Expanding Access to Medications for Opioid Use Disorder (MOUD)

BACKGROUND

On December 29, 2022, President Biden signed into law the Consolidated Appropriations Act of 2023. This omnibus budget bill included a wide range of healthcare-related provisions, including the Mainstreaming Addiction Treatment (MAT) Act. This now-enacted law removes a provision that required physicians to receive a waiver (DATA-Waiver, sometimes referred to as the "X-Waiver") to treat patients suffering from opioid use disorder (OUD) with certain medicines (including buprenorphine) and removes the limit on the number of OUD patients physicians may treat. This was done to streamline and expand access to medications for opioid use disorder (MOUD).

Since the passage of this law, the administrator of the Drug Enforcement Administration (DEA) issued a directive stating:

> Medication for opioid use disorder helps those who are fighting to overcome opioid use disorder by sustaining recovery and preventing overdose. At DEA, our goal is simple: we want medications for opioid use disorder to be readily and safely available to anyone in the country who needs it.
>
> All DEA registrants should be aware of the following:
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> - A DATA-Wavier registration is no longer required to treat patients with buprenorphine for opioid use disorder.
> - Going forward, all prescriptions for buprenorphine only require a standard DEA registration number. The previously used DATA-Waiver registration numbers are no longer needed for any prescription.
> - There are no longer any limits or patient caps on the number of patients a prescriber may treat for opioid use disorder with buprenorphine.
> - The Act does not impact existing state laws or regulations that may be applicable.

Separately, in mid-December 2022, the Health and Human Services (HHS) Substance Abuse and Mental Health Services Administration (SAMHSA) issued a proposed rule: "Medications for the Treatment of Opioid Use Disorder [OUD]" intended to improve Americans' access to, and experiences with, OUD treatment, in particular through Opioid Treatment Programs (OTPs). The proposed changes reflect the widespread desire by many stakeholders for SAMHSA to provide greater autonomy to OTP practitioners, positively support recovery, and continue certain flexibilities that were put in place at the start of the nation's COVID-19 public health emergency.

With most DEA-registered providers now having the ability to prescribe buprenorphine, and with the simplifications outlined in SAMHSA's proposed rule, it is likely that more patients suffering from OUD will be able to receive these important medications. With this expanded access, there may also be a corresponding increase in the demand for buprenorphine to support any rise in prescriptions.

OBLIGATIONS FOR DISTRIBUTING MOUD PRODUCTS

MOUD products are important, often lifesaving, medications aiding the treatment of opioid addiction. They are also scheduled opioids under the Controlled Substances Act (CSA), the statute governing the manufacture, distribution, dispensing and prescribing of controlled substances. While the Act removed a regulatory obligation for physicians, wholesalers' responsibilities regarding the distribution of MOUD products remain the same. Specifically, wholesale distributors must:

- Be appropriately registered with DEA;
- Provide effective controls and procedures to guard against the theft and diversion of controlled substances; and,
- Operate a system to identify suspicious orders of controlled substances and report those orders to DEA and any state agencies with similar reporting requirements.

IDENTIFYING AND REPORTING SUSPICIOUS ORDERS

Many distributors use thresholds to identify "suspicious orders" of controlled substances, including those of unusual size, pattern or frequency.[1] If an order is determined to be suspicious due to a distributor's internal processes for identifying such orders (which may involve automated thresholds and/or a manual due diligence review), the order should not be filled, and it must be reported. The July 2021 settlement entered into by three of the nation's largest distributors (the 2021 National Opioid Settlement Agreement) also requires using thresholds and specified methods that must be applied to their development and use. These methods were established in connection with heightened protocols and requirements around suspicious orders.

It is possible that, as more prescribers issue prescriptions for MOUD products, the pharmacies filling those prescriptions will have a corresponding increase in the volume of MOUD products ordered from distributors that may, in turn, result in more pharmacy orders being identified by distributors as suspicious under their respective suspicious order monitoring programs.

UPDATING ORDERING THRESHOLDS

Fortunately, most distributors have processes in place to amend and change customer thresholds. Threshold changes must be supported by documentation and may take time to approve. Ordering patterns for controlled

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[1] Pharmacists and prescribers also have a responsibility to help prevent diversion, although due to their respective roles in patient treatment, this responsibility differs from that of the manufacturer or wholesale distributor. For example, DEA's regulations (21 CFR 1306.04) state:

> "A prescription for a **controlled substance …** must be issued for *a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.* The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a **corresponding responsibility rests with the pharmacist who fills the prescription**. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of Section 309 of the Act (21 U.S.C. 829) and the person **knowingly filling** such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations …."

substances may change for various reasons, and there are many legitimate reasons for increasing customer thresholds. One such reason may relate to the increased availability of MOUD products considering the recent DEA and SAMSHA changes. Should pharmacies experience a legitimate need to purchase more MOUD products, they should work with their distributor to address their need in accordance with the distributor's processes and procedures.

Additionally, the distributors who are subject to the National Opioid Settlement have a multi-prong process for adjusting thresholds in the event a change is necessary. Under the agreement, a "distributor may increase or decrease a Customer Threshold as set forth in its CSMP policies and procedures, subject to Sections XII.C.3.b through XII.C.3.e [of the distributor settlement agreement].[2]

Many, if not most, of the wholesale distributors not subject to the settlement agreement maintain similar processes for adjusting thresholds if/when it is determined that modifications are warranted.

RESOURCES

Mainstreaming Addiction Treatment Act, Consolidated Appropriations Act, 2023.

Substance Abuse and Mental Health Services Administration. "Buprenorphine." Last updated: March 21, 2023. https://www.samhsa.gov/medications-substance-use-disorders/medications-counseling-related-conditions/buprenorphine. (Contains facts about buprenorphine, a checklist for providers treating Opioid Use Disorder, as well as suggestions for providers to minimize diversion risks.)

Drug Enforcement Administration (DEA). "DEA's Commitment to Expanding Access to Medication-Assisted Treatment." News Release, March 23, 2022. https://www.dea.gov/press-releases/2022/03/23/deas-commitment-expanding-access-medication-assisted-treatment#:~:text=Beginning%20in%20March%202022%2C%20practitioners,experiencing%20acute%20opioid%20withdrawal%20symptoms.

Virginia Department of Medicaid Assistance Services (DMAS). "Coverage of Medications for the Treatment of Opioid Use Disorder." MES Bulletin, March 17, 2022. https://vamedicaid.dmas.virginia.gov/bulletin/coverage-medications-treatment-opioid-use-disorder.

ABOUT THE HEALTHCARE DISTRIBUTION ALLIANCE

The Healthcare Distribution Alliance (HDA) represents primary pharmaceutical distributors — the vital link between the nation's pharmaceutical manufacturers and pharmacies, hospitals, long-term care facilities, clinics and others nationwide. Since 1876, HDA has helped members navigate regulations and innovations to get the right medicines to the right patients at the right time, safely and efficiently. The HDA Research Foundation, HDA's nonprofit charitable foundation, serves the healthcare industry by providing research and education focused on priority healthcare supply chain issues.

[2] *See*: PDF page 518; i.e., Page P-18 of EXHIBIT C AS OF 5.27.22; EXHIBIT G AS OF 01.10.23)