Position Statement on Access to Evidence-Based Treatment for Opioid Use Disorder

Adopted by FSMB House of Delegates, April 2024

The United States continues to grapple with the severity of a drug-related overdose and death epidemic, with overdose deaths rising to more than 107,000 in 2022.[1] Despite a decline in opioid analgesic prescriptions for 13 consecutive years, illicitly manufactured fentanyl, fentanyl analogs, stimulants and other substances are now the predominant contributors to this crisis.[2]

The urgency of addressing this public health emergency has led to significant changes recently in the landscape of opioid use disorder (OUD) treatment and policy. In 2021, of an estimated 2.5 million adults in the U.S. who had OUD in the previous year, only approximately 22% had received medications for opioid use disorder (MOUD).[3,4] Disparities remain among certain groups, with Black adults, Native Americans, women, those without employment and those living in non-metropolitan areas less likely to receive MOUD.[5] There are also disparities between access to methadone versus buprenorphine.[6] MOUD pharmaceuticals such as methadone, buprenorphine and naltrexone have been shown to be clinically effective[7] and patients may also benefit from combining MOUD with psychosocial treatment. As compared to other treatment interventions, MOUD pharmaceuticals have the strongest evidence for decreasing the risk of overdose.

Since the adoption in 2013 of *Model Policy on Data 2000 and Treatment of Opioid Addiction in the Medical Office* by the Federation of State Medical Board's (FSMB) House of Delegates, advances in research, law and policy have directly impacted the treatment of OUD. Policymakers at the state and local level have implemented – and are still implementing – changes to the laws that regulate the treatment of OUD. Their efforts are generally centered on individualizing care, diminishing stigma and other barriers to treatment and various harm reduction strategies, and integrating evidence-based OUD treatments into standard medical practice. These changes have occurred at the federal level, with requirements for ensuring access to MOUD the Federal Bureau of Prisons. Additionally, all Drug Enforcement Administration (DEA) registrants are now required to have a minimum amount of education related to substance use disorders (SUD). State-level policy changes have been implemented on multiple levels to enhance access to MOUD through, for example, removal of insurance prior authorization requirements, enforcement of mental health and substance use disorder parity laws, and other policy changes. State-level also exist related to dosage, counseling, and visit frequency for treatment. While it remains challenging for many individuals to access affordable, available OUD treatment, there is increasing acknowledgement by many stakeholders of the benefits of MOUD.

Strategies for Prescribing Opioids for the Management of Pain (FSMB House of Delegates 2024) sets forth guidelines that generally apply when treating patients with OUD, including the importance of patient evaluation, individualized treatment planning, patient education and informed consent, monitoring, and maintaining complete and accurate medical records. Critical concepts include the importance of patient-centered care, reducing stigma for both patients and clinicians, equity in treatment, utilization of evidence-based practices, striving to achieve

continuity of care and reducing barriers to treatment. When treating patients with OUD, physicians should recognize the following precepts and principles:

- OUD is a treatable, chronic illness.
- Care should be individualized and patient-centered, recognizing the diverse needs of specific patient populations, such as individuals from historically marginalized groups, adolescents, pregnant persons, and those with co-existing medical conditions.
- For most patients, treatment with MOUD, coupled with psychosocial treatment, promotes long-term recovery. Access to medication should not be contingent upon receipt of counseling services.
- Screening, evaluation, and access to treatment, including medications and recovery support services for substance use disorders should be equitable across demographics, regardless of age, sex, race, ethnicity or socioeconomic status.
- Physicians, regardless of specialty or where they are in their continuum of practice, should have a fundamental understanding of addiction and treatment.
- Stigma associated with OUD and other substance use disorders deters patients from seeking and committing to treatment,[8] and may also limit clinicians' willingness to treat patients with OUD and may diminish the quality of care patients receive. Research demonstrates that language used by health care professionals contributes to stigmatization and discrimination, and thereby negatively impacts patient care and outcomes. Useful resources, including continuing education, for reducing stigma among health professionals may be found at the National Institute on Drug Abuse (NIDA) and at the Substance Abuse and Mental Health Services Administration (SAMHSA), among others.[9]
- Physicians should actively promote and employ individual patient-tailored harm reduction strategies, such as lower barriers to care within their own clinical practice and educating patients about naloxone and syringe service programs (where they are lawfully permitted), including when MOUD pharmaceuticals are prescribed.[10]

Changes in federal law and regulatory policy will necessitate changes to state policies and clinical guidelines:

Removal of the "X-Waiver"

The *Consolidated Appropriations Act of 2023*, signed into law by President Biden, eliminated the requirement for physicians to obtain a waiver from the Drug Enforcement Administration (DEA), commonly referred to as the "X-waiver," to prescribe buprenorphine for OUD treatment, outside a federally regulated Opioid Treatment Program(OTP). This change has increased the number of eligible prescribers (i.e., physicians, dentists, physician assistants, nurse practitioners) from approximately 130,000 to 1.1 million. The *Medication Access and Training Expansion Act ("MATE Act")* was also included in this legislation, and it requires applicants for a DEA registration or renewal to affirm completion (with some exceptions) of a one-time 8-hour education requirement focused on the treatment and management of patients with opioid and other substance use disorders.[11] Although clinicians are no longer required to obtain an X-Waiver to prescribe buprenorphine for the treatment of OUD, there has yet to be a significant documented increase in the prescribing of these medications.[12]

Naloxone

While not a treatment for OUD, naloxone, an opioid reversal medication, continues to save thousands of lives. States have enacted laws to increase its availability, and have granted certain immunities for individuals seeking medical assistance during overdose events or experiencing an overdose through the passage of Good Samaritan laws. As of January 2024, one version of naloxone is available over the counter. Other versions are available without prescription through pharmacies and community-based groups. Naloxone needs to be made available not only to patients with OUD, but also to people who regularly come into contact people with OUD such as family members.[13]

DEA Tele-Prescribing Rules

In 2008, the *Ryan Haight Online Pharmacy Consumer Protection Act* was signed into law by President Bush, limiting the initial prescribing of controlled substances via telemedicine to only very specific circumstances. In response to the COVID-19 pandemic, the DEA established a waiver to allow such prescribing via telemedicine to facilitate access to care while reducing the risk of viral spread through personal encounter.

From 2020 to 2023, significant numbers of patients with OUD were able to access care via telemedicine, with a notable 143% increase in availability of outpatient SUD treatment services delivered via telehealth from 2020-2021.[14,15] In 2022, approximately 2.6 million people received SUD treatment via telehealth.[16] Several studies have suggested that remote access led to higher rates of buprenorphine treatment initiation and retention in care.[17] Facing a potential rollback of the prescribing waiver at the end of the COVID-19 public health emergency, concerns grew over the negative impact of reverting to previous in-person requirements could have on individuals undergoing such treatment. In response, the DEA created proposed rules aimed to limit, but not eliminate, the prescribing of controlled substances to a new patient via telemedicine. Under the proposed rules, patients who have received their buprenorphine via telemedicine would be mandated to have an in-person visit within 30 days to continue their prescriptions.[18]

The proposed rule received more than 37,000 comments and the DEA responded by extending the waiver until the end of 2024 while a final rule is developed. Studies conducted during this period demonstrated that the flexibilities for buprenorphine under the waiver not only enhanced access but also resulted in care that was comparable to in-person care.[19,20] In November 2023, the Office of the Inspector General (OIG) of the U.S. Department of Health and Human Services (HHS) released a report showing the risk of diversion of buprenorphine to be extremely low.[21] DEA's final rule regarding prescriptions first issued via telemedicine is expected to be finalized in 2024.

On January 31, 2024, the HHS, through SAMHSA, issued a final rule making permanent the pandemic-era waiver enabling providers affiliated with certified OTPs to order buprenorphine through telehealth, including audio-only consultations, without first requiring an in-person visit.[22] The rule also allows OTP clinicians to provide patients enrolled in their OTP with methadone for at-home use, ranging from seven to 28 doses of methadone, depending on the duration of the individual's treatment. Lastly, the rule removed the requirement that minors should have had at least two documented unsuccessful attempts to manage their drug withdrawal before receiving methadone or buprenorphine. The rule became effective April 2, 2024.

Access to Methadone

In 2019, more than 400,000 patients with OUD accessed methadone for treatment or withdrawal through OTP facilities. This number decreased to approximately 300,000 in 2020.[23] The limitations

imposed by the COVID-19 pandemic prompted SAMHSA to issue a guidance for OTPs that allowed states to request "blanket exceptions" for a certain amount of methadone to be given for take-home use, based on a patient's particular need. Specific exemptions stemming from this guidance remain in place in certain jurisdictions as of January 2024.

The requirement that patients with OUD access methadone only through OTP facilities has been highlighted as a significant barrier to care. In addition to the flexibilities promulgated during COVID-19, DEA authorized treatments for OUD to be dispensed by "mobile medication units" as long as they were in compliance with applicable federal and local laws.[24] There is also legislation pending before Congress that would create a process for certain addiction medicine physicians and addition psychiatrists to prescribe methadone for OUD treatment or withdrawal. Under this legislation, pharmacists could dispense methadone to individuals for unsupervised use within certain parameters around the quantities that may be dispensed.[25] If enacted, state medical boards could have a role in regulating the prescribing of methadone for OUD to meet the needs of patients with OUD in their respective states. Continued efforts by government agencies toward expanding access to methadone for treatment and withdrawal are expected.

Conclusion

The FSMB continues to support, as it has in the past, policies related to the appropriate prescribing of controlled substances, including opioids, and expanding access to evidence-based OUD treatments and overdose reversal medications. The FSMB will continue to collaborate with regulatory licensing colleagues in dentistry, nursing, and pharmacy, as well as with state, territorial and federal government agencies, to help identify and reduce barriers, educate physicians and other health professionals, and promote policies that enhance care, help reduce stigma and improve the health of patients with OUD, and reverse a national epidemic that has contributed to the deaths of more than one million people since 1999.

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[2] "Overdose Epidemic Report 2023," American Medical Association, 2023, https://end-overdose-epidemic.org/wp-content/uploads/2023/11/23-894446-Advocacy-2023-overdose-report_FINAL.pdf

[3] Christopher M. Jones, "Use of Medication for Opioid Use Disorder Among Adults with Past-Year Opioid Use Disorder in the US, 2021,"*JAMA Netw Open*, August 2023, doi:10.1001/jamanetworkopen.2023.27488

[4] Medications for the Treatment for Opioid Use Disorder (MOUD) refers to the medications that are FDA-approved for the treatment of Opioid Use Disorder (OUD), including methadone, buprenorphine, and naltrexone. "Policy on Physician Illness and Impairment: Towards a Model that Optimizes Patient Safety and Physician Health," Federation of State Medical Boards, April 2021, https://www.fsmb.org/siteassets/advocacy/policies/policy-on-physician-impairment.pdf

[5] Christopher M. Jones, "Use of Medication for Opioid Use Disorder Among Adults with Past-Year Opioid Use Disorder in the US, 2021,"*JAMA Netw Open*, August 2023, doi:10.1001/jamanetworkopen.2023.27488, Noa Krawczyk. "Medications for Opioid Use Disorder Among American Indians and Alaska Natives: Availability and Use Across a National Sample." *Drug and Alcohol Dependence.* March, 2021; https://pubmed.ncbi.nlm.nih.gov/32022884/ https://doi.org/10.1016/j.drugalcdep.2021.108512.)

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[9] Substance Abuse and Mental Health Services Administration, *Treatment Improvement Protocol 63: Medications for Opioid Use Disorder,* 1-3, 2021, https://store.samhsa.gov/sites/default/files/pep21-02-01-002.pdf
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[11] U.S. Department of Justice, *MATE Training Letter*, March 27 2023, https://deadiversion.usdoj.gov/pubs/docs/MATE_Training_Letter_Final.pdf
[12] Joanna Krupp, "Impact of Policy Change on Access to Medication for Opioid Use Disorder in Primary Care," *Southern Medical Journal*, April 2023, doi: 10.14423/SMJ.0000000000001544
[13] Amy Leiberman, "Legal Interventions to Reduce Overdose Mortality: Overdose Good Samaritan Laws," The Network for Public Health Law, July 17, 2023, https://www.networkforphl.org/resources/legal-interventions-to-reduce-overdose-mortality-overdose-good-samaritan-laws/
[14] Substance Abuse and Mental Health Services Administration (SAMHSA*), Key Substance Use and Mental Health Indicators in the United States: Results from the 2022 National Survey on Drug Use and Health*, (HHS Publication No. PEP23-07-01-006, NSDUH Series H-58), 2023, 53 https://www.samhsa.gov/data/sites/default/files/reports/rpt42731/2022-nsduh-nnr.pdf
[15] "For patients with OUD, these regulatory changes removed the requirement of the Ryan Haight Act to meet with a clinician in person before initiating MOUD. In preliminary qualitative and survey research, OUD clinicians reported that telemedicine has led to increased access to buprenorphine and higher rates of MOUD initiation, in part by removing transportation barriers and relieving the burdens of those with competing demands, such as childcare and work." Ruth Hailu, "Telemedicine Use and Quality of Opioid Use Disorder Treatment in the US During the COVID-19 Pandemic," *JAMA Net Open,* January 2023, doi: 10.1001/jamanetworkopen.2022.52381
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