## **Prescribing Controlled Psychostimulants for** Stimulant Use Disorder





A Brief Guide on Legal Considerations

## I. Background

Between 2010 and 2021, the incidence of U.S. overdose deaths involving both fentanyl and stimulants increased from 0.6% to 32.3%, and, in 2022, more than 50,000 overdose deaths involved stimulants, either alone or in combination with opioids.<sup>12</sup>

Evidence-based treatments for stimulant use disorder are limited, and there are no medications currently approved by the U.S. Food and Drug Administration (FDA) to treat stimulant use disorder (StUD). In November 2023, the American Society of Addiction Medicine (ASAM) and the American Academy of Addiction Psychiatry (AAAP) jointly released the Clinical Practice Guideline on the Management of Stimulant Use Disorder (StUD) (Guideline). The Guideline recommends that trained clinicians† consider prescribing certain psychostimulants for the treatment of cocaine use disorder and amphetamine-type stimulant use disorder.3 These recommendations build on growing research interest in this area, including several recent meta-analyses, and draft guidance from the FDA in October 2023 to support industry's development of drugs for the treatment of StUDs.<sup>45</sup>

#### This brief resource provides practitioners with:

- + An overview of the federal legal framework governing the use of psychostimulants for the treatment of StUD.
- + A snapshot of important state-level legal considerations for the use of psychostimulants for the treatment of StUD.
- + Guidance on how to assess a state's legal landscape, including questions to ask and where to find additional information and guidance.
- A list of additional resources.

## A Note on **Stigmatizing Language**

Many state laws contain stigmatizing and harmful language to describe substance use disorder and people who use(d) drugs. This resource will refer to such language where it appears in state laws because these outdated and often ambiguous terms bear on laws' scope and application.

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Disclaimer: The legal information provided in this document does not constitute legal advice or legal representation. For legal advice, individuals should consult with an attorney licensed to practice in their state.

<sup>&</sup>lt;sup>†</sup> The Guideline states that "[p]sychostimulant medications should only be prescribed to treat StUD by: physician specialists who are board certified in addiction medicine or addiction psychiatry; and physicians with commensurate training, competencies, and capacity for close patient monitoring." ASAM/AAAP Clinical Practice Guideline on the Management of Stimulant Use Disorder. 2023. Accessed September 1, 2024.



## II. Overview of the Federal Legal Framework

The federal Controlled Substances Act (CSA) does not impose any unique limitation on dispensing (including prescribing) of controlled substances for withdrawal management or the treatment of substance use disorder (SUD) other than the use of Schedule II "narcotic drugs." Prescription psychostimulants fall outside the definition of "narcotic drugs" and thus outside the scope of the more stringent restrictions that can apply to methadone (and formerly buprenorphine) under federal law.

# How does federal law define "narcotic drug"?

"Narcotic drug" includes opioids, poppy straw, coca leaves, cocaine, ecgonine, and related substances.

See <u>21 USC 802(17)</u> for complete definition.

Prescribing psychostimulants for the treatment of StUD is governed by the general rule for authorized prescribing of any controlled substance: a prescription must be issued for a legitimate medical purpose by an individual practitioner acting within the usual course of their professional practice.<sup>7</sup>

## III. State-level Legal Considerations

Outside the context of Schedule II "narcotic drugs" for withdrawal management or SUD treatment, states are the primary regulators of medical practice, and practitioners must understand if and how the jurisdiction(s) where they practice impose requirements or limitations on the prescribing of psychostimulants to treat StUD. Accordingly, the ASAM/AAAP <u>Clinical Practice Guideline on the Management of Stimulant Use Disorder (StUD)</u> instructs that "clinicians should be aware of state law where they practice that may restrict prescribing of psychostimulant medications for StUD."<sup>8</sup>

## **Overview of State Legal Frameworks**

#### **General Considerations**

Complexity. A state's legal framework for regulating medical practice generally and controlled substance prescribing specifically can be unclear with little guidance on scope and applicability. Moreover, enforcement may vary and not align with what is written. Practitioners should be aware of potential legal issues and opportunities to seek clarification.

Varied Sources. Various sources and authorities should be considered, including legislatively enacted statutes, administrative regulations (also sometimes referred to as administrative rules), case law, authoritative interpretations, guidance, and prior enforcement actions. Each can have different enforcement authority, consequences for violations, and pathways for reform:

- + Enforcement authority can be civil (including administrative), criminal, or both (e.g., medical boards vs. law enforcement vs. employer peer review or health center credentialing authority).
- + Consequences for violations (e.g., criminal prosecution vs. professional discipline).
- + Pathways for reform (e.g., legislative vs. administrative).

General Controlled Substance Applicability. States may generally regulate controlled substances and associated medical practice, which can affect the prescribing of psychostimulants for the treatment of StUD. For example, states can define their own general prescribing standards for controlled substances, as well as how those standards are interpreted and enforced. States also define their own grounds for professional discipline.

## **Specific Considerations**

Some states have specific state statutes and rules/regulations that can affect the prescribing of psychostimulants for StUD.9 Most can be classified into one or more of the following four categories:

#### 1. Restricted indications for psychostimulants.

Some states limit the indications for the prescribing of specific psychostimulants (i.e., enumeration of specific permitted and/or prohibited indications for which specified psychostimulants may be prescribed).

**Example:** Physicians in Ohio may only utilize a Schedule II stimulant for the following six indications: narcolepsy and other hypersomnias; ADHD and/or related disorders; major or mild neurocognitive disorder due to TBI or substance/medication-induced major or mild neurocognitive disorder; depression that is unresponsive to other therapies; as an adjunct in the treatment of chronic pain; and binge eating disorder.10 Ohio Admin. Code § 4731-11-03(B)(2).

## 2. Heightened standards and/or additional requirements for psychostimulants.

Some states impose a heightened standard or specific additional steps when prescribing psychostimulants (e.g., for off-label uses, for specified populations, or in general).

**Example:** In Arkansas, off-label prescriptions of Schedule II psychostimulants must be "justified with appropriate medical rationale and documentation of evidence-based research and experience." Ark. Medical Board Rule #7.

3. Restrictions or prohibitions on prescribing controlled substances for the purpose of (a) withdrawal management and/or SUD treatment; (b) continuing an individual's "drug dependence"; or (c) maintaining an individual's "customary use."

This category has substantial variation. Some states restrict or prohibit prescribing controlled substances (including controlled psychostimulants) for withdrawal management and/or the treatment of SUD generally. Other states more specifically restrict or prohibit prescribing controlled substances for the purpose of continuing a patient's "dependency" or maintaining their "customary use."

**Example:** In Michigan, "good faith" prescribing of a controlled substance excludes a prescription for the treatment of an "individual's physical or psychological dependence on or addiction to a controlled substance" except as specifically authorized. MCL § 333.7333(1).

**Example:** South Dakota prohibits prescribing a controlled substance for the purpose of continuing a patient's drug dependency.<sup>13</sup> S.D. Admin. R. 44:58:08:04.

4. Restrictions or prohibitions on prescribing controlled substances to individuals because of their current and/or past SUD, "drug dependency," or substance misuse.

This category also has wide variation but generally functions to restrict or prohibit prescribing controlled substances (including controlled psychostimulants) to patients with current or prior SUD, dependency, or misuse, *independent of the indication for the prescription.*<sup>‡</sup> In other words, this category targets a specific patient cohort regardless of diagnosis or indication for a particular controlled medication.

**Example:** Oklahoma deems it unprofessional conduct to prescribe any controlled substance to an "addict," "habitue," or "previously drug dependent" person, except as otherwise permitted by law. 4 Okla. Admin. Code § 435:10-7-4(25).

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<sup>‡</sup> The terminology in this category frequently features highly stigmatizing terms such as "drug abuser," "habitue," and "addict."

## What does this mean for the treatment of people with StuD?

States can hinder clinical practice and their legal frameworks can reflect stigmatizing attitudes toward patients with current or prior SUD, substance dependency, or substance misuse. While many of these state legal frameworks have been in place for decades, others are more recent. States should assess whether and how their approaches are out of step with current research and best practice, as well as how they help or hinder a practitioner's ability to fulfill their responsibility to provide optimal, patient-centered, and individualized care that is free of stigma and discrimination.

## IV. Assessing a State's Legal Landscape

This section provides a step-by-step guide on how practitioners can assess the legal landscape in the jurisdiction(s) where they practice. Vital Strategies will publish an issue brief that details many relevant statutes and rules/regulations by state in Winter 2024-2025.

## Review statutes and rules/regulations for relevant provisions.

TIP: Relevant provisions may be in different areas of state codes, from general criminal laws to medical practice laws to pharmacy laws. Applicable administrative rules/regulations may be issued by, for example, medical/pharmacy boards, state health departments, law enforcement agencies, or general licensing agencies.

TIP: Always review how relevant terms are defined, which may differ from common understanding.

#### **Key Questions to Ask:**

- 1. What is the general standard for prescribing controlled substances in the state?
- 2. Does the provision restrict the indications for prescribing psychostimulants? If so,
  - a. Which types of psychostimulants are covered? Are any non-covered psychostimulants clinically appropriate for StUD?
    - TIP: State controlled substance schedules may differ from federal controlled substance schedules. To determine which types of psychostimulants are covered, you should first identify whether state and/or federal controlled substance schedules are applicable and where particular medications fall within the applicable schedules.
  - b. For which indications may covered psychostimulants be prescribed? Would any of the permitted indications encompass StUD?
  - c. Does the provision establish a process to obtain approval to prescribe covered psychostimulants for non-permitted indications?



- Does the provision impose heightened standards and/or additional requirements for prescribing psychostimulants? If so,
  - a. Does the provision apply a different standard for prescribing for off-label uses?
  - b. Are there additional requirements or limitations when prescribing to specific populations (e.g., pregnant individuals)?
- 4. Does the provision restrict or prohibit prescribing controlled substances for the purpose(s) of withdrawal management, SUD treatment, to continue a patient's "dependency," or to maintain "customary use"? If so,
  - a. Which purpose(s) are restricted or prohibited?

## **Purpose versus Patient?**

It can be difficult to parse the provisions that fall into questions 4 and 5.

While not an exact science, it may be helpful to ask yourself "is this provision targeting the purpose(s) of a prescription or is it about some current or prior characteristic/ status of the patient receiving the prescription?"

- b. Which types of controlled substances are covered? Is it limited to narcotic drugs or apply more broadly?
- c. If prescribing is restricted rather than prohibited, what criteria must be met and/or exceptions apply?
- 5. Does the provision restrict or prohibit prescribing controlled substances to individuals because of their current and/or past SUD, "drug dependency," or substance misuse? If so,
  - a. Does the provision apply to a patient's current status, past status, or both?

    TIP: Examples of how a provision refers to status could be "addict(ed)," "drug dependent person," "drug abuser," or "habitual user."
  - b. Which types of controlled substances are covered? Is it limited to narcotic drugs or apply more broadly?
  - c. If prescribing is restricted rather than prohibited, what criteria must be met and/or exceptions apply?

#### 6. Universal questions:

There are some questions that should be considered universally when assessing a state's statutes and rules/regulations around prescribing psychostimulants. Remember to consider the following questions for *each* relevant provision.

- a. Which types of practitioners are covered?
- b. What conduct is covered (e.g., prescribing, dispensing, administering, furnishing)?
- c. How are key terms defined (e.g., "dispensing" can be defined to include prescribing or administering, states vary in how they define "drug dependency")?
- d. Which entity (or entities) enforces the provision and is there evidence of recent enforcement involving circumstances analogous to prescribing psychostimulants for StUD?
- e. What are the potential consequences for violations (e.g., criminal prosecution, civil fines, professional discipline)?

Review any guidance or authoritative interpretations of state statutes or rules/regulations and identify whether there is any relevant case law.

State statutes and rules/regulations affecting the prescribing of psychostimulants can be complex and may be ambiguous as written. For this reason, it is valuable to consult other sources and authorities when available to clarify the scope and application of these provisions. Some options to consider include:

- 1. Guidance, advisory opinions, or policy statements from relevant bodies, such as state medical boards or boards of pharmacy.
- 2. Authoritative interpretations, such as a formal opinion from a state attorney general.
  - TIP: Note that these kinds of interpretations can be informative but often are not legally binding.
- 3. Case law showing how the provision(s) has been interpreted and applied in particular situations.
  - TIP: Case law can be informative, persuasive, or binding. When consulting a given case, assess what level of authority it has in the jurisdiction(s) where you practice.

#### Identify opportunities to seek additional guidance.

Where the kinds of resources described in the previous step do not exist, practitioners may consider seeking additional guidance from authorities in their jurisdiction(s). In some jurisdictions, it is possible for a licensee to directly request guidance from the state board(s) that oversees the licensee's profession.<sup>15</sup> Advisory opinions from a state attorney general often must be requested by a state or local official.

### Consult an attorney licensed to practice in your state.

The legal landscape for prescribing of psychostimulants in the jurisdiction(s) where you practice may be unclear even after doing all the above – seek official legal advice when necessary!

## V. Additional Resources

- 1. ASAM/AAAP Clinical Practice Guideline on the Management of Stimulant Use Disorder.
- 2. Information on federal law
  - a. Ruan v. United States (2022) (Supreme Court decision holding that a criminal conviction for unlawful dispensing under the Controlled Substances Act requires the government to prove beyond a reasonable doubt that an otherwise authorized dispenser knowingly or intentionally acted in an unauthorized manner).
  - b. Suen LW, Coffin PO, Boulton KE, Carr DH, Davis CS. Prescribing psychostimulants for the treatment of stimulant use disorder: Navigating the federal legal landscape. Journal of Addiction Medicine. Published online January 23, 2025. DOI: <a href="http://doi.org/10.1097/ADM.0000000000001437">http://doi.org/10.1097/ADM.00000000000001437</a>
- 3. Information on states
  - a. Boards
    - i. Federation of State Medical Boards, Contact a State Medical Board.
    - ii. National Association of Boards of Pharmacy, Boards of Pharmacy.
    - iii. National Council of State Boards of Nursing, Contact a U.S. Member.

#### 4. Additional

a. Centers for Disease Control and Prevention. A Stimulant Guide: Answers to Emerging
 Questions about Stimulants in the Context of the Overdose Epidemic in the United States.
 National Center for Injury Prevention and Control, Centers for Disease Control and Prevention,
 U.S. Department of Health and Human Services, 2022.

## **Endnotes**

- 1. Friedman J, Shover CL. Charting the fourth wave: Geographic, temporal, race/ethnicity and demographic trends in polysubstance fentanyl overdose deaths in the United States, 2010-2021. Addiction. 2023 Dec;118(12):2477-2485. https://pubmed.ncbi.nlm. nih.gov/37705148/
- 2. National Institute on Drug Abuse. Drug Overdose Death Rates, Accessed September 1, 2024, https:// nida.nih.gov/research-topics/trends-statistics/ overdose-death-rates. There were 57.497 overdose deaths that involved stimulants in 2022.
- 3. ASAM/AAAP Clinical Practice Guideline on the Management of Stimulant Use Disorder. 2023. Accessed September 1, 2024. https://journals.lww. com/journaladdictionmedicine/fulltext/2024/05001/ the\_asam\_aaap\_clinical\_practice\_guideline\_on\_ the.1.aspx. The Guideline recommends that clinicians consider prescribing mixed amphetamine salts with modafinil or topiramate for cocaine use disorder and methylphenidate for amphetamine-type stimulant use disorder (see pgs. 4-5).
- 4. See Tardelli VS, Bisaga A, Arcadepani FB, Gerra G, Levin FR, Fidalgo TM. Prescription psychostimulants for the treatment of stimulant use disorder: a systematic review and meta-analysis. Psychopharmacology. 2020;237(8):2233-2255. https:// pubmed.ncbi.nlm.nih.gov/32601988/. See Sharafi H, Bakouni H, McAnulty C, et al. Prescription psychostimulants for the treatment of amphetamine-type stimulant use disorder: A systematic review and meta-analysis of randomized placebo-controlled trials. Addiction. 2024 Feb;119(2):211-224. https:// pubmed.ncbi.nlm.nih.gov/37880829/
- 5. U.S. Food and Drug Administration. Draft Guidance for Industry, Stimulant Use Disorders: Developing Drugs for Treatment. Oct. 2023. Accessed September 1, 2024. https://www.fda.gov/media/172703/ download.
- 6. 21 USC 823(h).
- 7. 21 CFR 1306.04(a).
- 8. ASAM/AAAP Clinical Practice Guideline on the Management of Stimulant Use Disorder. 2023. Accessed September 1, 2024. https://journals.lww. com/journaladdictionmedicine/fulltext/2024/05001/ the\_asam\_aaap\_clinical\_practice\_guideline\_on\_ the.1.aspx (see pg. 22).

- 9. Insurance Considerations: Practitioners should be aware that insurance laws and policies can also affect patient access to psychostimulants for StUD even if a practitioner may lawfully prescribe them.
- 10. Ohio Admin. Code 4731-11-03 (Lexis Advance through updates effective June 15, 2024).
- 11. 060-01 Ark. Code R. § 001, Rule No. 7 (Lexis Advance through May 2024. The Arkansas Register: Volume 49, Number 5, May 2024).
- 12. MCL 333.7333(1) (LexisNexis, Lexis Advance through Act 57 of the 2024 Regular Legislative Session and E.R.O. 2024-1).
- 13. S.D. Admin. R. 44:58:08:04 (Lexis Advance through the South Dakota Register, Vol. 50 Pg. 159, dated June 17 2024).
- 14. Okla. Admin. Code § 435:10-7-4 (25) (Lexis Advance through Oklahoma Register Volume 41, Number 17, May 15, 2024).
- 15. See Nevada as an example. NAC 630.450. See also advisory opinions from the Louisiana State Board of Medical Examiners ("These opinions are based upon the Board's review of a defined set of circumstances provided by the requesting party, and are consistent with the rules and law at the time that the opinion was requested.").