Federal Administrative Pathways to Promote Access to Quality Methadone Treatment

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Synopsis

The National Academies of Science, Engineering, and Medicine commissioned this paper for *Methadone Treatment for Opioid Use Disorder: Examining Federal Regulations and Laws – A Workshop*. It surveys pathways through which federal agencies could promote access to quality methadone treatment by utilizing existing legal authorities, without the need for federal or state legislation. It reviews existing analyses identifying specific pathways that federal agencies already have authority to utilize and points to promising areas in which further research may reveal additional flexibilities. Topic areas include the Substance Abuse and Mental Health Services Administration's (SAMHSA) standard-setting and Drug Enforcement Administration's (DEA) waiver authorities under the Controlled Substances Act; Health and Human Services Office of Inspector General (HHS OIG) authorities related to the antikickback statute; statutory and constitutional checks on state and opioid treatment program (OTP) restrictions; and payment authorities related to Medicare, Medicaid, and employer-sponsored insurance.

* The author is responsible for the content of this article, which does not necessarily represent the views of the National Academies of Sciences, Engineering, and Medicine.

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Introduction

A 2019 National Academies Report explained that although methadone is an effective treatment for opioid use disorder, significant and inequitable barriers impede access.[1] This paper surveys possible pathways through which federal administrative agencies could overcome or mitigate some barriers to quality methadone treatment, without the need for legislation. It builds on prior literature either establishing (as legally permissible) or exploring (as worthy of further consideration) such pathways.[2] The paper does not necessarily endorse utilization of the pathways it identifies, but simply notes their availability or potential availability.

Agencies have two main ways to effectuate legal change without legislation. Statutes often give agencies broad authority over implementation. Where current legal requirements stem from regulation, they can usually be changed through notice-and-comment rulemaking so long as the new rules remain within the underlying statutory mandate. In other cases,

[1] NATIONAL ACADS. OF SCIENCES, ENGINEERING, AND MED., MEDICATIONS FOR OPIOID USE DISORDER SAVE LIVES at 9-10 (2019).

[2] Bridget C.E. Dooling & Laura Stanley, *Extending Pandemic Flexibilities for Opioid Use Disorder Treatment: Unsupervised Use of Opioid Treatment Medications*, 105 MINN. L. REV. HEADNOTES 74 (2021); Corey S. Davis and Derek H. Carr, *Legal and policy changes urgently needed to increase access to opioid agonist therapy in the United States*, 73 INT. J. DRUG POL'Y 42-48 (2019).

agencies are charged with enforcing statutes, regulations, or even constitutional provisions. Enforcement policy can ordinarily be changed by the agency without rulemaking.

I. Controlled Substances Act

A. Dispensing

Section 823(g) of the Controlled Substances Act (CSA) requires "practitioners who dispense narcotic drugs" for maintenance of detoxification treatment to obtain an annual registration.[3] It also provides that registrations should be granted only to practitioners who meet standards "established by [SAMHSA]" governing practitioner qualifications, the security of narcotics, and their provision for unsupervised use.[4] The standards established by the Substance Abuse and Mental Health Services Administration (SAMHSA) create the category of "Opioid Treatment Programs (OTPs),"[5] set rules governing OTPs,[6] and provide for accreditation bodies to oversee OTP operations.[7]

Dooling and Stanley point out that CSA "plainly gives SAMHSA broad authority to establish the standards practitioners must follow in order to be registered," which includes the power to change those standards.[8] Davis and Carr also read the statute to grant SAMHSA broad discretion and call for a variety of changes in the current regulatory requirements.[9]

In addition to SAMHSA's standard-setting authority, CSA gives the Drug Enforcement Administration (DEA) authority to "waive the requirement for registration of certain manufacturers, distributors, or dispensers if [DEA] finds it consistent with the public health and safety."[10] DEA recently employed this waiver authority to create mobile van flexibilities.[11]

SAMHSA's standard-setting authority and DEA's waiver authority are promising pathways for administrative adoption of essentially any of the changes in CSA requirements that scholars have proposed. For example, Pytell and colleagues recommend changes "to expressly allow for hospitals to initiate and adjust the dose of methadone."[12] Such reforms could be made through notice and comment rulemaking using either the Secretary's standard-setting authority or the Attorney General's waiver authority.

B. Distribution

Reports suggest that hospitals and skilled nursing facilities have difficulty obtaining sufficient quantities of methadone to administer to eligible patients.[13] Buprenorphine

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[3] 21 U.S.C. § 823(g).
[4] *Id.* § 823(g)(2).
[5] 42 C.F.R. § 8.12.
[6] *Id.*
[7] *Id.* § 8.13.
[8] Dooling & Stanley, *supra* note 2 at 12.
[9] Davis & Carr, *supra* note 2.
[10] 21 U.S.C. § 822(d).
[11] 86 Fed. Reg. 33861 (2021); Taleed El-Sabawi et al., *The New Mobile Methadone Rules and What They Mean for Treatment Access*, HEALTH AFFAIRS BLOG, August 4, 2021.
[12] Jarratt D. Pytell et al., *Facilitating Methadone Use in Hospitals and Skilled Nursing Facilities*, 180 JAMA INTERN. MED. 6-7 (2019).
[13] David Gifford et al., *Additional Barriers to Methadone Use in Hospitals and Skilled Nursing Facilities*, 180 JAMA INTERN. MED. 615 (2020).

shortages trace in part to pharmacies' fear that ordering sufficient quantities will place them above an unwritten threshold that triggers DEA investigation.[14] To address this barrier, DEA could clarify in guidance that increasing stocks of methadone to provide to hospitals or skilled nursing facilities will not trigger enforcement consequences.

C. Quality

The Methadone Manifesto describes the withholding of methadone as a form of punishment by some OTPs as a barrier to maintenance of treatment.[15] SAMHSA could potentially use its standard-setting authority to address these concerns. Alternatively, the agency could, through its routine oversight of accreditation bodies, press for greater scrutiny of OTP conduct.[16]

Further research could also explore the possibility of litigation challenging OTP behavior under the Due Process Clause of the U.S. Constitution. Through the "state action doctrine," courts may deem a private actor to be acting as a government actor and subject to constitutional requirements. A thorough analysis of how the complicated legal test for the state action doctrine applies to OTPs in light of their unique role under the CSA would be necessary to determine the viability of this pathway to check OTP behavior.

II. Antikickback Statute and Civil Monetary Penalties Statute

Contingency management is a treatment employing rewards that can be effective for stimulants increasingly used alongside opioids.[17] Take-up of this form of treatment has been limited, however, in part by provider concerns that the provision of rewards to patients may give rise to liability under the federal antikickback statute (AKS) or the civil monetary penalty statute (CMP).[18] Generally speaking, these laws limit offering remuneration to patients unless a safe harbor is present.[19]

The Department of Health and Human Services (HHS) Office of Inspector General (OIG) enforces these statutes and has authority to implement safe harbors. OIG has declined to create a safe harbor for contingency management.[20] This does not mean that contingency management violates the law, but it leaves violation in any individual case a fact-intensive determination that providers may wish to avoid. OIG could mitigate this barrier by using its authority to promulgate safe harbors by regulation,[21] or use its enforcement discretion to describe situations in which contingency management will not be subject to liability. Furthermore, "incentives offered as part of a CMS-sponsored model may qualify for protection under the safe harbor" for payment models.[22] Thus, the Centers for Medicare &

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[14] Hannah Cooper et al., *When Prescribing Isn't Enough—Pharmacy-Level Barriers to Buprenorphine Access*, 383 NEW ENG. J. MED. 703 (2020).
[15] Urban Survivors Union, *Methadone Manifesto* at 29, https://sway.office.com/UjvQx4ZNnXAYxhe7?ref=Link&mc_cid=9754583648&mc_eid=51fa67f051.
[16] *See* HHS OIG, *SAMHSA's Oversight of Accreditation Bodies for Opioid Treatment Programs Did Not Comply with Some Federal Requirements* (A-09-18-01007).
[17] 85 Fed. Reg. 77791 (Dec. 2, 2020).
[18] *Id.*
[19] 42 U.S.C. § 1320a-7b(b); 42 U.S.C. § 1320a-7a(a)(5).
[20] 85 Fed. Reg. 77791 (Dec. 2, 2020); *see also id.* (discussing application of $75 *de minimis* exception).
[21] 42 U.S.C. § 1320a-7b(b)(3)(E).
[22] 85 Fed. Reg. at 77792.

Medicaid Services (CMS) could, by creating or expanding payment models for methadone treatment, render connected contingency management protected from liability under these statutes.

III. State Restrictions

Many states impose restrictions on methadone prescribing that are more stringent than federal requirements.[23] Two pathways to overcome these barriers warrant further consideration. The Department of Justice's Office of Civil Rights, which has reportedly discussed an "Opioid Initiative," may be the best positioned federal agency unit to explore these pathways.

First, because the U.S. Constitution makes federal law the "supreme Law of the Land,"[24] state laws that are inconsistent with federal statutory or regulatory requirements can be "preempted" — rendered void — as a result of that inconsistency.[25] Preemption doctrine is complex,[26] but future research might explore whether there are ways that current or future DEA waivers (e.g., the mobile van waiver), SAMHSA standards, or CMS payment models could be preemptive.

Second, state barriers to methadone treatment may themselves violate federal law or the U.S. Constitution. Friedman and Trent describe several theories on which restrictions on access to methadone in prison or in other institutional settings might run afoul of prohibitions on discrimination against individuals with disabilities in the Americans with Disabilities Act and Rehabilitation Act of 1973.[27] Furthermore, a work in progress by the author concludes there is a reasonable legal argument that unjustified state restrictions on access to methadone implicate a fundamental liberty interest under the Fourteenth Amendment.[28]

IV. Payment

A. Traditional Medicare

Provider participation and patient access are both a function of the generosity of payment.[29] Traditional Medicare now covers OTP services without payer utilization management or cost sharing through a bundled payment model.[30] In 2021 CMS issued an emergency rule to prevent a cut in reimbursement rates for this bundle for 2022, and the agency is now considering a revision to its formula to ensure appropriate compensation for

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[23] Corey S. Davis & Amy Judd Lieberman, *Access to Treatment for Individuals with Substance Use Disorder* at 115 Covid-19 Policy Playbook (2021) (discussing state barriers).
[24] U.S. CONST. art. VI, cl. 2.
[25] *See generally* Jonathan Nash, *Null Preemption*, 85 NOTRE DAME L. REV. 1015 (2010).
[26] *Id.*
[27] Sally Friedman & Melissa Trent, *Defense Lawyers and the Opioid Epidemic: Advocating for Addiction Medication* at 26, NACDL.Org.
[28] Matthew B. Lawrence, *Addiction and Liberty* (work in progress).
[29] Rebecca L. Haffajee et al., *Policy Pathways to Address Provider Workforce Barriers to Buprenorphine Treatment*, 54 AM. J. PREV. MED. (2018).
[30] *See generally* 84 Fed. Reg. 62673 (Nov. 15, 2019).

OTPs in future years.[31] This ongoing administrative proceeding is a ready legal path by which the agency could promote access to methadone.

Additionally, it is unclear how methadone provided through pharmacies, hospitals, or primary care would be paid through the existing Medicare bundled model, so it may be appropriate for CMS to consider offering alternative payment options — including coverage as a preferred drug (like buprenorphine) through Medicare Part D — to promote the financial viability of such reforms.[32] CMS has broad authorities to implement payment reforms through the regulatory process.[33]

B. Medicare Advantage

Medicare Advantage (MA) plans must now cover methadone, but they may currently limit that coverage with cost-sharing requirements for beneficiaries and/or utilization management (including prior authorization, step therapy, and utilization review).[34] Utilization management can be a significant barrier to medication-assisted treatment (MAT),[35] and CMS has indicated that it is "considering strategies . . . to monitor the implementation of the OTP benefit by MA plans . . . including what data might be available to evaluate plan performance."[36]

Two administrative pathways are available to CMS to mitigate the risk that MA plans will impose unjustified barriers through utilization management. First, CMS reviews the adequacy of MA plans' networks at various stages of plan creation and administration to ensure adequate coverage of essential services, including time and distance criteria for 27 provider specialty types.[37] CMS's guidance on the specialties it includes in this review does not currently include OTPs.[38] CMS could update this guidance to include OTP coverage in its assessment of network adequacy.

Second, MA plans are paid through a "risk adjustment" system that mitigates insurers' incentive to impose artificial barriers to treatment for properly adjusted diagnoses.[39] The Affordable Care Act required CMS periodically to "evaluate and revise the [MA] risk adjustment system . . . in order to, as accurately as possible, account for higher medical and care coordination costs associated with . . . a diagnosis of mental illness."[40] CMS has to date failed to meaningfully perform this evaluation and revision, and doing so would offer a pathway to promote access to methadone treatment.[41]

C. Medicaid

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[31] 86 Fed. Reg. 66031 (Nov. 19, 2021).
[32] *Cf.* 86 Fed. Reg. 66031-32 ("methadone cannot be dispensed by a pharmacy . . . and therefore is not covered under Medicare Part D").
[33] *E.g.*, § 1115A; 42 U.S.C. § 1395(d)(5)(i)(I).
[34] 84 Fed. Reg. 62762 (Nov. 15, 2019).
[35] Daniel M. Hartung et al., *Buprenorphine Coverage in the Medicare Part D Program for 2007 to 2018*, 321 JAMA 607–609 (2019).
[36] 84 Fed. Reg. at 62762 (Nov. 15, 2019).
[37] CMS, *Medicare Advantage Network Adequacy Criteria Guidance* (Jan. 10, 2017).
[38] 85 Fed. Reg. at 62762.
[39] T. G. McGuire, *Achieving Mental Health Care Parity Might Require Changes in Payments and Competition*, HEALTH AFFAIRS, 35, No. 6 (2016): 1029-1035.
[40] 42 U.S.C. 1395w-23(a)(1)(C)(iii)(III).
[41] Matthew B. Lawrence, *Regulatory Pathways to Promote Treatment for Substance Use Disorder or Other Under-Treated Conditions Using Risk Adjustment*, 46 JLME 935 (2019).

Section 1006(b) of the SUPPORT [Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities] Act required all states to cover methadone through Medicaid. Seventy-five percent of Medicaid enrollees are in a managed care plan that may impose barriers to methadone treatment through unjustified prior authorization, step therapy, annual or lifetime caps, or utilization review requirements.[42]

Federal law restricts coverage limitations in Medicaid to situations where it is medically necessary or needed to prevent waste.[43] CMS has the authority to enforce these requirements,[44] but it is currently difficult for the agency to assess compliance because "[d]ata submitted by managed care plans to states and by states to CMS vary in their consistency, availability, and timeliness."[45] CMS's statutory authority regarding data submissions by managed care plans and states,[46] then, is a promising legal avenue to develop the data necessary for more effective enforcement. By requiring more uniform and comprehensive submission of data regarding utilization management practices, CMS could position itself to assess the scope of inappropriate barriers and enforce or strengthen existing requirements.

More broadly, Medicaid is subject to two major administrative authorities that offer pathways to address social determinants that fuel the epidemic and impede access to treatment.[47] Section 1115 empowers CMS to grant federal matching payments for state costs that are not ordinarily matchable through the program.[48] The statute does not require these payments to be budget neutral.[49] North Carolina has received a waiver under this authority, for example, to pay for housing, transportation, and other supports aimed at the social determinants of health.[50] CMS has issued reports surveying steps that states have taken and might take to support housing for people with substance use disorder through the Medicaid program.[51] For any states interested in addressing social and economic barriers to methadone treatment, section 1115 holds the potential to serve as a significant source of funding and flexibility.

Section 1115A empowers CMS to test innovative payment models within Medicare or Medicaid. It has already developed two such models relevant to methadone, the Maternal Opioid Misuse model[52] and the Integrated Care for Kids model.[53] Section 1115A could offer a vehicle for administrative adoption of any other payment reforms policy makers deem beneficial.

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[42] J.V. Jacobi, *The ABCs (Accessibility, Barriers, and Challenges) of Medicaid Expansion: Medicaid, Managed Care, and the Mission for the Poor*, ST. LOUIS UNIV. J. OF HEALTH LAW & POL'Y 9, no. 2 (2016).

[43] 42 U.S.C. § 1396r–8(d); 42 C.F.R. § 440.230; 42 U.S.C. § 1396o-1(c) (addressing preferred drugs).

[44] *See* 42 U.S.C. §§ 1396u–2, 1396n(b), 1315(a).

[45] Medicaid & CHIP Payment & Access Comm'n, *Report to the Congress: The Evolution of Managed Care in Medicaid* 64 (June 2011).

[46] *E.g.,* 42 U.S.C. § 1927(g) (describing drug use review programs).

[47] *See* Nabarun Dasgupta, Leo Beletsky, & Daniel Ciccarone, *Opioid Crisis: No Easy Fix to Its Social and Economic Determinants*, 108 AM. J. PUB. HEALTH 182 (2018) (discussing root causes).

[48] Matthew B. Lawrence, *Fiscal Waivers and State "Innovation" in Health Care*, 62 WM. & MARY L. REV. 123 (2020).

[49] *Id.*

[50] https://www.kff.org/report-section/a-first-look-at-north-carolinas-section-1115-medicaid-waivers-healthy-opportunities-pilots-issue-brief/.

[51] U.S. Department of Health and Human Services, *Report to the President and Congress Section 1018 Action Plan for Technical Assistance and Support for Innovative State Strategies to Provide Housing-Related Supports to Individuals with Substance Use Disorder Under Medicaid* (July 2019).

[52] https://innovation.cms.gov/innovation-models/maternal-opioid-misuse-model.

[53] https://innovation.cms.gov/innovation-models/integrated-care-for-kids-model.

D. Employer-Sponsored Insurance

Finally, patients who have insurance through an employee benefit plan may also face unjustified barriers to coverage.[54] The Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008[55] offers some protection, prohibiting discrimination against mental illness in the design and administration of benefits. The law is administered by the Department of Labor, which recently issued a report noting that "health plans and health insurance issuers are failing to deliver parity for mental health and substance-use disorder benefits to those they cover."[56] For example, one large employer plan with 7,600 beneficiaries excluded coverage for methadone altogether without imposing analogous restrictions on physical health treatments and without the required comparative supporting analysis.[57]

The 2021 Consolidated Appropriations Act gave the Department of Labor new authorities related to the investigation of parity requirements through non-quantified treatment limitations (e.g., prior authorization and medical necessity review),[58] and the agency is now beginning to implement these authorities despite limited resources and enforcement powers.

Conclusion

Significant legal change to promote access to quality methadone treatment could be accomplished without legislation. There are promising pathways toward such change within the authorities of the Department of Health and Human Services (CMS, OIG, and SAMHSA), the Department of Justice (DEA and Office for Civil Rights), and the Department of Labor.

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[54] Daniel Polsky et al., *Private Coverage of Methadone in Outpatient Treatment Programs*. 71 PSYCHIATR. SERV. 303-306 (2020).
[55] Pub. L. No. 100-343 § § 511-12, 122 Stat. 365 (codified at 29 U.S.C. § 1185a & 42 U.S.C. § 300gg-26 (2012)).
[56] https://www.dol.gov/newsroom/releases/ebsa/ebsa20220125.
[57] *Id.*
[58] Section 203, CAA.