 42 C.F.R. pt. 8).

requirement for the federal correctional system, leaving the OTP requirement intact in the community. To that end, the DEA should amend Section (b) to include a specific exception for the federal prison system, as follows:

(b) Nothing in this section shall prohibit:

(1) a physician who is not specifically registered to conduct a narcotic treatment program from administering (but not prescribing) narcotic drugs to a person for the purpose of relieving acute withdrawal symptoms when necessary while arrangements are being made for referral for treatment. Not more than one day's medication may be administered to the person or for the person's use at one time. Such emergency treatment may be carried out for not more than three days and may not be renewed or extended, or

(2) a practitioner who is not specifically registered to conduct a narcotic treatment program but is providing health care services within a federal correctional facility from administering, dispensing, or prescribing narcotic drugs to a narcotic dependent person in federal custody for the purpose of induction, maintenance, or withdrawal treatment.[244]

The DEA has recognized and acted when exceptional circumstances indicate that traditional OTP requirements should be waived. Section (b) of 21 C.F.R. § 1306.7 currently provides an exception for practitioners administering (but not prescribing) methadone for the purpose of "relieving acute withdrawal symptoms" of OUD patients for a maximum of three days.[245] Similarly, Section (c) of 21 C.F.R. § 1306.07 provides an exception for physicians dispensing methadone for the treatment of OUD as "an incidental adjunct to medical or surgical treatment of conditions other than addiction," or for the treatment of pain.[246]

Collectively, the federal agencies[247] responsible for methadone and OTP regulations have issued exemptions for vulnerable populations and exceptional circumstances.[248] Here, a similar exemption for federal correctional facilities is warranted for two main reasons. First, federal

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[244] 21 C.F.R. § 1306.07(b) (2023).

[245] *Id.*

[246] 21 C.F.R. § 1306.7(c).

[247] In addition to the DEA, the Substance Abuse and Mental Health Services Administration (SAMHSA) has also incorporated exceptions into its regulations. Of note, "long-term care facilities" and hospitals are not required to become certified as OTPs to provide methadone for the treatment of OUD. 42 C.F.R. § 8.11(h) (2023).

[248] *See supra* notes 235, 237–38.

prisoners are a vulnerable population. They are wholly dependent[249] on the Bureau of Prisons (BOP) for their constitutionally guaranteed[250] health care, and they have been disproportionately impacted by the opioid overdose crisis.[251]

Second, the exemptions themselves recognize the medical value of methadone for the treatment of OUD. Both the DEA and SAMSHA allow *facilities providing long-term health care services* to dispense and administer methadone for the treatment of OUD, so long as OUD is not the primary morbidity.[252]

Due to mandatory minimum sentencing, the lack of parole in the federal prison system, and other policies, *federal prisons are long-term health care facilities* – with the average sentence served in federal correctional facilities increasing from 17.9 months in 1988 to 37 months in 2021.[253] In 2021, over 54% of all federal prisoners were serving sentences of greater than ten years.[254]

Longer sentences imposed and fewer opportunities for release also mean that the age demographic[255] for the federal prison population is

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[249] *See* NATHAN JAMES, CONG. RSCH. SERV., IF11629, HEALTH CARE FOR FEDERAL PRISONERS1 (2020).

[250] *See supra* Section V.A.

[251] *See supra* Section III.

[252] 21 C.F.R. § 1306.07(c) (2023); 42 C.F.R. § 8.11(i)(2).

[253] *Prison Time Surges for Federal Inmates*, PEW CHARITABLE TRS. (Nov. 18, 2015), https://www.pewtrusts.org/en/research-and-analysis/issue-briefs/2015/11/prison-time-surges-for-federal-inmates; Mark Motivans, *Federal Justice Statistics, 2021*, FED. BUREAU OF PRISONS 12 (Dec. 2022), https://bjs.ojp.gov/sites/g/files/xyckuh236/files/media/document/fjs21.pdf. The average length of imprisonment went up for 25 of the 28 specific federal crimes that the Bureau of Justice Statistics tracked in 1988 and 2012. Sentences imposed for violent or drug-related crimes in 2021 were even longer, at 96 months and 70 months, respectively. Under the Sentencing Reform Act of 1984, federal prisoners are only eligible for release after completing a minimum of 85% of their sentence behind bars. *Prison Time Surges for Federal Inmates*, *supra* note 253.

[254] *Federal Offenders in Prison – March 2021*, U.S. SENT'G COMM'N 2 (Mar. 2021), https://www.ussc.gov/sites/default/files/pdf/research-and-publications/quick-facts/BOP_March2021.pdf.

[255] *Supporting America's Aging Prisoner Population: Opportunities & Challenges for Area Agencies on Aging*, NAT'L ASS'N OF AREA AGENCIES ON AGING 3, https://www.ncchc.org/wp-content/uploads/n4a_AgingPrisoners_23Feb2017REV-2.pdf (last visited Dec. 29, 2023). Between 2007 and 2010, the number of state and federal prisoners aged 65 and older grew at a rate 94 times greater than the overall prison population, making it the fastest growing demographic. *Id.*

changing. It is estimated that one-third of all prisoners will be over the age of fifty-five years old by 2030.[256]

Prisoners experience increased incidences of chronic health problems and develop chronic illnesses ten to fifteen years earlier[257] than non-incarcerated persons. While many of the factors contributing to their poorer health pre-date incarceration, prison itself is significant factor, as "older adults leave prison in worse health than when they arrived and in worse health than community-dwelling persons of the same age."[258]

The net result is a federal prison system that must now house and serve an older prisoner population for longer periods of time, many with chronic health conditions or in need of assistance with daily personal care.[259] In sum, an exemption for federal prisons from the OTP requirement is consistent with current needs-based exemptions, while preserving the OTP system in the community.

VI. CONCLUSIONS AND FUTURE DIRECTIONS

In sum, the federal correctional system simultaneously represents a population in need and a system empowered for change. Prisoners in federal custody have been disproportionately affected by the opioid crisis, and federal regulations surrounding access to methadone for opioid use disorder (OUD) are a significant barrier to care for those in federal prison, who are dependent on the Bureau of Prisons (BOP) for their constitutionally-protected health care.[260] The First Step Act of 2018 (FSA), as well as the National Drug Control Policy from the White House,[261] both advocate for increasing access to methadone for federal prisoners – an action that the DEA is authorized to take.

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[256] Maura Ewing, *When Prisons Need to Be More Like Nursing Homes*, MARSHALL PROJECT (Aug. 27, 2015, 7:15 AM), https://www.themarshallproject.org/2015/08/27/when-prisons-need-to-be-more-like-nursing-homes.

[257] Nathan A. Boucher et al., *Older Adults Post-Incarceration: Restructuring Long-term Services and Supports in the Time of COVID-19*, J. OF AM. MED. DIRS. ASS'N (Sept. 29, 2020), https://www.jamda.com/article/S1525-8610(20)30830-6/fulltext. Incarcerated persons are considered an "older adult" by age 55, ten years earlier than un-incarcerated persons. *Id.*

[258] Boucher et. al., *supra* note 257.

[259] *See The Impact of an Aging Inmate Population on the Federal Bureau of Prisons*, U.S. DEP'T OF JUST. 6–10 (Feb. 2016), https://oig.justice.gov/reports/2015/e1505.pdf.

[260] *See supra* Section III, IV.C.

[261] *National Drug Control Strategy*, OFF. OF NAT'L DRUG CONTROL POL'Y 46, 55 (2022), https://www.whitehouse.gov/wp-content/uploads/2022/04/National-Drug-Control-2022Strategy.pdf

Correctional facilities at the state and local levels have taken the initiative to increase access to methadone, with encouraging results. After an Albany County, New York jail provided methadone to persons in their custody, recidivism in that jurisdiction decreased so dramatically that the Sheriff decommissioned over 100 unoccupied jail cells for lack of use.[262] In 2021, Maine's Department of Corrections began offering universal access to methadone for prisoners diagnosed with OUD, and upon release, supplied those re-entering society with naloxone[263] and fentanyl test strips, which allow users to test for the presence of the powerful opioid in other drugs.[264] Since this program's inception, drug smuggling, violence, and suicide attempts inside Maine's prisons significantly decreased, and fatal overdoses among individuals leaving prison dropped sixty percent.[265]

In 2023, California received the first ever partial waiver of the Medicaid Inmate Exclusion Policy, which bans Medicaid from reimbursing for health services during incarceration.[266] Numerous other states have similar Section 1115[267] waiver requests pending with the Centers for Medicare and Medicaid Services (CMS).[268] The federal government should incentivize states to take similar innovative steps

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[262] All MOUD, including methadone, were provided. Bethany Bump, *Albany County Jail to Expand Treatment for Opioid-Addicted Inmates*, TIMES UNION (Jan. 17, 2019, 8:09 PM), https://www.timesunion.com/news/article/Albany-County-Jail-to-expand-treatment-for-13541822.php; Jim Franco, *Albany County Jail to House the Homeless Too*, SPOTLIGHT NEWS (Sept. 10, 2019), https://spotlightnews.com/news/2019/09/10/albany-county-jail-to-house-the-homeless-too/.

[263] *See Naloxone, supra* note 15.

[264] All MOUD, including methadone, were provided. Krista Mahr, *Maine's Prisons Taught Washington a Crucial Lesson in Fighting Opioids*, POLITICO (Jan. 08, 2023, 7:00 AM), https://www.politico.com/news/magazine/2023/01/08/maines-prisons-opioids-00076822.

[265] *Id.*

[266] *See* Sweta Haldar & Madeline Guth, *Section 1115 Waiver Watch: How California Will Expand Medicaid Pre-Release Services for Incarcerated Populations*, KAISER FAM. FOUND. (Feb. 7, 2023), https://www.kff.org/policy-watch/section-1115-waiver-watch-how-california-will-expand-medicaid-pre-release-services-for-incarcerated-populations/; *see also Incarcerated Medicare Beneficiaries*, CTRS. FOR MEDICARE & MEDICAID SERVS., https://www.cms.gov/training-education/partner-outreach-resources/incarcerated-medicare-beneficiaries (last visited Dec. 29, 2023).

[267] *About Section 1115 Demonstrations*, MEDICAID.GOV, https://www.medicaid.gov/medicaid/section-1115-demonstrations/about-section-1115-demonstrations/index.html (last visited Dec. 29, 2023).

[268] *Medicaid Waiver Tracker: Approved and Pending Section 1115 Waivers by State*, KAISER FAM. FOUND. (July 17, 2023), https://www.kff.org/medicaid/issue-brief/medicaid-waiver-tracker-approved-and-pending-section-1115-waivers-by-state/.

toward expanded access to methadone in both the community and in correctional settings.

A study from the Kentucky Opioid Response Effort (KORE) reported that every dollar invested in substance use disorder (SUD) treatment was offset by $3.63 in future correctional savings.[269] How governments spend that net gain is important as well, because the goal – for at least 85.7% of prisoners[270]– is a return to family, friends, and society. While this Note proposes a federal prison-targeted path for increased access to methadone for OUD, the broader approach,[271] calling for universal practitioner prescribing and pharmacy dispensing of methadone for OUD allows continuity of care for recently released prisoners. In addition to regulatory reform, the federal government should allocate funding for the training of professionals in substance use and mental health services, similar to the AmeriCorps[272] or Teach For America[273] models. By adhering to evidence-based practices, listening to people with lived experiences, and leading with innovation, the United States can turn the tide in the opioid crisis.

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[269] Martha Tillson et al., *Criminal Justice Kentucky Treatment Outcome Study: FY2020*, KY. DEP'T OF CORR. 2, 36 (Aug. 11 2021), https://corrections.ky.gov/Divisions/ask/Documents/CJKTOS_FY2020%20Report_FINAL.pdf.

[270] In 2021, one out of seven sentences in the U.S. were life sentences. Ashley Nellis, *No End in Sight: America's Enduring Reliance on Life Sentences*, SENT'G PROJECT (Feb. 17, 2021), https://www.sentencingproject.org/reports/no-end-in-sight-americas-enduring-reliance-on-life-sentences/.

[271] *See supra* Section V.B.2.i.

[272] *GO Americorps Fellows: Improving Equity & Outcomes*, GO FOUND., https://gofellows.org/?gh_camp=ga&gclid=EAIaIQobChMI8NLXmMHP_wIV1GtMCh0C9QsZEAAYAiAAEgKP-vD_BwE (last visited Dec. 29, 2023).

[273] *Internships and Fellowships*, TEACH FOR AM., https://www.teachforamerica.org/applying-to-tfa/internships-and-fellowships (last visited Dec. 29, 2023).