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Policy Rounds

Exploring Policies Shaping Addiction Medicine

ASAM American Society of Addiction Medicine

Improving Access to Methadone Treatment for Opioid Use Disorder in Federally Qualified Health Centers

The ongoing overdose crisis, driven by high potency synthetic opioids like fentanyl, has particularly impacted populations served by Federally Qualified Health Centers (FQHCs), namely individuals with opioid use disorder (OUD) who are uninsured or publicly insured and those who are members of racial and ethnic minority groups.[1,2]

Medications for OUD (MOUD) are effective, but face access barriers that have led to disparate outcomes for people of color, those with lower incomes, and people living in rural areas.[3] Their use in FQHCs remains low, especially methadone - only 29% of patients in FQHCs received methadone in 2020, and only 7% of FQHCs provided it in 2019.[4,5,6]

Federal regulations currently limit outpatient methadone for the treatment of OUD to federally certified opioid treatment programs (OTPs) that meet certain requirements that were not designed for FQHCs, which have historically focused on delivering primary health care services.[7] While many FQHCs now offer buprenorphine and naltrexone for the treatment of OUD, methadone remains an outlier.[8]

The Role of FQHCs in OUD Treatment

Insurance coverage of OUD treatment poses a major barrier. Over 52% of people with OUD either have Medicaid coverage or are uninsured. Low reimbursement rates, especially in the Medicaid program, have been shown to deter clinician enrollment, thereby limiting clinicians' participation in behavioral health networks. For uninsured individuals, finding a clinician willing to treat patients without insurance coverage is even more difficult.

FQHCs may be uniquely positioned to help close this treatment gap due to their focus on underserved populations and ability to address medical and behavioral comorbidities. In 2023, almost 70% of FQHC patients were on Medicaid or uninsured.[9] Furthermore, the latest statistics suggest that FQHCs employed over 57,000 personnel who treated over 2.6 million people with a substance use disorder (SUD) in 2023, including over 200,000 who received MOUD.[10]

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Barriers to Methadone Access in FQHCs

Accessing methadone treatment for OUD in FQHCs faces several barriers. Federal law[11] limits the dispensing of "narcotic drugs"[1] for addiction treatment in schedule II (e.g., methadone) to applicants that have specially registered with the US Attorney General (AG) for that purpose. This registration is granted only if the applicant: (1) is determined to be qualified to provide this treatment; (2) complies with specified medication security and records requirements; and (3) complies with protocols regarding the quantities of medications that can be provided for unsupervised use.

Federal regulations at 42 CFR Part 8 specify the process for dispensing methadone for the treatment of OUD, with HHS delegating oversight to SAMHSA. SAMHSA has outlined federal rules for the dispensing of methadone for the treatment of OUD, including requiring program applicants to obtain appropriate state licensing, SAMHSA accreditation/certification, and Drug Enforcement Administration (DEA) registration. As a result, FQHCs' options for providing methadone treatment for OUD are limited.

DUE TO FEDERAL LAW, FQHCS' OPTIONS FOR PROVIDING METHADONE TREATMENT FOR OUD ARE LIMITED.

First, FQHCs can apply to become an OTP. This may be an unviable option for FQHCs that do not primarily provide treatment for OUD like OTPs. Second, FQHCs may coordinate with OTPs to provide medication dispensing units. Third, FQHCs could establish referral relationships with OTPs. However, patients in rural areas can face significant challenges in accessing an OTP.

Additional barriers such as staffing shortages[12], stigma, payment rates, infrastructure, and state regulations/policies[13] also create significant hurdles for FQHCs interested in providing methadone for the treatment of OUD.

Recent Federal Actions to Expand Access to Behavioral Health and OUD Treatment in FQHCs

In addition to expanding care management services in FQHCs, the Centers for Medicare and Medicaid Services (CMS) has finalized rules to allow telehealth for mental health/SUD services and Marriage and Family Therapists and Mental Health Counselors are now recognized as FQHC practitioners.

However, federal efforts have been more limited for FQHCs when it comes to methadone for OUD. While SAMHSA recently updated 42 CFR Part 8 to provide more flexibility for methadone access for OUD, it still largely restricts its delivery through OTPs. Additionally, federal law now allows Medicare coverage of OUD treatment services delivered by OTPs. While FQHCs can provide intensive outpatient (IOP) services for OUD in addition to the outpatient OUD services they offer, FQHCs may bill for the OTP Medicare benefit only if they are formally registered as a SAMHSA-certified OTP. It is unclear how dualling designations of FQHCs (their traditional definition plus an OTP credential) have impacted FQHC Medicare payments.

Regulatory Considerations for Expanding Access to Methadone via FQHCs

Given the overlap of the patient demographics of FQHCs and people living with OUD, existing treatment infrastructure within FQHCs, and recent limited federal actions to expand services for SUD and mental health in FQHCs, there is an opportunity for federal regulators to consider more robust actions to expand access to methadone via FQHCs.

SAMHSA could revise 42 CFR Part 8 to create an alternative pathway for FQHCs to be deemed to meet OTP certification/treatment standards. Since federal law delegates to HHS the authority to determine whether an applicant is "qualified" to meet those requirements, SAMHSA could explore simplifying them for FQHCs by aligning them with the existing federal standards FQHCs already meet for reimbursement purposes.

Additionally, for FQHCs, the DEA could adapt "OTP" medication security and records requirements to align them with those for Schedule II medications under pharmacy regulations. FQHCs with onsite pharmacies could then dispense methadone for OUD.

Conclusion

Despite federal efforts to modernize the SUD treatment infrastructure, more work is needed to extend these improvements to FQHCs. While SAMHSA has modernized access to methadone for the treatment of OUD for OTPs, long-term care facilities, jails, and prisons, the agency, in conjunction with the DEA, may want to explore additional federal regulatory changes to make methadone more accessible in FQHCs, which can help close the treatment gap, reduce socioeconomic disparities in access to methadone, and improve care delivery for even more patients with OUD.

Acknowledgements and Disclaimer

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This educational brief does not reflect the official public policy of ASAM. The information herein is provided for educational purposes only.

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End Notes

[1] The Controlled Substances Act at 21 CFR § 1300.01 defines "narcotic drugs" as: "any of the following whether produced directly or indirectly by extraction from substances of vegetable origin or independently by means of chemical synthesis or by a combination of extraction and chemical synthesis:

1. Opium, opiates, derivatives of opium and opiates, including their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers whenever the existence of such isomers, esters, ethers and salts is possible within the specific chemical designation. Such term does not include the isoquinoline alkaloids of opium.
2. Poppy straw and concentrate of poppy straw.
3. Coca leaves, except coca leaves and extracts of coca leaves from which cocaine, ecgonine and derivatives of ecgonine or their salts have been removed.
4. Cocaine, its salts, optical and geometric isomers, and salts of isomers.
5. Ecgonine, its derivatives, their salts, isomers and salts of isomers.
6. Any compound, mixture, or preparation which contains any quantity of any of the substances referred to in paragraphs (1) through (5) of this definition."

This definition does not include prescription psychostimulants.

References

[1] National Association of Community Health Centers. "Community Health Centers: Providers, Partners and Employers of Choice 2024 Chartbook." Available at: https://www.nachc.org/nachc-content/uploads/2024/07/2024-2022-UDS-DATA-Community-Health-Center-Chartbook.pdf

[2] National Association of Community Health Centers. "Closing the Primary Care Gap: How Community Health Centers Can Address the Nation's Primary Care Crisis." February 2023. Available at: https://www.nachc.org/nachc-content/uploads/2023/06/Closing-the-Primary-Care-Gap_Full-Report_2023_digital-final.pdf

[3] Miller, NS. Racial disparities in opioid addiction treatment: a primer and research roundup. The Journalist's Resource. 2021. https://journalistsresource.org/home/systemic-racism-opioid-addiction-treatment/. Accessed July 23, 2021.

[4] Substance Abuse and Mental Health Services Administration, National Survey of Substance Abuse Treatment Services (N-SSATS): 2020. Data on Substance Abuse Treatment Facilities. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2021.

[5] Sharac, J., Markus, A., Tolbert, J., & Rosenbaum, S. (2020, April 14). Community Health Centers in a time of change: Results from an Annual survey. KFF. https://www.kff.org/medicaid/issue-brief/community-health-centers-in-a-time-of-change-results-from-an-annual-survey/

[6] The increase from 2019 to 2020 could be attributed to opioid treatment programs (OTPs) gaining Medicare coverage for the first time in 2020 in the federal SUPPORT Act of 2018.

[7] Medications for the Treatment of Opioid Use Disorder, 42 C.F.R. § 8.1 (2024). https://www.ecfr.gov/current/title-42/chapter-I/subchapter-A/part-8

[8] Sharac, J., Markus, A., Tolbert, J., & Rosenbaum, S. (2020, April 14). Community Health Centers in a time of change: Results from an Annual survey. KFF. https://www.kff.org/medicaid/issue-brief/community-health-centers-in-a-time-of-change-results-from-an-annual-survey/

[9] Health Resources and Services Administration. (2023). National Health Center Program Uniform Data System (UDS) Awardee Data. National Health Center Program Uniform Data System (UDS) awardee data. https://data.hrsa.gov/tools/data-reporting/program-data/national

[10] Ibid

[11] Controlled Substances Act, 21 U.S.C. § 823(h)(1). https://www.law.cornell.edu/uscode/text/21/823

[12] (2022). Current State of the Health Center Workforce: Pandemic Challenges and Policy Solutions to Strengthen the Workforce of the Future. NACHC. https://www.nachc.org/wp-content/uploads/2022/03/NACHC-2022-Workforce-Survey-Full-Report-1.pdf

[13] Schulman, M., Jasko, A. (2024, January). Opportunities to Promote Medications for Opioid Use Disorder in Federally Qualified Health Centers. Center for Health Care Strategies. https://www.chcs.org/resource/opportunities-to-promote-medications-for-opioid-use-disorder-in-federally-qualified-health-centers/

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advocacy@ASAM.org ASAM.org/advocacy