What's New About Medications for Opioid Use Disorder: A Perspective from SAMHSA

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Georgia Academy of Family
American Academy of Family Physicians
Friday, November 10, 2023

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Disclosure to Learners

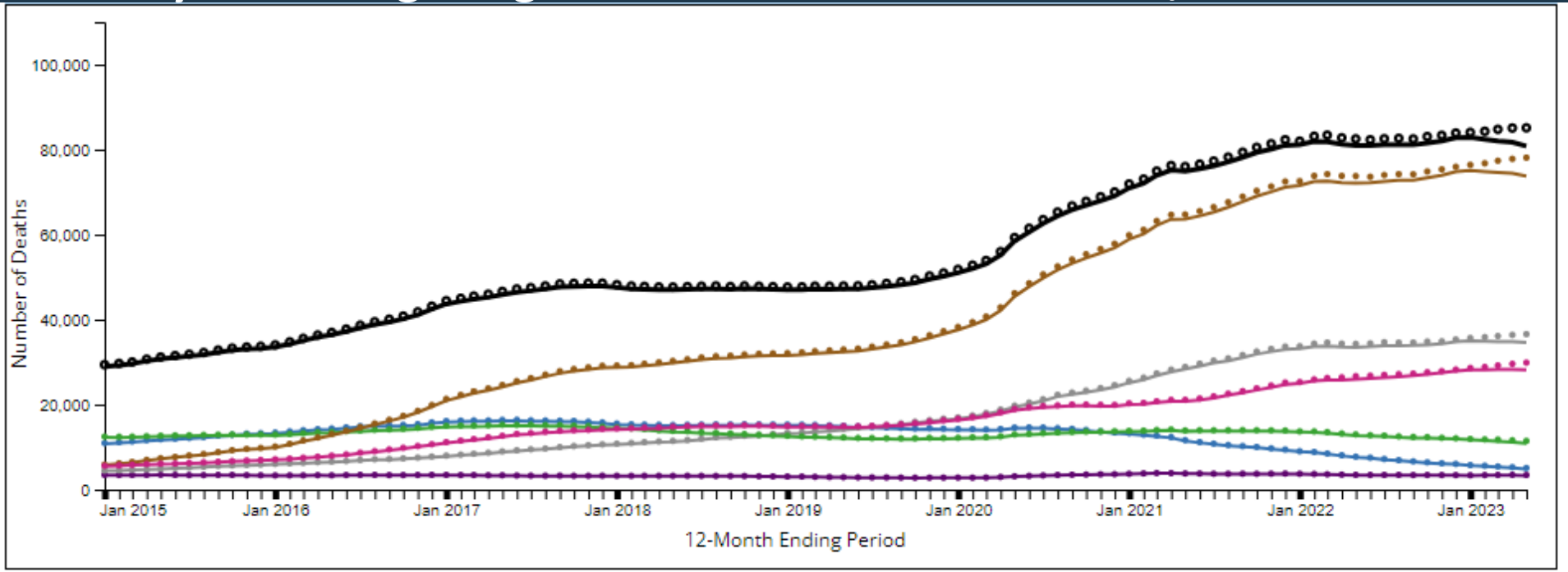
None of the content controllers for this activity have any relevant financial relationships to disclose with ineligible companies.

Learning Objectives

After participating in this session, attendees should be able to:

- Discuss 3 changes made to the treatment of opioid use disorder in the Consolidated Appropriations Act, 2023
- Identify at least 2 resources to make changes to existing systems, policies, and practices related to the treatment and management of substance use disorders, including opioid use disorder
- Apply at least one best practice related to opioid and/or other substance use disorder treatment and management

Fentanyl Is Driving Drug Overdose Deaths – Over 109,000 Lives Lost



Legend for Drug or Drug Class

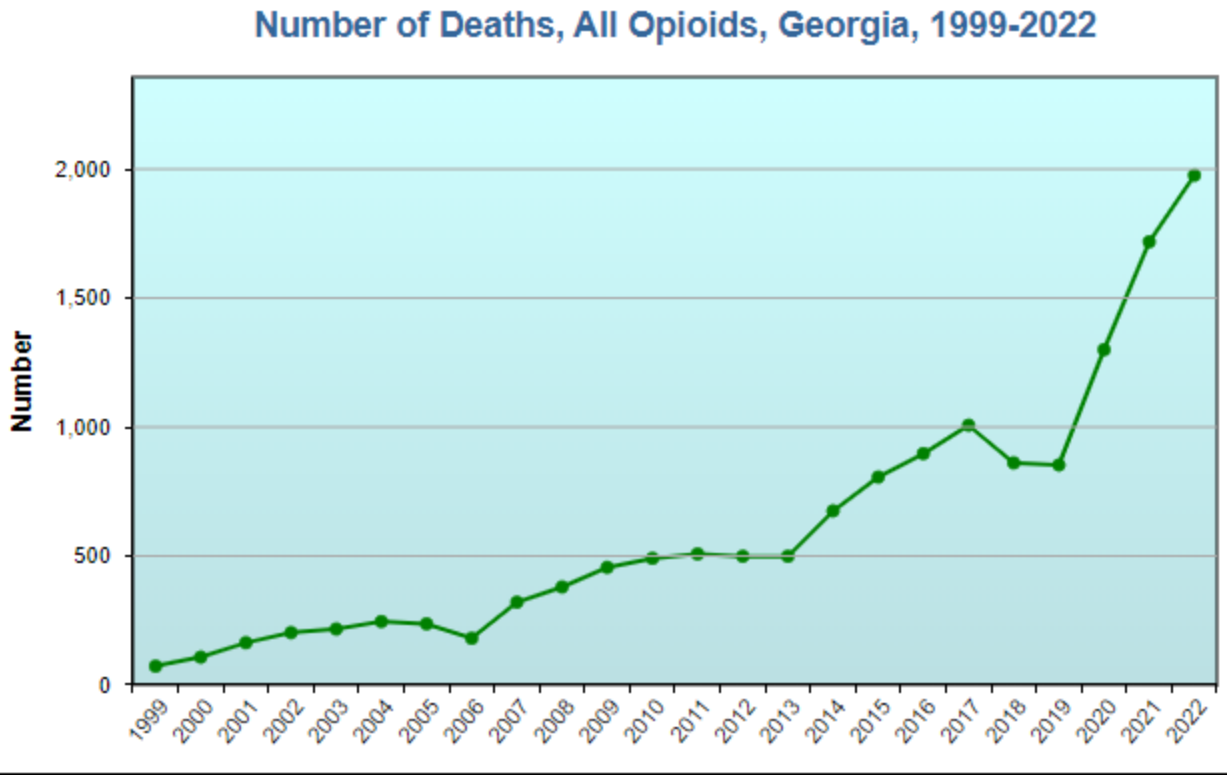
- Cocaine (T40.5)
- Heroin (T40.1)
- Methadone (T40.3)
- Natural & semi-synthetic opioids (T40.2)
- Opioids (T40.0-T40.4,T40.6)
- Psychostimulants with abuse potential (T43.6)
- Synthetic opioids, excl. methadone (T40.4)

---- Reported Value

O Predicted Value

Source: National Center for Health Statistics/Centers for Disease Control and Prevention. *Vital Statistics Rapid Release Provisional Drug Overdose Death Counts*, available at https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm (Based on data available for analysis on: October 1, 2023)

Georgia Overdose Crisis



https://oasis.state.ga.us/trendingtool/MortalityDrugOverdoses

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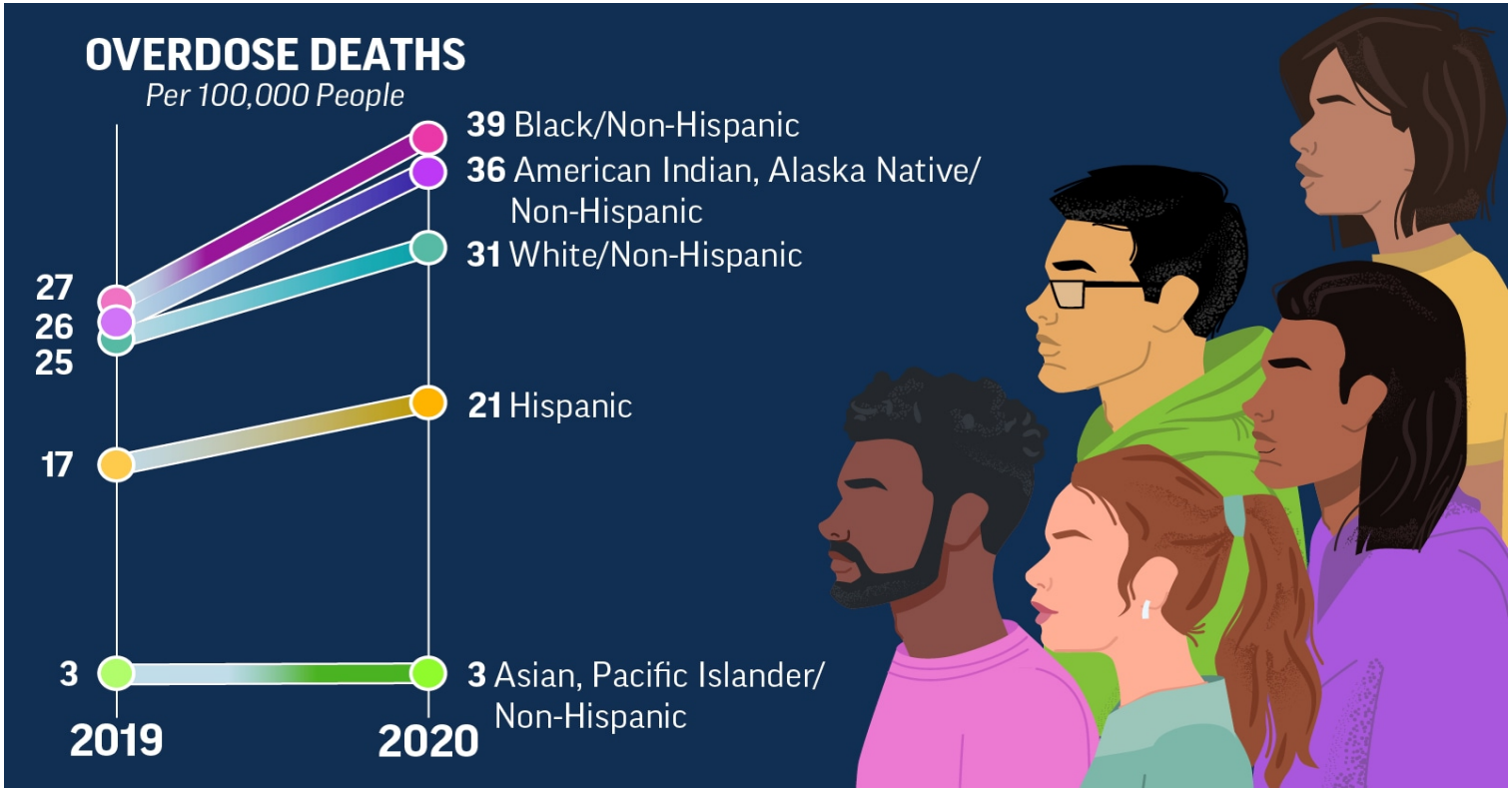
Disparities in 2020 Overdose Death Rates



CDC, 2022

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SAMHSA Priorities and Overarching Principles

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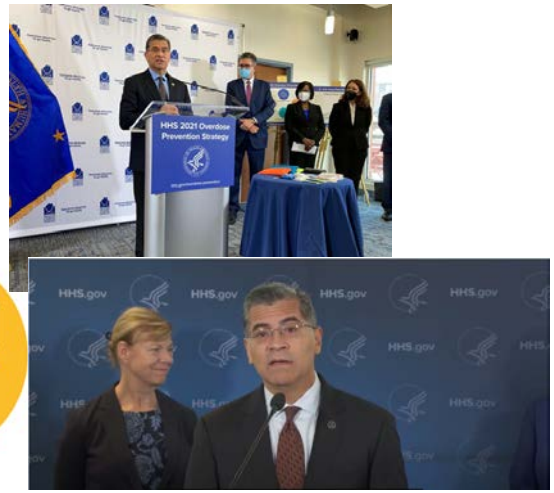
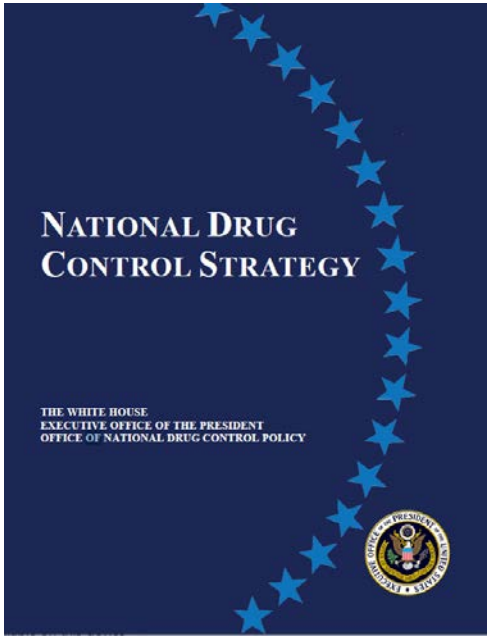
Focus on Overdose

HHS Overdose Prevention Strategy



https://www.hhs.gov/overdose-prevention/



https://www.whitehouse.gov/wp-content/uploads/2022/04/National-Drug-Control-2022Strategy.pdf

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Expanding Access to Evidence-Based Treatment

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The Evidence Underlying Expanding Access

- Research demonstrates that methadone and buprenorphine can reduce mortality up to 59%[1]
- MOUD is evidenced to be the most effective treatment strategy for decreasing opioid-related death[2]
- Recent evidence indicates that approximately 86.6% of people with OUD who could benefit from MOUD, do not receive it[3]
- Barriers to MOUD utilization include:
  - Stigma related to both prescribing and receiving these medications[4]
  - Strict monitoring and regulations for providers and patients[5]
  - Geographic and transportation challenges[6]
  - A lack of providers and care settings providing MOUD[7]

1. Larochelle MR, Bernson D, Land T, Stopka TJ, Wang N, Xuan Z, Bagley SM, Liebschutz JM, Walley AY. (2018). Medication for Opioid Use Disorder After Nonfatal Opioid Overdose and Association With Mortality: A Cohort Study. Ann Intern Med. Aug 7;169(3):137-145. doi: 10.7326/M17-3107.
2. Wakeman SE, Larochelle MR, Ameli O, et al. Comparative Effectiveness of Different Treatment Pathways for Opioid Use Disorder. JAMA Netw Open. 2020;3(2):e1920622. doi:10.1001/jamanetworkopen.2019.20622
3. Krawczyk, N., Rivera, B. D., Jent, V., Keyes, K. M., Jones, C. M., & Cerdá, M. (2022). Has the treatment gap for opioid use disorder narrowed in the US?: A yearly assessment from 2010 to 2019". International Journal of Drug Policy, 110, 103786.
4. Dickson-Gomez J, Spector A, Weeks M, Galletly C, McDonald M, Green Montaque HD. "You're Not Supposed to be on it Forever": Medications to Treat Opioid Use Disorder (MOUD) Related Stigma Among Drug Treatment Providers and People who Use Opioids. Subst Abuse. 2022 Jun 27;16:11782218221103859. doi: 10.1177/11782218221103859. PMID: 35783464; PMCID: PMC9243471.
5. Madden, E. F., Barker, K. K., Guerra, J., Villanueva, C., & Sulzer, S. H. (2022). Variation in intervention stigma among medications for opioid use disorder. SSM-Qualitative Research in Health, 2, 100161.
6. Cioe, K., Biondi, B. E., Easly, R., Simard, A., Zheng, X., & Springer, S. A. (2020). A systematic review of patients' and providers' perspectives of medications for treatment of opioid use disorder. Journal of substance abuse treatment, 119, 108146.
7. Stringer, K. L., Langdon, K. J., McKenzie, M., Brockmann, B., & Marotta, P. (2021). Leveraging COVID-19 to sustain regulatory flexibility in the treatment of opioid use disorder. Journal of Substance Abuse Treatment, 123, 108263.

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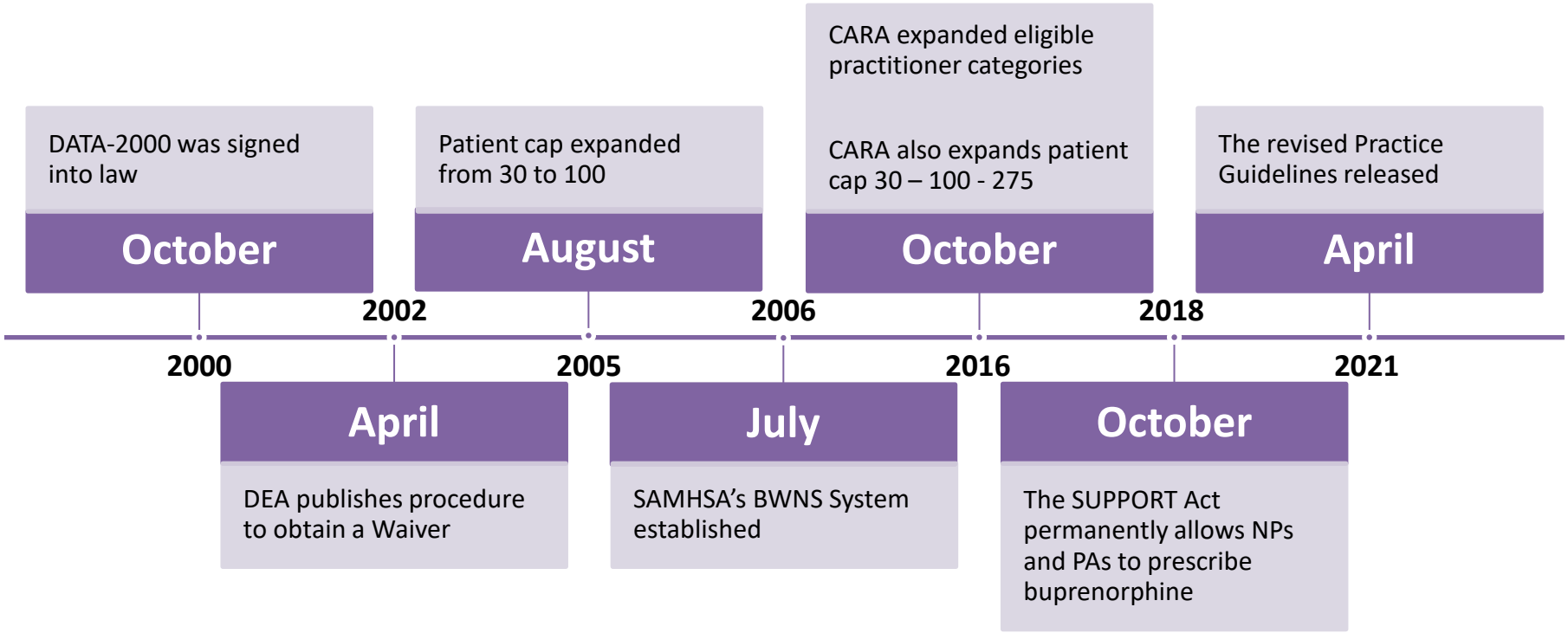
History of the Buprenorphine "X-Waiver"



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December 2022 – Removal Of The DATA-Waiver

On December 29, 2022, the President signed into law H.R. 2617, the "Consolidated Appropriations Act, 2023."

Mainstreaming Addiction Treatment (MAT) Act	Medication Access and Training Expansion Act (MATE)
Removes the DATA-2000 Waiver to prescribe buprenorphine	Requirement for a non-recurring, 8-hour training on SUD for practitioners renewing or applying for registration from the DEA
Lifts caps on number of patients who can be treated; removes counseling and reporting requirements	Met through addiction board certification, as part of or post-healthcare professional degree training

Implementation of MAT and MATE requires close collaboration and coordination between the DOJ/DEA and HHS/SAMHSA

2023 – Current Status

- “With this provision, and effective immediately, SAMHSA will no longer be accepting NOIs (waiver applications).”

- “All practitioners who have a current DEA registration that includes Schedule III authority, may now prescribe buprenorphine for Opioid Use Disorder in their practice if permitted by applicable state law and SAMHSA encourages them to do so.”

https://www.samhsa.gov/medications-substance-use-disorders/removal-data-waiver-requirement

SAMHSA Actions to Reduce Barriers

Messaging to practitioners through FAQs, publications and the SAMHSA website

Work with Federal partners, in particular the DEA and FDA

Training and TA – The Provider's Clinical Support System, Publications, TA provided through SAMHSA-funded platforms

Outreach to professional associations to encourage prescribing

Buprenorphine pharmacy access August 2022 summit

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Some Frequent Questions

- How does 42 CFR part 2 intersect with removal of the DATA-Waiver?
- Does Section 1262 of the Consolidated Appropriations Act, 2023 require existing buprenorphine prescribers to alter how they deliver care?
- How does the Consolidated Appropriation Act of 2023 change the intersect with state and statutory and regulatory requirements?

Visit https://www.samhsa.gov/medications-substance-use-disorders/waiver-elimination-mat-act for more questions and answers

The Evidence Underlying Expanding Access

- National averages for retention in outpatient buprenorphine treatment is low, with less than 50% remaining in treatment at 6 months with most people who start taking the medication discontinuing treatment within the first few months of treatment, due to a variety of barriers[1]

- Buprenorphine non-adherence or inconsistent dosing during early treatment is a predictor of attrition[2]

- It is essential to support access, and to not impose barriers.

1. Hser, Y. I., Saxon, A. J., Huang, D., Hasson, A., Thomas, C., Hillhouse, M., Jacobs, P., Teruya, C., McLaughlin, P., Wiest, K., Cohen, A., & Ling, W. (2014). Treatment retention among patients randomized to buprenorphine/naloxone compared to methadone in a multi-site trial. Addiction, 109(1), 79-87. https://doi.org/10.1111/add.12333
2. Warden, D., Subramaniam, G. A., Carmody, T., Woody, G. E., Minhajuddin, A., Poole, S. A., Potter, J., Fishman, M., Bogenschutz, M., Patkar, A., & Trivedi, M. H. (2012). Predictors of attrition with buprenorphine/naloxone treatment in opioid dependent youth. Addictive Behaviors, 37(9), 1046-1053. https://doi.org/10.1016/j.addbeh.2012.04.011

The Evidence Underlying Expanding Access

- There are some concerns that opioid partial agonists such as buprenorphine may be diverted.
- During the COVID-19 pandemic, there does not appear to be an increase in the proportion of overdose deaths involving buprenorphine.[1]
- Even prior to the pandemic, overdoses that were primarily attributable to buprenorphine, as opposed to another substance also present at death, were quite rare.[2]
  - The diversion of buprenorphine that does occur has primarily been for the purpose for which it was intended – helping people with OUD to reduce use of other opioids and to treat symptoms of withdrawal.[3]
  - Buprenorphine diversion, when it occurs, can lead to initiation of professional OUD care, and is associated with longer retention in care.[4]

1. Tanz LJ, Jones CM, Davis NL, Compton WM, Baldwin GT, Han B, Volkow ND. Trends and Characteristics of Buprenorphine-Involved Overdose Deaths Prior to and During the COVID-19 Pandemic. JAMA Netw Open. 2023 Jan 3;6(1):e2251856. doi: 10.1001/jamanetworkopen.2022.51856. PMID: 36662523; PMCID: PMC9860517.
2. Wightman RS, Perrone J, Scagos R, Krieger M, Nelson LS, Marshall BDL. Opioid Overdose Deaths with Buprenorphine Detected in Postmortem Toxicology: a Retrospective Analysis. J Med Toxicol. 2021 Jan;17(1):10-15. doi: 10.1007/s13181-020-00795-3. Epub 2020 Jul 9. PMID: 32648229; PMCID: PMC7785599.
3. Chilcoat, H. D., Amick, H. R., Sherwood, M. R., & Dunn, K. E. (2019). Buprenorphine in the United States: Motives for abuse, misuse, and diversion. Journal of substance abuse treatment, 104, 148–157. https://doi.org/10.1016/j.jsat.2019.07.005
4. Williams, A. R., Mauro, C. M., Feng, T., Wilson, A., Cruz, A., Olfson, M., Crystal, S., Samples, H., & Chiodo, L. (2022). Non-prescribed buprenorphine preceding treatment intake and clinical outcomes for opioid use disorder. Journal of substance abuse treatment, 139, 108770. https://doi.org/10.1016/j.jsat.2022.108770

Policy To Expand Access

- At the state level, policy makers can support practitioners in receiving robust and evidence-based education that meets the requirements of the MATE Act
- Facilitate access to SAMHSA-funded support such as PCSS which offers peer-to-peer technical assistance
- Ensure that drug stores and pharmacies carry adequate supplies of buprenorphine
- Support patient access to practitioners through telehealth, low-barrier models of care, and OTP mobile medication units
- At the federal level, we support these activities through policy reform, grant funding and promotion of best practices

Section 1263 (MATE Act) Actions To Date

Requirements for training for Medication Assisted Treatment as part of the MATE Act (PDF) (March 27, 2023)

Please see the letter which outlines the requirements for training for Medication Assisted Treatment as part of the MATE Act, which was part of the Omnibus Bill at the end of December 2022. DEA was given 90 days to let practitioners know how to meet the MATE Act's training requirement which is tied to their initial or renewal DEA registration beginning on June 27, 2023. This letter provides the information to the practitioners as to how they can meet those training requirements.

Guidance / Questions and Answers

- **Updated DEA Registration Certificate after Removal of X-Waiver**
- **Buprenorphine (MOUD) Q&A**
- **Registration Q&A**

https://www.deadiversion.usdoj.gov/pubs/docs/index.html

Training requirement effective as of June 27, 2023

https://www.samhsa.gov/medications-substance-use-disorders/provider-support-services/recommendations-curricular-elements-substance-use-disorders-training

Recommended elements include:

Substance Use Disorders

- Established screening tools for substance use or risk factors for substance use, including mental disorders
- Assessment of those who screen positive for SUDs
- Intervening along the continuum of levels of risk and use disorder
- FDA approved medications for SUDs (opioids, alcohol and tobacco)
- Medication initiation and management
- Polysubstance considerations
- Different biologic needs (metabolism – i.e., medication interactions or altered metabolism; physiology – i.e., the pregnant patient, or those with organ dysfunction)
- Patient and chosen family education
- Safety (diversion control; safe storage; use of naloxone)

Effective Treatment Planning

- Use of patient-centered language and decision making
- Use of evidenced-based communication (Shared decision-making/Motivational Interviewing)
- Social Determinants of Health
- Awareness of the disparities in pain and addiction treatment
- Collaborating with others/ensuring access to medications/referrals to services
- Naloxone distribution
- Legal and ethical issues involved in the care of patients with SUD
- Management of co-occurring mental illness and SUD

Dynamics of pain management and substance misuse

- Assessing Patients in Pain
- Components of developing an effective treatment plan
  - General principles of nonpharmacologic and pharmacologic analgesic therapy (non-opioids and opioids)
  - Multidisciplinary treatment interventions to manage pain and to improve function
- Alternatives to opioids
- Managing patients on opioid analgesics, including tapering off the medication
- Recognizing signs of OUD

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Telemedicine Flexibilities Extension

DEA United States Drug Enforcement Administration

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DEA and HHS Extend Telemedicine Flexibilities through 2024

October 06, 2023

Announcement

DEA received more than 38,000 comments on its proposed telemedicine rules and recently held two days of public listening s
continue to carefully consider the input received and are working to promulgate a final set of telemedicine regulations by the
medical practitioners time to plan for, and adapt to, the new rules once issued. Accordingly, DEA, jointly with the Department
has extended current telemedicine flexibilities through December 31, 2024. The full text of the extension, entitled "Second Te
Telemedicine Flexibilities for Prescription of Controlled Medications," was submitted to the Federal Register jointly with HHS

Second Temporary Extension of COVID-19 Telemedicine Flexibilities for Prescription of Controlled Medications

A Rule by the Drug Enforcement Administration and the Health and Human Services Department on 10/10/2023

PUBLISHED DOCUMENT

AGENCY:

Drug Enforcement Administration, Department of Justice; Substance Abuse and Mental Health Services Administration, Department of Health and Human Services.

ACTION:

Temporary rule.

SUMMARY:

On March 1, 2023 the Drug Enforcement Administration (DEA), in concert with the Department of Health and Human Services (HHS), promulgated two notices of proposed rulemakings (NPRMs) soliciting comments on proposals to allow for prescribing of controlled medications pursuant to the practice of telemedicine in

DOCUMENT DETAILS

Printed version:
PDF

Publication Date:
10/10/2023

Agencies:
Drug Enforcement Administration
Department of Health and Human Services

Dates:
As of November 11, 2023, the end of the effective period for the temporary rule published at 88 FR 30037 on May 10, 2023, is extended from November 11, 2024, to December 31, 2024. This rule is effective November 11, 2023.

Goal of extension: Avoiding lapses in patient care as public comments considered and final rules developed

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MOUD Expansion as a Tool and a Connector

In correctional Settings

In harm reduction programs

Across specialty addiction treatment settings

Across healthcare

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SAMHSA's Proposed Changes To 42 CFR Part 8

- In 2001, regulations governing methadone treatment for Opioid Use Disorder (OUD) shifted from FDA to SAMHSA
- SAMHSA reduced the scope of regulations that had been in place since 1972, but retained many original restrictions on methadone treatment
- These restrictions posed barriers to patient enrollment, but many factors precluded revisions
- The COVID-19 pandemic necessitated quickly creating regulatory flexibilities in key areas
  - Expanded parameters of take home methadone dosing
  - Initiation of buprenorphine via telehealth
- The ongoing overdose crisis calls for patient-centered, accessible care
- Feedback from multiple stakeholder groups request and/or endorse continuation of the flexibilities and other changes to the rules
- Aspects of the 2001 rules are outdated

Data supports these changes as a safe approach

- A recent CDC study published in JAMA Psychiatry found that overdose rates related to methadone have not increased as a result of expanded take home doses
- Recently conducted research surveys by George Washington University found that diversion of methadone is low among patients receiving take home doses under the COVID-19 PHE flexibility.
- Studies have also shown that the rate of diversion with methadone is lower than that of oxycodone or hydrocodone.

Highlights – Making Current Flexibilities Permanent

- Makes permanent flexibilities for the provision of unsupervised doses of methadone and the use of telehealth, including audio-only, in initiating buprenorphine

- Also, revises criteria for take home methadone doses by:
  - Reframing from rule-based to clinical judgment-based
  - Allowing patients eligibility for take home doses upon entry into treatment
  - Maintaining position of federal law not preempting state rules

Other Highlights - Expanding Access

- Updates and details admission criteria including removal of the one-year requirement for opioid addiction before admission to an OTP, in favor of consideration of problematic patterns of opioid use

- Defines and details medication initiation and services possible in mobile medication units

- Expands access through incorporation of telehealth and integration of care:
  - Initiation of methadone using audio-visual technology (SAMHSA is not extending this change to the use of audio-only telehealth platforms in assessing new patients who will be treated with methadone)

- The proposed rule is not applicable to, nor authorizes, the prescription of methadone pursuant to a telehealth visit

Other Highlights – Modernizing Practice and Language

- Updates Part 8 to reflect evidence-based practice, treatment standards, and the workforce currently providing services in OTP
- Promotes shared decision-making to align with common medical practice
- Adds new definitions, such as split dosing and harm reduction, to support evidence-based practice
- Removes stigmatizing language (e.g., “drug abuse”, “detoxification”, “legitimate treatment use”)

The Role of Harm Reduction

- Harm reduction supports people, helping prevent injury, infectious disease transmission, and death.
- Harm reduction meets people where they are and helps them move forward.
- Harm reduction supports multiple pathways to recovery.
- Harm reduction addresses social determinants of health and focuses on increasing protective factors.

See - https://www.samhsa.gov/find-help/harm-reduction

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Addressing Overdose Through Harm Reduction

https://www.samhsa.gov/find-help/harm-reduction/framework-comment-form

Finalizing Harm Reduction Framework

- Result of first-ever collaborative Harm Reduction Summit
- Established to inform harm reduction activities, policies, programs, and practices

Innovative and community-based harm reduction strategies continue

- ✓ Lives are being saved
- ✓ Social determinants of health being addressed
- ✓ Cultural humility and traditions incorporated
- ✓ Infectious diseases prevented
- ✓ Community partnerships formed
- ✓ Policies updated
- ✓ Innovative practices implemented
- ✓ Increasing access to care
- ✓ Access to live-saving supplies increasing
- ✓ Stigma and community education being addressed

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Naloxone Saturation Plans

https://www.mlive.com/news/muskegon/2021/12/vending-machine-stocked-with-free-narcan-aims-to-curb-overdose-deaths-in-muskegon.html

NALOXONE saves lives

Source: FDA

https://www.indystar.com/story/news/2018/05/05/indiana-health-officials-give-free-naloxone-prevent-overdose-deaths/582337002/

Jan 25th and 26th:
State Opioid Response Learning Community: Strengthening State Naloxone Saturation Plans and Implementation

10 State Policy Academy held July 18th and 19th

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SAMHSA Definition of Recovery

A process of change through which individuals improve their health and wellness, live self-directed lives, and strive to reach their full potential.

SAMHSA National Recovery Agenda Goals

- Inclusion
- Equity
- Peer Services
- Social Determinants
- Wellness

SAMHSA Resources

The SAMHSA Evidence-Based Practice Resource Center (EBRC) contains resources for a range of audiences related to best practices for the treatment of OUD/SUDs

www.samhsa.gov/resource-search/ebp

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SAMHSA website – Practitioner Training

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Home » Practitioner Training

Practitioner Training https://www.samhsa.gov/practitioner-training

SAMHSA's practitioner training offers tools, training, and technical assistance to practitioners in the fields of mental health and substance use disorders.

Technical Training Assistance Centers

State Opioid Response/Tribal Opioid Response Technical Assistance (SOR/TOR-TA)

Technology Transfer Centers (TTC) Program

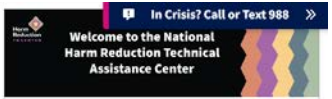
The purpose of the Technology Transfer Centers (TTC) is to develop and strengthen the specialized behavioral healthcare and primary healthcare workforce that provides prevention, treatment and recovery support services for substance use disorder (SUD) and mental illness.

National Center on Substance Abuse and Child Welfare (NCSACW)

NCSACW is a national resource center providing information, expert consultation, training and technical assistance to…

National Family Support Technical Assistance Center (NFSTAC)

The National Family Support Technical Assistance Center (NFSTAC) is the nation's first Substance Abuse and Mental…



National Harm Reduction Technical Assistance Center (NHRTAC)

The National Harm Reduction Technical Assistance Center (NHRTAC) provides free help to anyone in the country providing…

National Institutes of Health (NIH) Training Resources

As the nation's medical research agency, the National Institutes of Health (NIH) offers multiple training opportunities.

National Technical Assistance Centers for Mental Health Recovery

The National Technical Assistance Centers for Mental Health Recovery (also known as the National Consumer and Consumer-…

National Training and Technical Assistance Center for Child, Youth, and Family Mental Health (NTTAC)

NTTAC provides states, tribes, and communities with training and technical assistance (TTA) on children's behavioral…

Providers Clinical Support System (PCSS)

Providers Clinical Support System (PCSS) is a national training and clinical mentoring project developed in response to…

Provider's Clinical Support System–Universities (PCSS-Universities)

The purpose of this program is to expand/enhance access to medications for substance use disorder (SUD) services for…

Rural Opioid Technical Assistance Regional Centers (ROTA-R)

The purpose of the ROTA-R is to develop and disseminate training and technical assistance addressing opioid and…

Summary

- New policies impact how care is provided to patients
- SAMHSA plays a key role in many of these areas
- Partnerships and collaboration is key to realizing the promise of these changes

Thank you!

1-877-SAMHSA-7 (1-877-726-4727) | 1-800-487-4889 (TTY)
www.samhsa.gov | @samhsagov

1-877-SAMHSA-7 (1-877-726-4727) ● 1-800-487-4889 (TDD)

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Visit www.OpioidResponseNetwork.org
Email orn@aaap.org
Call 401-270-5900

Evaluation Survey Link

Please scan the below QR code or use the link below to access a very brief survey.

The survey will ask about your satisfaction with the training program you just completed as well as some basic demographic information. Your responses will help the Opioid Response Network improve the services they provide.

Thank you in advance for completing this survey!

Opioid Response Network