Vital Strategies

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48th Annual AMERSA Conference

# **Psychostimulants for Stimulant Use Disorder:** Current Evidence and Legal Landscape

*The information in this presentation does not constitute legal advice or legal representation. For legal advice, you should consult with an attorney licensed to practice in your state.*

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Visit **www.vitalstrategies.org/overdose-prevention/**

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# Disclosures

- Kate Boulton and Derek Carr, employees of Vital Strategies, have no disclosures.
- Leslie Suen has no disclosures
- Phillip Coffin has no disclosures
- Corey Davis has no disclosures
- Sarah Leyde has no disclosures
- Vital Strategies and the Network for Public Health Law are non-profit organizations.

**Disclaimer:** *This workshop includes discussion of off-label uses of FDA approved medications, including controlled substances.*

# Learning Objectives

1. Describe the current state of evidence for prescribing psychostimulants to treat stimulant use disorder.

2. Assess whether and how federal and state laws restrict or prohibit the prescribing of psychostimulants to treat stimulant use disorder.

3. Identify opportunities to address real and perceived legal, policy, and clinical barriers to prescribing psychostimulants for stimulant use disorder.

# Agenda

- **Clinical Evidence & Background**
  - Methamphetamine use & stimulants as a driver of fatal drug overdoses
  - Current evidence on using psychostimulants to treat StUD
- **Understanding the Legal Landscape**
  - Federal legal considerations
  - State legal considerations
- **Small Group Activity**
- **Large Group Discussion & Wrap Up**

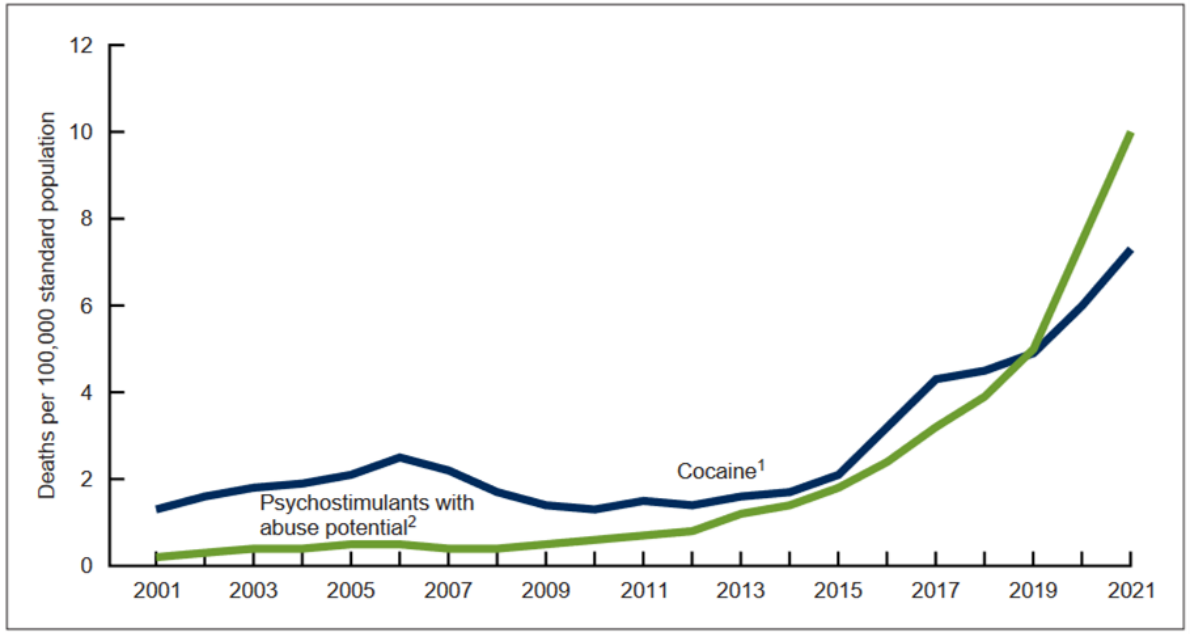
**Language Disclaimer:** *Many state laws contain stigmatizing and harmful language to describe substance use disorder and/or people who use(d) drugs. This workshop includes references to such language where it appears in state laws because these outdated and often ambiguous terms bear on laws' scope and application and reflect the language practitioners are likely to encounter in their own state(s).*

# Clinical Evidence & Background

## Setting the Context

# Stimulants as a Driver of Fatal Drug Overdoses

- More than half (57.1%) of fatal overdoses in 2022 involved stimulants, alone or in combination with opioids (30 jurisdictions).[1]
- Age-adjusted rates of overdose deaths involving:
  - Amphetamines (including methamphetamine) doubled from 5.0 in 2019 to 10.0 in 2021.
  - Cocaine increased from 6.0 in 2020 to 7.3 in 2021.[2]
- Substantial racial and ethnic disparities in rates of stimulant-involved fatal overdose.[3]



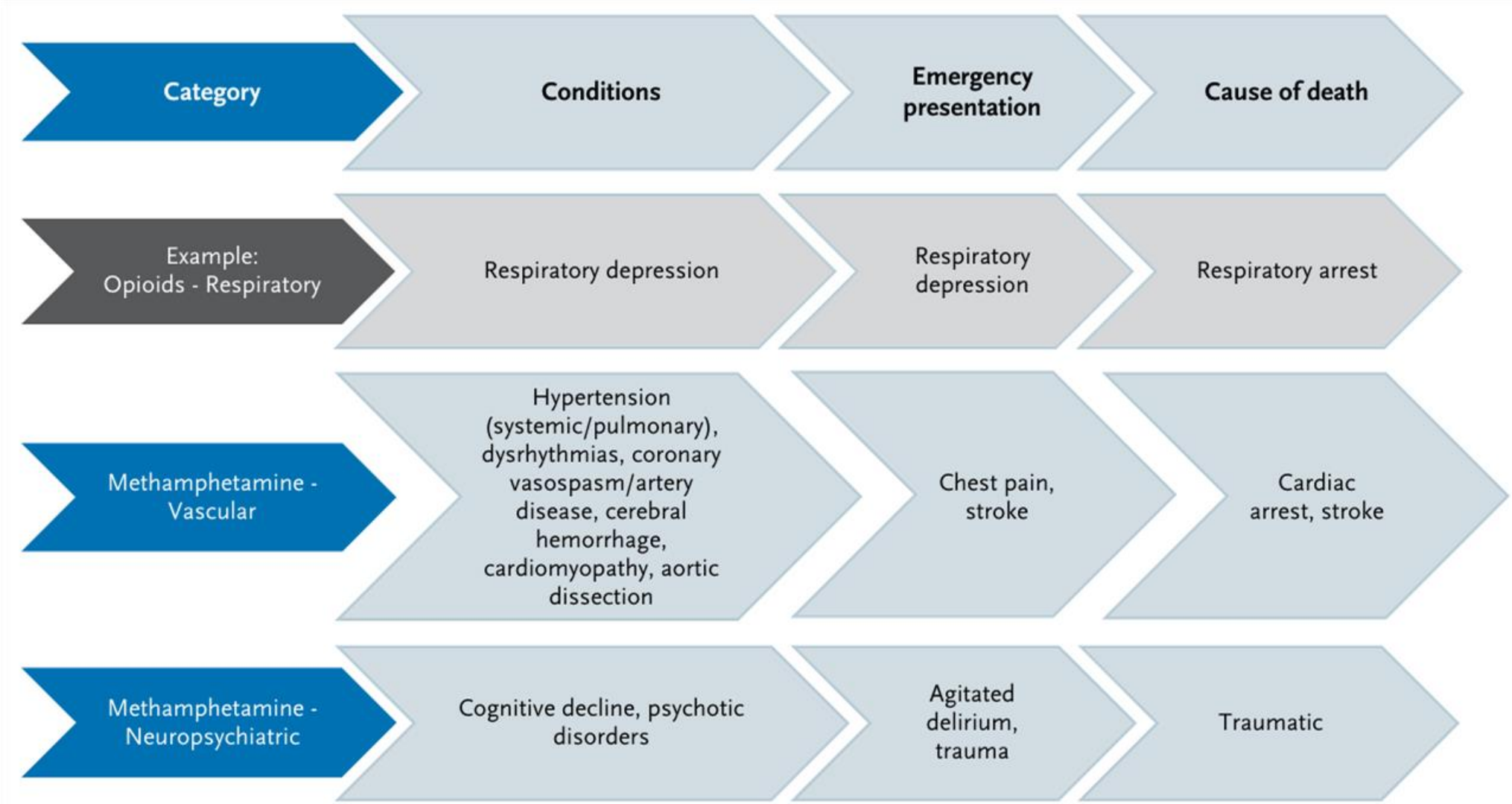

Age-adjusted rate of drug overdose deaths involving stimulants, by type of stimulant: United States, 2001-2021[2]

[1] Centers for Disease Control and Prevention. State Unintentional Drug Overdose Reporting System (SUDORS). Final Data. Atlanta, GA: US Department of Health and Human Services, CDC; February 26, 2024. Access at: https://www.cdc.gov/overdose-prevention/data-research/facts-stats/sudors-dashboard-fatal-overdose-data.html

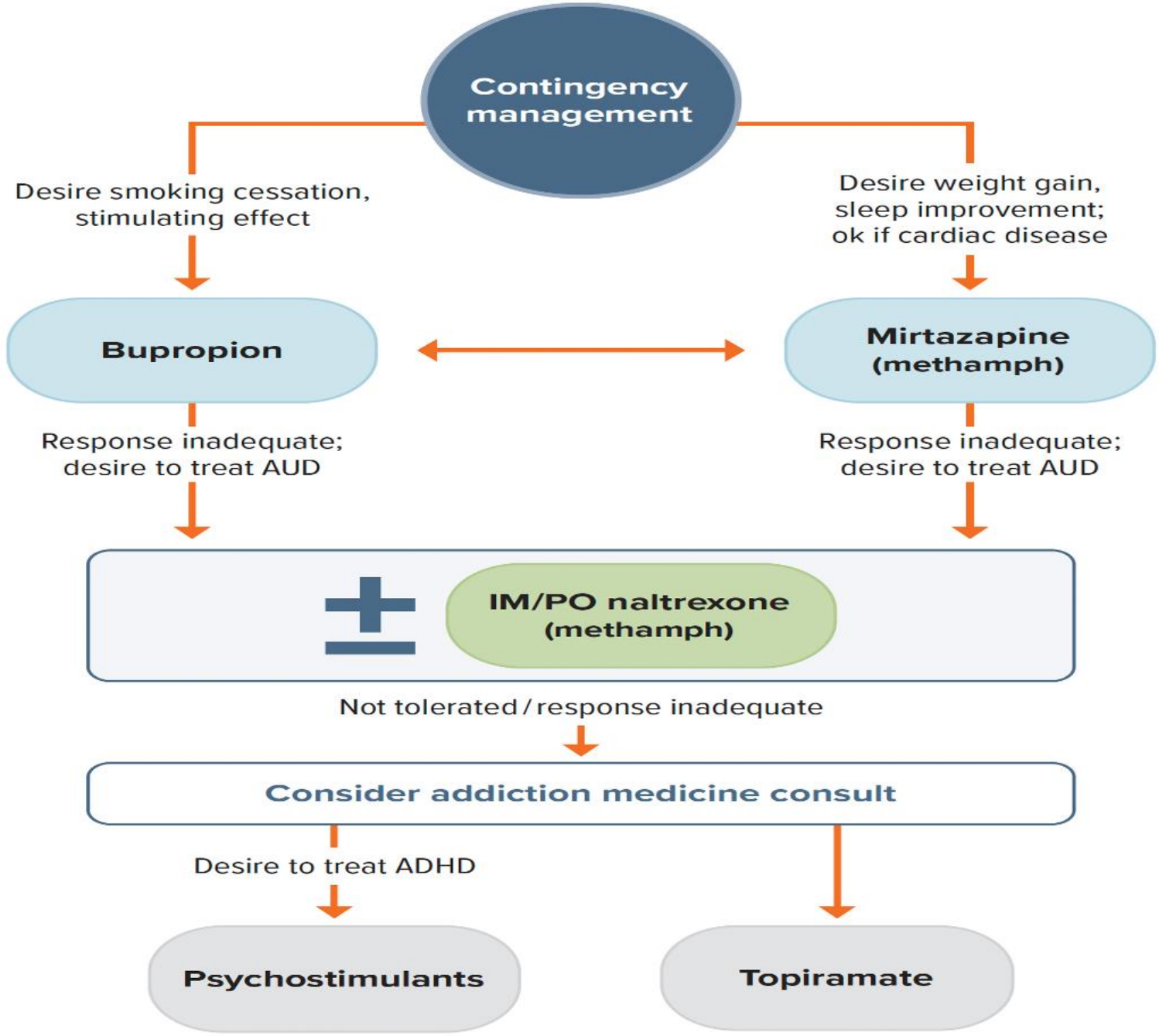
[2] Spencer MR. Drug Overdose Deaths in the United States, 2001–2021. Centers for Disease Control and Prevention; 2022. Accessed December 20, 2023. https://www.cdc.gov/nchs/data/databriefs/db457.pdf.

[3] Kariisa M, Seth P, Scholl L, Wilson N, Davis NL. Drug overdose deaths involving cocaine and psychostimulants with abuse potential among racial and ethnic groups – United States, 2004–2019. Drug and Alcohol Dependence. 2021;227:109001.

# Conceptualizing Stimulant Use Toxicities



# Treating Stimulant Use Disorders



# What is the evidence supporting psychostimulants for methamphetamine use disorder? Results are mixed though promising

Studies of dextroamphetamine, methylphenidate, and modafinil have found reduced self-reported methamphetamine use, diminished craving, or decreased depressive symptoms.

One randomized study (n=56) of sustained-release methylphenidate showed fewer urine positive tests for methamphetamine (p=0.03) though only 39% participants completed trial.

No other studies have found reductions in urine positivity in methamphetamine drug screens (the accepted gold standard).

One observational study of 13,965 persons with methamphetamine use disorder in Sweden found lisdexamfetamine associated with a lower all cause mortality (aHR 0.43; 95% CI, 0.24-0.77)

*Chan et al, Addiction 2019; Rezaei et al, Daru 2015; Heikkinen et al, JAMA Psychiatry 2023.*

# What is the evidence supporting psychostimulants for cocaine use disorder? *Promising results, though low quality evidence*

A meta-analysis found that **mixed amphetamine salts + topiramate** had positive effects for achieving a period of cocaine abstinence during treatment compared to placebo

Meta-analyses demonstrate that **prescription psychostimulant medications** (methylphenidate, mixed amphetamine salts, lisdexamfetamine, and dextroamphetamine) are associated with reported sustained abstinence from cocaine and cocaine-negative urine drug testing

*Tardelli et al, Psychopharmacology, 2020; Castells et al, Cochrane Review, 2016*

# ASAM/AAAP Guidelines for Stimulant Use Disorder

The ASAM/AAAP Clinical Practice Guideline on the Management of Stimulant Use Disorder. *Journal of Addiction Medicine*. 2024;18(1S):1-56. doi:10.1097/adm.0000000000001299. https://bit.ly/3AWLjJh

## General Psychostimulant Medication Recommendations

- Recommendations related to the prescription of psychostimulant medications to treat StUD are only applicable to:
  - Clinicians who are board certified in addiction medicine or addiction psychiatry; and
  - Clinicians with commensurate training, competencies, and capacity for close patient monitoring (Clinical consensus, Strong Recommendation).
- When prescribing psychostimulant medications for StUD, clinicians should maintain a level of monitoring commensurate with the risk profile for the given medication and patient.
- Monitoring may include pill counts, drug testing, more frequent clinical contact, and more frequent PDMP checks (Clinical consensus, Strong Recommendation).

# What might this look like?

# Example: Using methylphenidate to treat MeUD

**First visit:**

1) Establish a diagnosis of methamphetamine use disorder +/- ADHD per DSM-5 criteria
2) Discuss patient goals
3) Weigh risks/benefits of stimulant medication
4) Discuss expectations of provider:
   - Timely refills
   - Prior Authorization
   - Individualized care
5) Discuss expectations of patient:
   - Frequent visits every 1-2 weeks until dose stable, then monthly
   - Urine toxicology testing
6) Start methylphenidate 18mg ER with instructions to quickly titrate to 36mg ER

**Subsequent visits:**

1) Monitor heart rate, BP, weight, symptoms of overamping
2) Discuss if/how medication is aligning with pt goals
3) Adjusting dose (sometimes past the “max dose” of 60mg)

# Understanding the Legal Landscape

## Federal and State Legal Considerations

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# Prescribing Controlled Psychostimulants for StUD
## **Federal Legal Landscape: Off-label Prescribing**

- There are no medications currently approved by FDA for StUD, so use of any prescription medications for those indications is off-label.
    - FDA regulates the marketing and distribution of drugs, not the practice of medicine.
    - Off-label prescribing – including of controlled substances – is common and accepted practice, and not inherently illegal or problematic.
    - Approximately 1 in 5 prescriptions are issued off-label.

# Prescribing Controlled Psychostimulants for StUD
## **Federal Legal Landscape: Differences with OUD Treatment**

- As you are likely aware, federal law imposes various restrictions on the use of certain “narcotic drugs” for SUD treatment.
    - Only methadone and buprenorphine may be used for such treatment, and methadone treatment is heavily regulated.

- These restrictions **do not apply** to Schedule II psychostimulants such as amphetamines and amphetamine-like stimulants, because they are not “narcotic drugs” (as defined by federal law).[1]

[1] 21 USC § 802(17) (defining “narcotic drug”)

# Prescribing Controlled Psychostimulants for StUD
## **Federal Legal Landscape: General Restrictions on CS Rx**

- Federal law broadly requires that all controlled substance prescriptions be "issued for a legitimate medical purpose" by a practitioner "acting in the usual course" of professional practice.

- To convict a practitioner of prescribing or dispensing a controlled substance in violation of this law, the government must show that they did so *knowing* or *intending* that doing so was outside the bounds of medical practice.
    - Negligence, failure to meet a standard of care, or malpractice alone are *not* sufficient to obtain a conviction.

# Prescribing Controlled Psychostimulants for StUD
## **Federal Legal Landscape: General Restrictions on CS Rx**

- This standard is somewhat amorphous; there is no specific guideline, and different federal courts have analyzed it in different ways.
- In 2022, the U.S. Supreme Court ruled that the government must show that the prescriber *knew* or *intended* that the Rx violated the law w*hen they issued it*.[1]
    - This is high bar, particularly in the context of otherwise legitimate medical practice.

[1] Xiulu Ruan v. United States, 597 U.S. 450 (2022)

# Prescribing Controlled Psychostimulants for StUD
## **State Legal Landscape: General Considerations**

- States are the primary regulators of medical practice.
- Legal frameworks often unclear – little guidance on scope and applicability.
  - Varied sources (e.g., statutes, regulations, case law guidance) and types (e.g., general medical practice laws, controlled substance laws)
    - Differences in enforcement authority & potential consequences
    - Different potential pathways for reform
  - Complexity
  - Alignment (or lack thereof) between written law & enforcement practices.

*"Clinicians should be aware of state law where they practice that may restrict prescribing of psychostimulant medications for StUD."*

Source: The ASAM/AAAP Clinical Practice Guideline on the Management of Stimulant Use Disorder. Journal of Addiction Medicine. 2024;18(1S):1-56. doi:10.1097/adm.0000000000001299. https://bit.ly/3AWLjJh

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# Prescribing Controlled Psychostimulants for StUD
# **State Legal Landscape: Specific Considerations**

**Findings from a systematic review of medical practice and controlled substance statutes and regulations in all 50 states + D.C that could affect prescribing psychostimulants for StUD**

Laws current as of September 1, 2023

Laws that **restrict the indications** for prescribing *psychostimulants*

Laws that impose **heightened standards and/or additional requirements** when prescribing *psychostimulants* (e.g., off-label uses, specified populations)

Laws that **restrict or prohibit prescribing** *controlled substances* **for drug dependency and/or addiction treatment**

Laws that **restrict or prohibit prescribing** *controlled substances* to individuals **based on their current and/or past substance misuse**

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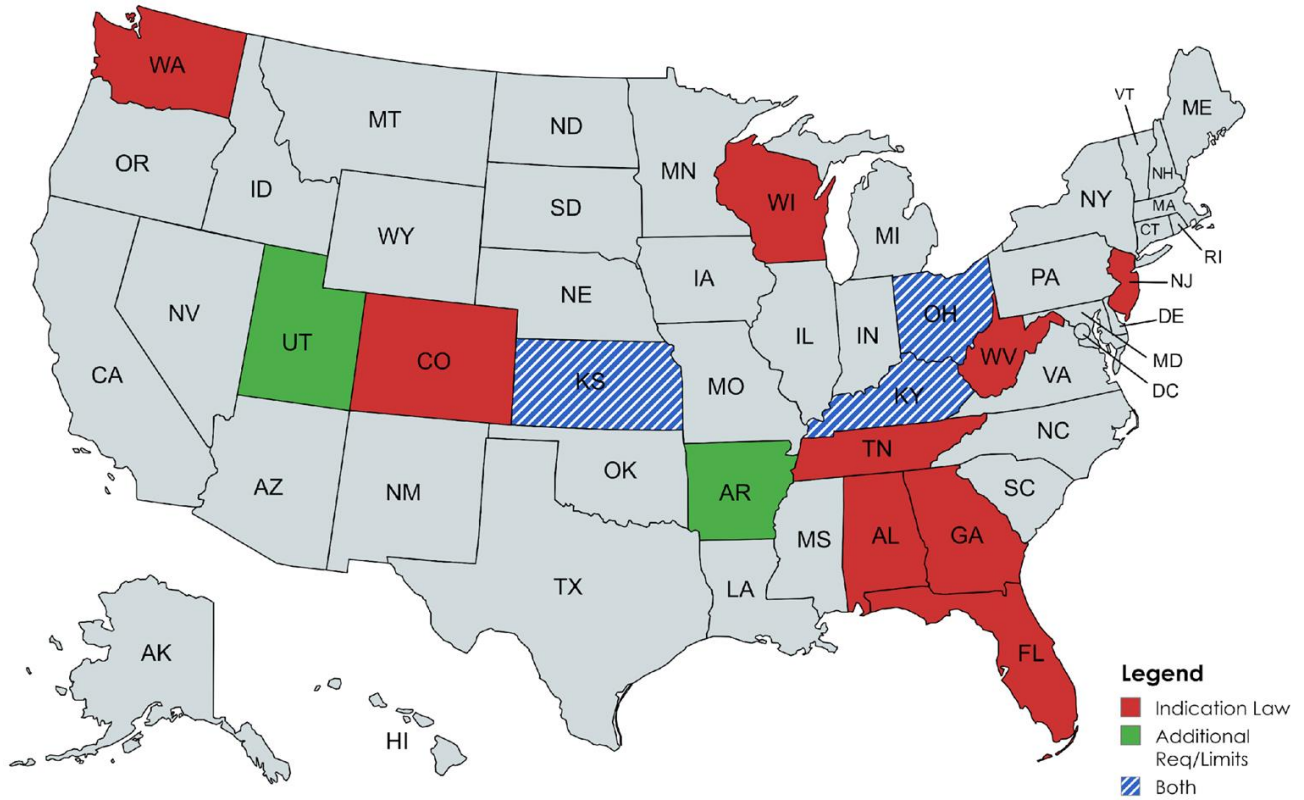
# Prescribing Controlled Psychostimulants for StUD
## State Legal Landscape (as of September 1, 2023)

- Twelve (12) states regulated the indications for which a practitioner could prescribe specified psychostimulants.
  - Most applied to SII stimulants only
  - All included ADHD, and nine included "drug-induced brain dysfunction"
  - Variation in practitioner applicability.
- Five (5) states imposed additional requirements or limitations when prescribing controlled psychostimulants.
  - Example: Off-label uses of SII psychostimulants must "be justified with appropriate medical rationale and documentation of evidence-based research and experience."

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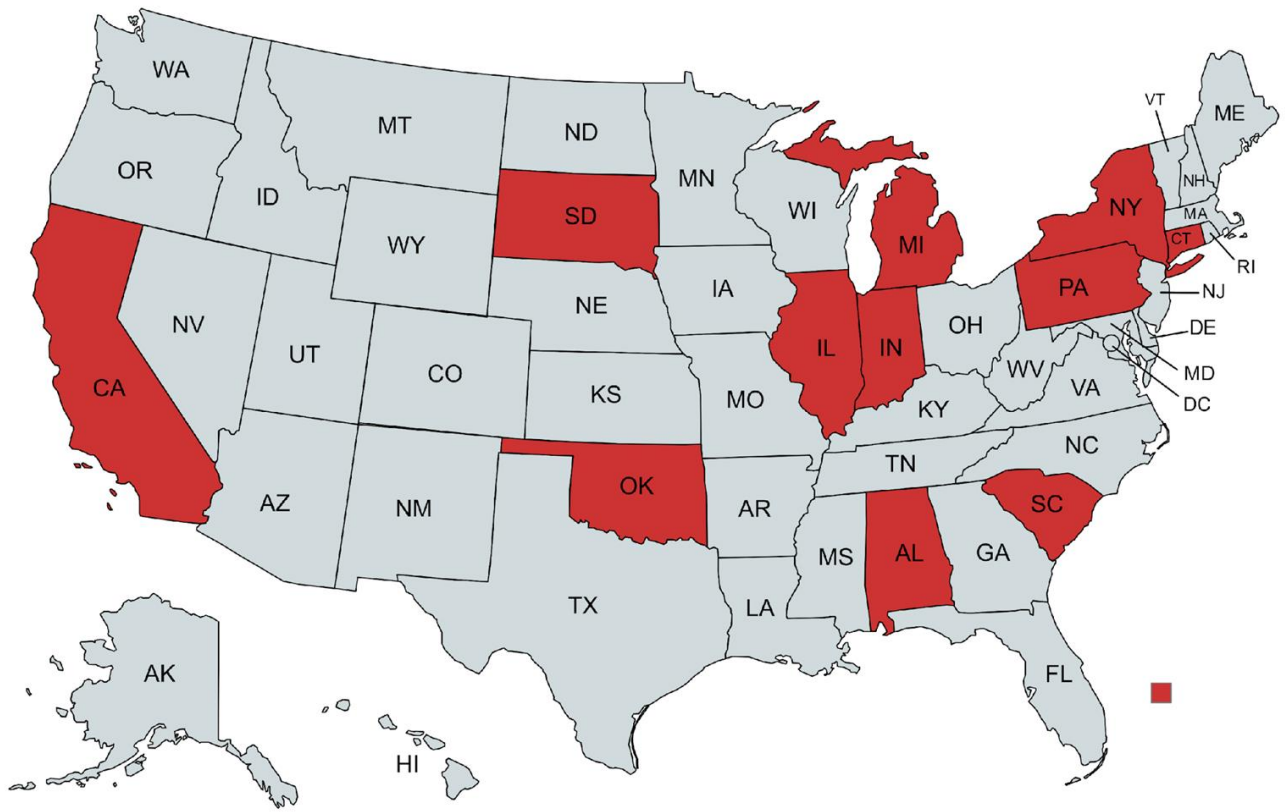
# Prescribing Controlled Psychostimulants for StUD
## State Legal Landscape (as of September 1, 2023)

- Eleven (11) states had laws explicitly regulating the use of controlled substances with respect to drug dependency and/or addiction.
- Significant variation in type and scope:
  - Use of CS to treat drug dependency prohibited unless affirmatively authorized by law (2 states).
  - General authority to prescribe and/or dispense CS excluded drug dependency and/or addiction (5 states).
  - Restricted use of CS to maintain a person's drug dependency (6 states).
  - Restricted or prohibited use of CS to maintain an individual's "customary use" (3 states).

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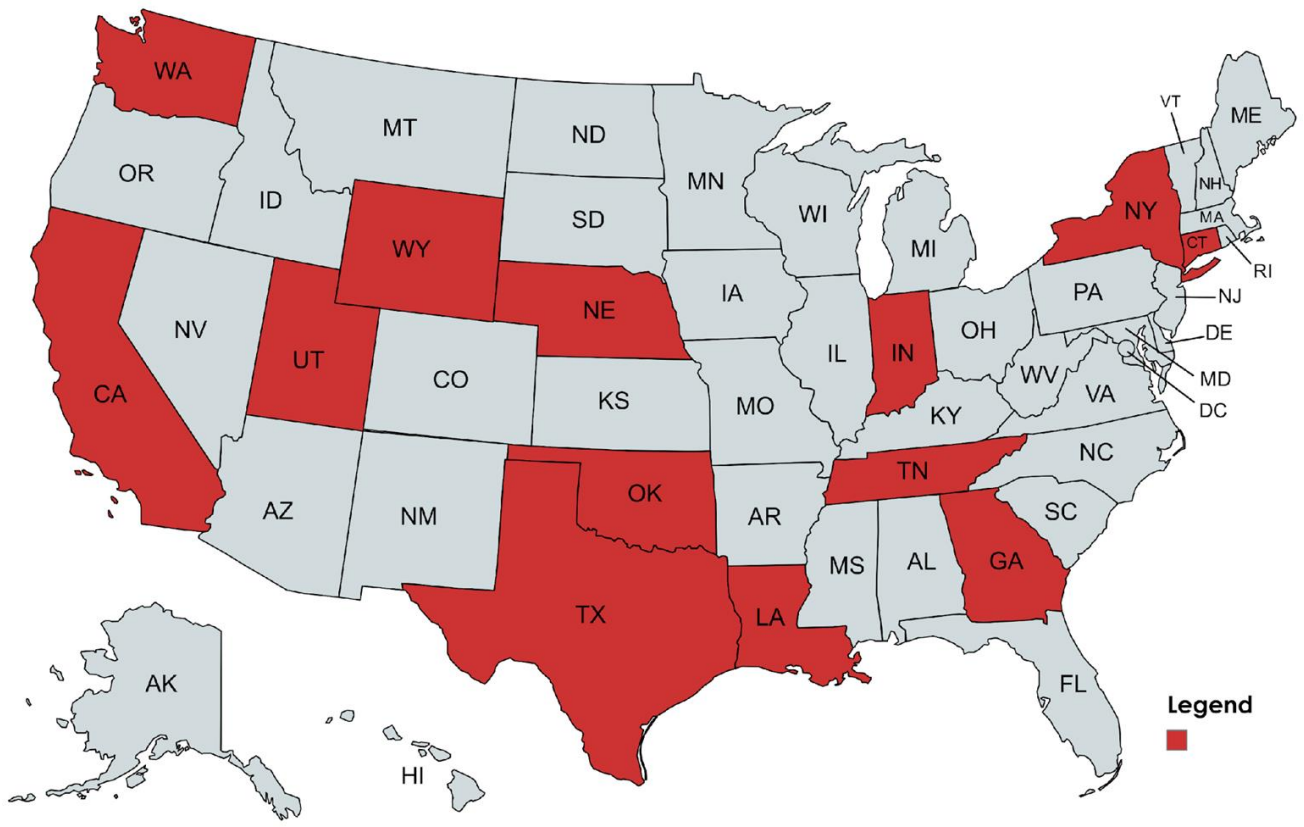
# Prescribing Controlled Psychostimulants for StUD
## State Legal Landscape (as of September 1, 2023)

More than a quarter (13/51) states had laws restricting or prohibiting the provision of controlled substances based on an individual's substance misuse.

- No CS prescriptions to an "drug dependent person" or "addict or habitual user" unless specifically authorized by law (8 states).
- No Rx for a "drug abuser or habitual user of legend drugs" if Rx not issued "in the course of professional treatment" (2 states).
- Idiosyncratic requirements/limits (2 states)
- Texas imposes an unqualified prohibition on prescribing CS to "an abuser of … drugs."
- Two (2) states extend laws to "any person previously drug dependent."

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# Questions?

# Small Group Activity: Instructions

- Break into **small groups** (or stick with your table) – try to include people you don't know!
  - **Clinician and attorney facilitators will float among groups.**
- Each small group will **receive handouts** with:
  - One hypothetical patient scenario (varies across groups).
  - Three hypothetical state laws (the same across all groups).
  - A table for note-taking.
- The goal is to **assess how you would approach** the **patient scenario under** *each* of the three **different hypothetical state laws**. Your small group will **complete the row** in the table **corresponding to your assigned patient scenario.**
- **You'll have 20 minutes to complete this task**. We recommend spending the first 5-7 minutes individually reviewing the patient scenario and state laws and the next 13-15 minutes discussing and outlining your thoughts as a group.
- It's okay if you get stuck or don't make it through the entire exercise!.

# Small Group Activity: Potential Guiding Questions

- What are your **initial impressions** of how each legal scenario would affect how a practitioner could respond to the patient scenario?
  - What is the **key/operative language** in the legal scenario?
  - How do **different provisions** within a **particular** legal scenario affect your analysis?
  - With respect to **Hypothetical State Law #2 and Hypothetical State Law #3**, consider whether the provision(s) target the **purpose(s) of a prescription** or some **current or prior characteristic/status of the patient** receiving the prescription?
- What **additional information (clinical or legal)** would you want to know before moving forward?
- How might you **seek additional guidance** on the legal landscape?

# Large Group Discussion

# Patient Case 1

32-year-old individual with longstanding attention deficit disorder and methamphetamine use disorder.

- Treated with dextroamphetamine twice daily since teen
- Began agreeing to methamphetamine use ~5 years ago to be more appealing as an aging escort
- Psychiatrist discontinued dextroamphetamine due to methamphetamine use
- Methamphetamine use escalated, requests dextroamphetamine
- Psychiatry documented in ALL CAPS in chart that patient cannot be prescribed ATS due to methamphetamine use
  - Tried atomoxetine with no benefit
  - Increasingly disorganized
  - Beginning to have delusions

# Patient Case 1, continued

32-year-old individual with longstanding attention deficit disorder and methamphetamine use disorder.

- ATS reconsidered for patient, however psychosis had progressed to such an extent that psychiatry felt that it was no longer be acceptable
- Smoked “methamphetamine” from a friend’s pipe that was actually fentanyl and died

# Patient Case 2

45-year-old individual with methamphetamine use disorder c/b auditory hallucinations + depression.

- Voices are ego-syntonic and she perceives them as helpful. Not interested in antipsychotic meds.
- Currently injects methamphetamine 5x/day.
- Goal: harm reduction, gradual reduction of methamphetamine use over time, eventual abstinence.
- Living in a permanent supportive housing unit and volunteering at a harm reduction org.
- Treatment course
  - Tried 450mg XR bupropion + IM naltrexone. IM naltrexone discontinued due to intolerable headache + nausea.
  - Tried mirtazapine. Experienced intolerable fatigue.
  - Not interested in abstinence-focused psychosocial treatment. Finds it stigmatizing.
  - Difficulty tolerating extreme fatigue associated with reductions in methamphetamine use.
  - She asks about prescribed stimulants…

# Patient Case 2, continued

- Methylphenidate ER started at 18mg and uptitrated to 36mg and then 54mg
- Methamphetamine use reduced by >75%
- Close monitoring of pulse, blood pressure, mental health symptoms / no significant changes
- Now engaged in additional recovery-oriented activities: NAMI volunteering, peer support specialist training, exercise, reconnection with son.
- Working on moving out of supportive housing building and into Section 8 housing before trying for methamphetamine abstinence (eventual goal)

# Patient Case 3

28-year-old woman who is new to your practice.

- She moved from out of state 3 years ago & works as a bartender
- She occasionally uses methamphetamine from coworkers to help her stay up through shifts
- She reports being diagnosed with ADHD as a child but never opted for medications, does not have records
- She also has depression which she is taking an SSRI
- She is having trouble concentrating as she is hoping to study for exams to become a realtor
- Hoping to come to you for a prescription for psychostimulant to avoid having to use methamphetamines

# Patient Case 3, continued

- **Considerations**
  - No confirmation of ADHD diagnosis before age 12
  - Recreational use of methamphetamine though does not meet criteria for use disorder
  - May have uncontrolled depression which may be causing her concentration issues
- **Treatment course**
  - Confirmed that her depression is well controlled
  - Discussed recommendations to stop methamphetamine use
  - Offered lisdexamfetamine and set boundaries about conditions for prescribing
  - Started on lisdexamfetamine 30mg and feels her symptoms are now much better
  - UDS done quarterly and have been negative

# Questions?

# Additional Resources

- **The ASAM/AAAP Clinical Practice Guideline on the Management of Stimulant Use Disorder**
  https://www.asam.org/quality-care/clinical-guidelines/stimulant-use-disorders
- **ASAM/AAAP StUD Clinical Practice Guideline Webinar Series**
  https://elearning.asam.org/stimulants-2
- **Methamphetamine Toxicities and Clinical Management (Coffin & Suen, 2023)**
  https://evidence.nejm.org/doi/full/10.1056/EVIDra2300160
- **Stimulant Use Disorders: Developing Drugs for Treatment (Oct. 2023 FDA Guidance)**
  https://www.fda.gov/regulatory-information/search-fda-guidance-documents/stimulant-use-disorders-developing-drugs-treatment
- **New Resources**
  - Practitioner-oriented legal primer from Vital Strategies & ASAM
  - Commentary on navigating the federal legal landscape (accepted in JAM)
  - Issue brief with detailed results of 50 state systemic legal review (forthcoming 2025)

# Contact Information

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