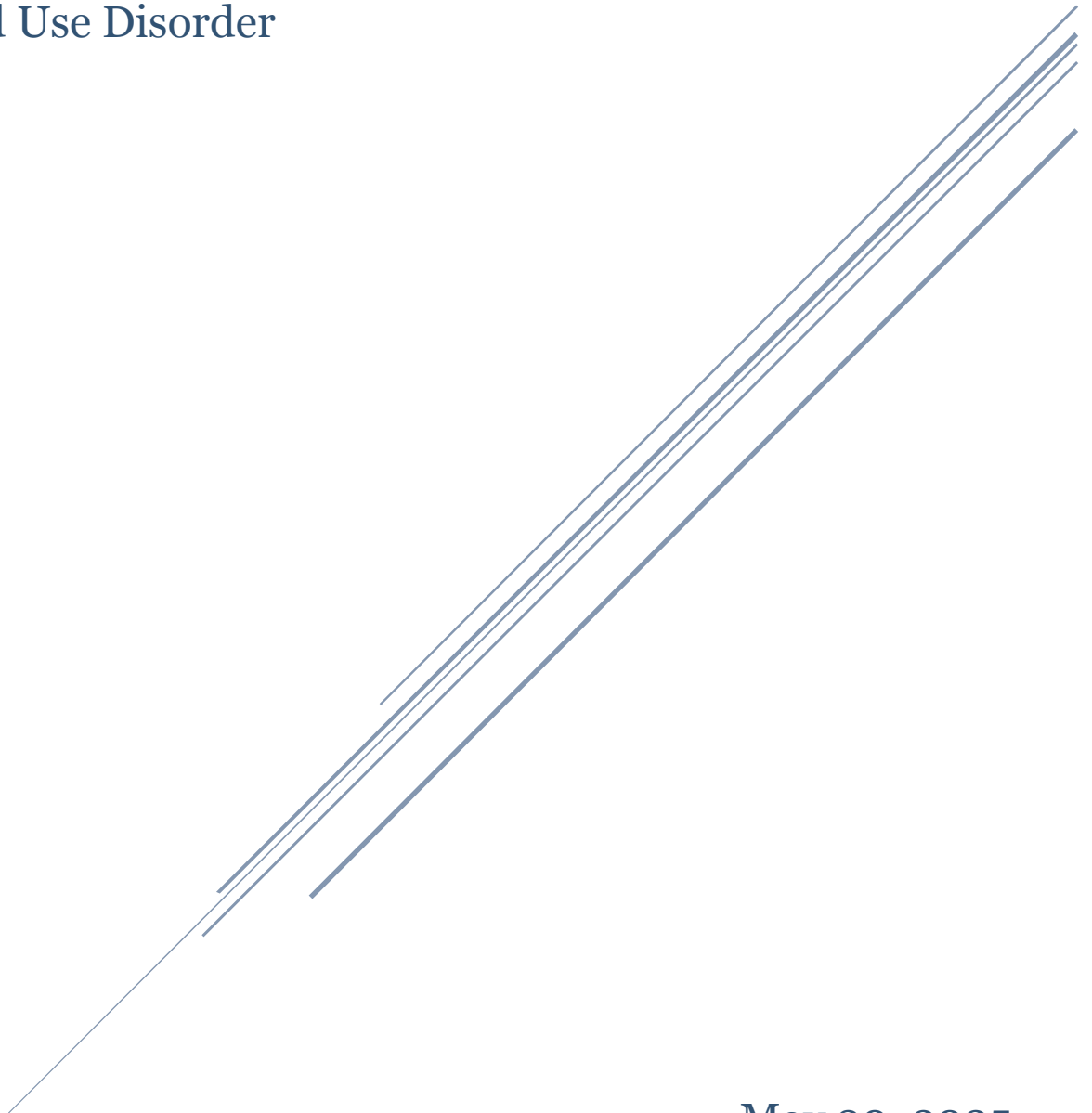




## AATOD STATEMENT

The Role of the Drug Enforcement Administration in  
Approving the Use of Methadone Products in Treating  
Opioid Use Disorder



May 20, 2025

## **The Role of The Drug Enforcement Administration in Approving the Use of Methadone Products in Treating Opioid Use Disorder**

There have been a number of policy discussions and statements with regard to methadone prescribing for opioid use disorder in physician practices. These discussions hinge on the idea that the Drug Enforcement Administration (DEA) has the independent regulatory authority to allow physicians to prescribe methadone to treat opioid use disorder. In our reading of the law, this is not the case.

The Controlled Substances Act, passed by Congress in 1970, prohibits the use of methadone outside of the scope of OTPs in treating opioid use disorder.

Methadone, as a Schedule II opioid, can only be administered or dispensed through an opioid treatment program. It is important to reference the founding regulation, which support this conclusion. The Food and Drug Administration (FDA) commissioned the Institute of Medicine (IOM) to develop a report with regard to the federal regulation of methadone treatment. The report makes a number of important references.

The report, published in 1995, based on the U.S. Public Health Service (Contract No. 282-992-0079) cited the following policies. "The Drug Enforcement Administration has responsibility, under the Controlled

Substances Act of 1970 and the Narcotic Addict Treatment Act of 1974, for preventing the diversion and abuse of methadone by establishing and monitoring security and record-keeping procedures for licensed methadone programs." (1) [Institute of Medicine - Federal Regulation of Methadone Treatment, National Academy Press 1995]

The report goes on to say that the law enforcement sections of the federal regulations had consolidated all prior federal statutes into "the Controlled Substances Act and the Controlled Substances Import and Export Act (Titles II and III of the Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 U.S.C. 801 et seq.), which established a 'closed system' of distribution for manufacturing, distributing, and dispensing controlled substances, including methadone, morphine, codeine, and hydrocodone." (2)

It is important to keep in mind that the authority for the DEA in this policy arena was established under the Controlled Substances Act and the Narcotic Addict Treatment Act of 1974, which was related to the registration of OTP applicants.

Accordingly, "Practitioners who continued to dispense narcotic drugs for maintenance or detoxification without proper registration could face legal consequences under the Controlled Substances Act. This includes potential prosecution. Specifically, the phrase refers to practices related to medications like methadone used in medication-assisted treatment (MAT), where practitioners must be registered to dispense these drugs for their intended purpose. The main concern is the potential for diversion and misuse of these medications..." (3)

This practice exists at the present time, which is why OTPs, registered through the DEA and SAMHSA, are the only entities that can treat OUD with methadone, as a Schedule II opioid.

It is important to reference the federal regulations, which continue in force until the present day. This is why the Drug Enforcement Administration does not have the independent regulatory authority to allow practitioners to prescribe methadone without amending the Controlled Substances Act of 1970. This represents the established law.

#### References:

- (1) Institute of Medicine (US) Committee on *Federal Regulation of Methadone Treatment*. Washington, DC: National Academy Press (US), 1995. – Page 98
- (2) Institute of Medicine (US) Committee on *Federal Regulation of Methadone Treatment*. Washington, DC: National Academy Press (US), 1995. – Page 124
- (3) Institute of Medicine (US) Committee on *Federal Regulation of Methadone Treatment*. Washington, DC: National Academy Press (US), 1995. – Page 96