

# 42 CFR Part 8 Final Rule: State Level Implications

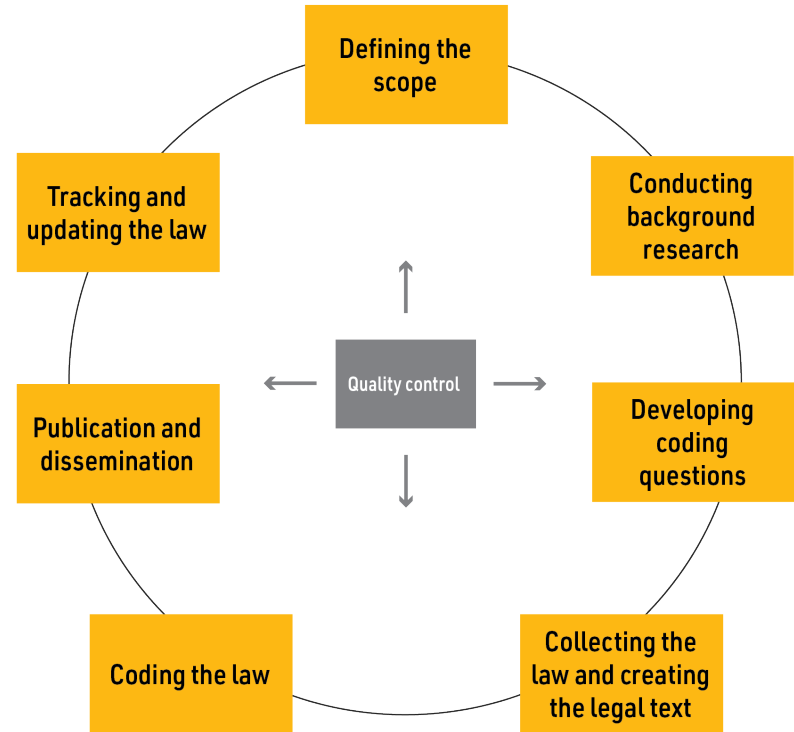
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# Center for Public Health Law Research

# Introduction

- **Legal epidemiology** is the deployment and scientific study of **law as a factor** in the cause, distribution, and prevention of disease and injury in a population
- A team of lawyers/policy analysts follow the **policy surveillance process** to collect and code the law
- Turning text of the law into **numeric legal data**





## Buprenorphine Prescribing Requirements and Limitations

FOCUS  EXPLORE

CREATED BY: Center for Public Health Law Research  
Staff & Vital Strategies

UPDATED THROUGH: March 1, 2023

Medications for opioid use disorder (MOUD), particularly agonist medications buprenorphine and methadone, are one of the most effective tools for reducing opioid overdose deaths. Research shows that agonist medications can reduce mortality by up to 50% for people with opioid use disorder (OUD). Unlike methadone, which must be dispensed through a federally certified opioid treatment program, buprenorphine may be prescribed directly by practitioners in office-based settings. While the federal X-waiver requirement for buprenorphine prescribing was eliminated in late 2022, state laws on buprenorphine prescribing for OUD remain, with some state regulatory schemes maintaining restrictive barriers to buprenorphine treatment access. These barriers include constraints on dosage, product formulation, and prescription length; and imposing high-threshold practices such as mandatory counseling and frequent drug testing. Conversely, state laws can be protective, such as by requiring the provision of the opioid overdose reversal drug naloxone and prohibiting punitive responses when patients decline counseling or other ancillary services.

This dataset is cross-sectional and displays key features of state-level statutes and regulations regarding buprenorphine prescribing for OUD outside of federally certified opioid treatment programs. The dataset includes laws across all 50 states and the District of Columbia in effect as of March 1, 2023. The dataset does not include laws or policies that regulate buprenorphine prescribing exclusively within state Medicaid programs. The research protocol includes additional information on the scope of state laws captured by this dataset.

*These data were created with support from the Vital Strategies Overdose Prevention Program.*



DATA



CODEBOOK

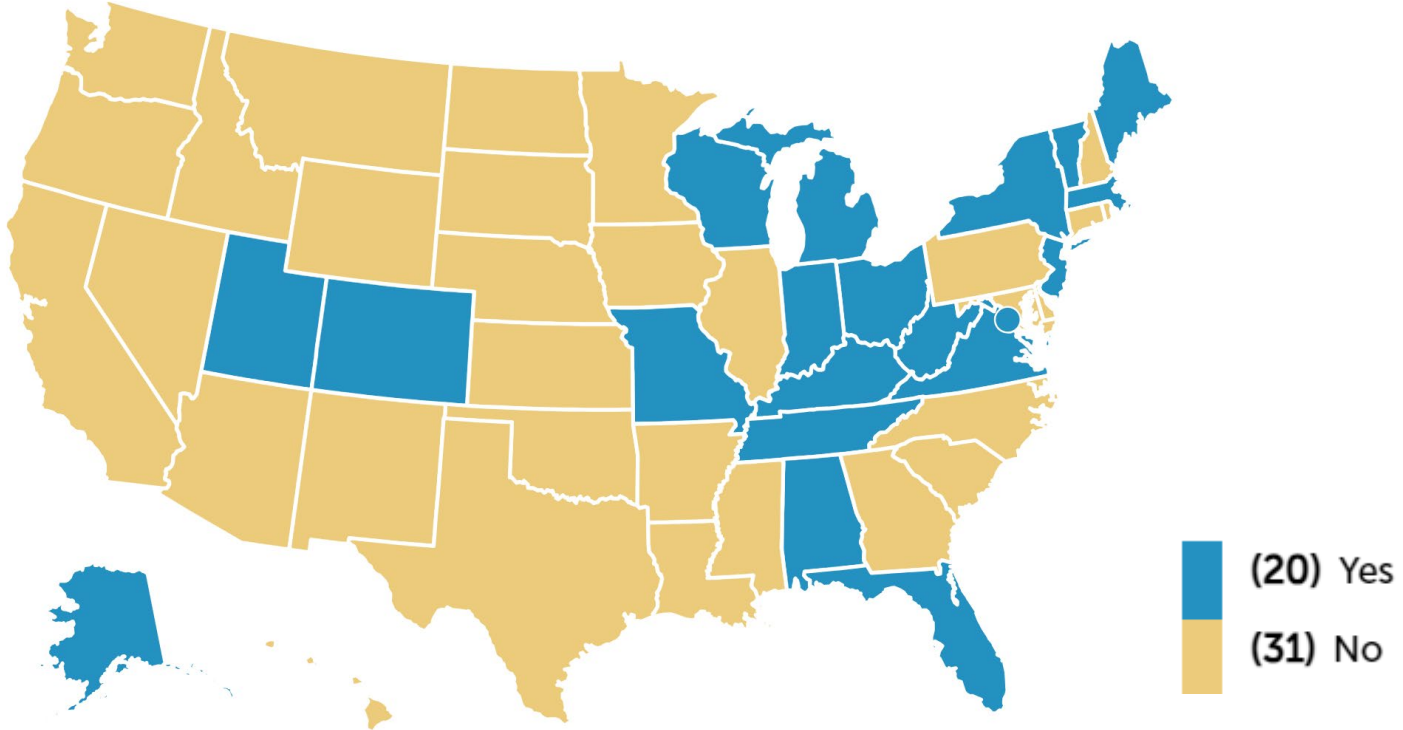


PROTOCOL



SUMMARY

# Does the state explicitly regulate buprenorphine prescribing for opioid use disorder?



📍 Alaska

1. Does the state decriminalize buprenorphine possession?

**No**

2. Does the state explicitly regulate buprenorphine prescribing for opioid use disorder (OUD)?

§ **Yes**

2.1. When are practitioners that prescribe buprenorphine for OUD explicitly regulated?

- § **⚠️ • When a particular type of practitioner prescribes buprenorphine for OUD**
- When the practitioner is at a certain type of practice setting**

Excerpts from the law:

Alaska Stat. § 08.64.363(b)(3)

...  
(3) the treatment of a patient's substance abuse or opioid dependence; the licensee may write a prescription for an opioid approved for the treatment of substance abuse or opioid dependence for the quantity needed to treat the patient's substance abuse or opioid dependence; the licensee shall document in the patient's medical record the reason for the prescription of an opioid approved for the treatment of substance abuse or opioid dependence in a quantity that exceeds a seven-day supply and indicate that a nonopioid alternative was not appropriate for the treatment of substance abuse or opioid dependence.

Alaska Stat. § 08.64.363. Maximum dosage for opioid prescriptions

**Effective: 7/26/17 - Through: 3/1/23**

(a) A licensee may not issue

(1) an initial prescription for an opioid that exceeds a seven-day supply to an adult patient for outpatient use;

(2) a prescription for an opioid that exceeds a seven-day supply to a minor; at the time a licensee writes a prescription for an opioid for a minor, the licensee shall discuss with the parent or guardian of the minor why the prescription is necessary and the risks associated with opioid use.

(b) Notwithstanding (a) of this section, a licensee may issue a prescription for an opioid that exceeds a seven-day supply to an adult or minor patient if, in the professional medical judgment of the licensee, more than a seven-day supply of an opioid is necessary for

the patient's acute medical condition, chronic management, pain associated with cancer, pain experienced while the patient is in

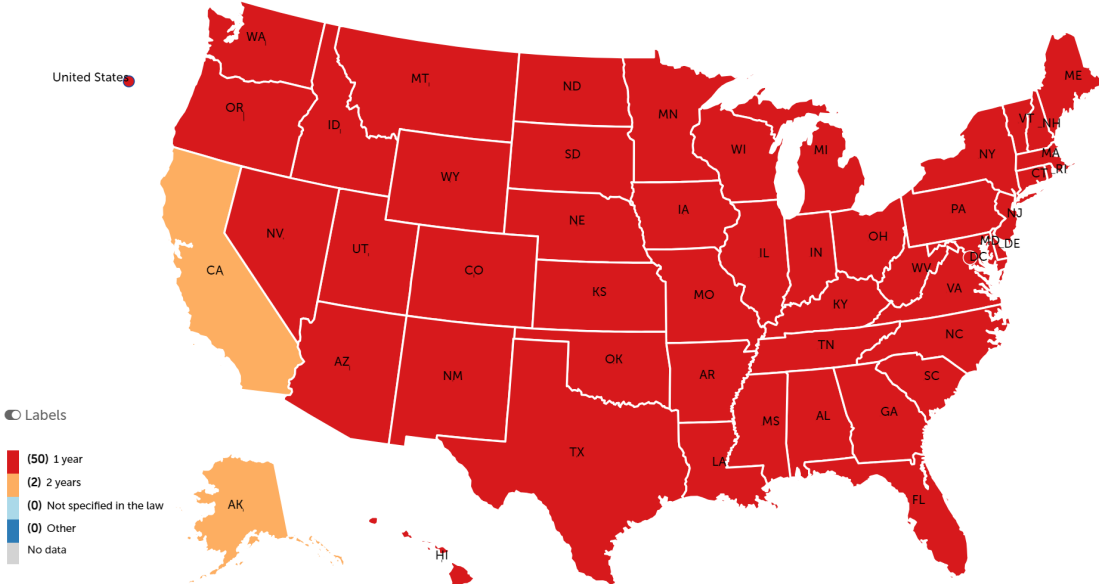
**⚠️ Caution Note:**

Statutory changes adopted after the promulgation of Alaska Admin. Code tit. 12, § 40.943(b) and Alaska Admin. Code tit. 12, § 44.925(d) may affect the applicability of these regulations. See Alaska Stat. §§ 08.64.364(b), 08.68.710(b).

# Medication-Assisted Treatment with Methadone (MAT) Laws

Medication-Assisted Treatment (MAT) uses medications, such as Methadone, in conjunction with behavioral therapy and counseling to treat opioid addiction. MAT with methadone is required to be distributed to individuals through an Opioid Treatment Program (OTP). MAT with methadone for opioid addiction is subject to federal law, with specific requirements such as physician evaluations, toxicology testing, counseling, and treatment planning. Some states go beyond what is required by the federal law and place stricter restrictions on OTPs, while other states simply defer to the federal law. This dataset examines federal and state laws that address the requirements of MAT with methadone.

10/1/16 What is the standard minimum length of dependence permissible for new patient admission into an OTP?





# 42 CFR Part 8 Final Rule

## Overview of Changes

# 42 CFR Part 8 Final Rule

- Regulations that guide opioid treatment programs (OTPs)
  - Set federal baseline
  - Preserves states' authority to regulate OTPs
- 42 CFR Part 8 HHS revision via SAMHSA
  - Published February 2, 2024
  - Effective April 2, 2024
  - Compliance date October 2, 2024
- General changes
  - “promotes practitioner autonomy, removes stigmatizing or outdated language, supports a patient-centered approach, and reduces barriers to receiving care.” - SAMHSA

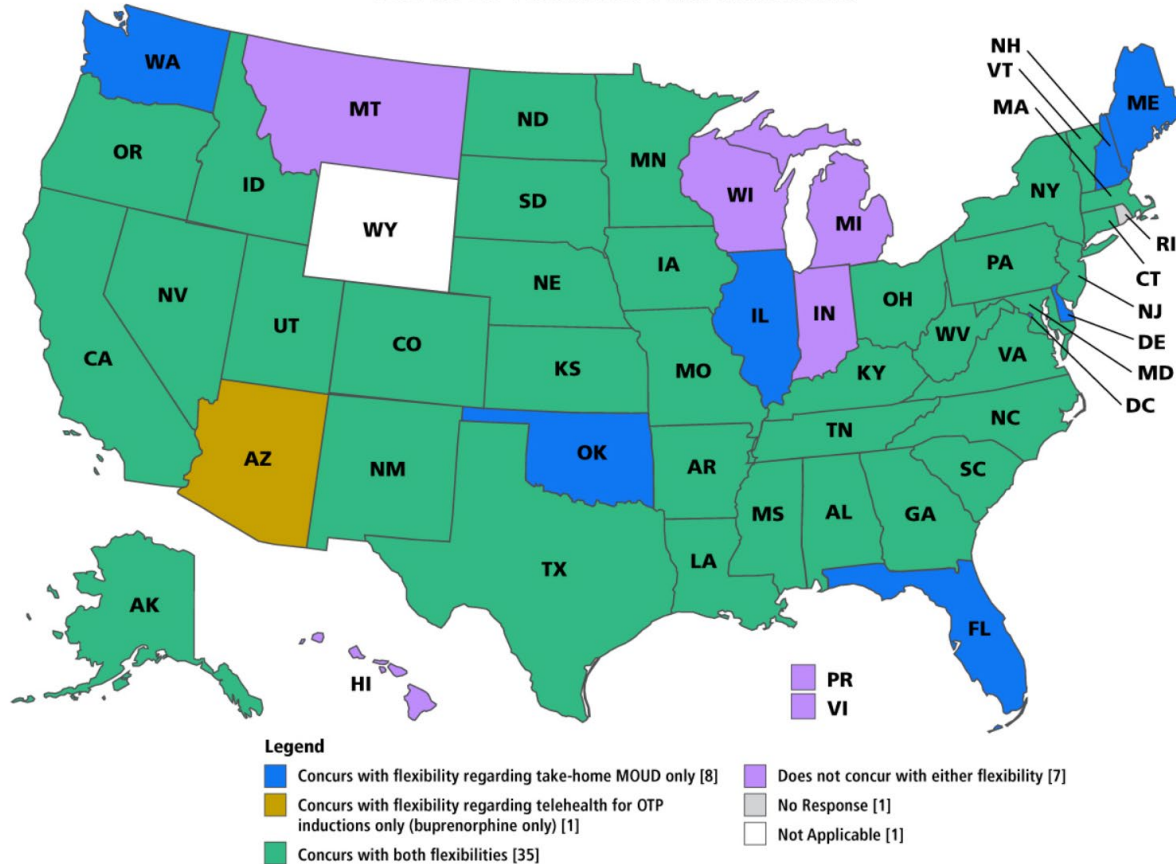
# Changes with State Law Implications

- **Admissions:** Eliminates 1-year opioid addiction history requirement
- **Take-Home Doses:** Expansion of criteria for take-home doses of methadone
- **Telehealth:** Buprenorphine and methadone initiation doses
- **Scope of Practice Expansion:** NPs & PAs ordering MOUD
- **Accreditation & Compliance:** Clarified responsibilities and extended corrective action timelines

# Take-Home Doses

- March 2020: SAMHSA exemptions permitting states to request blanket exceptions to allow more take-home doses of methadone during COVID-19
  - 43 States & DC
- OTPs allowed to dispense up to 28 days of take-home methadone to “stable” patients
  - Up to 14 doses of take-home methadone to “less stable patients”
- Subsequent SAMHSA guidance (Nov. 2021 & April 2023) extended methadone take-home flexibility for 1 year past the end of the COVID-19 PHE (May 11, 2024)
- Final Rule makes this permanent

## SAMHSA Certified Opioid Treatment Programs Post COVID Flexibilities State Concurrence

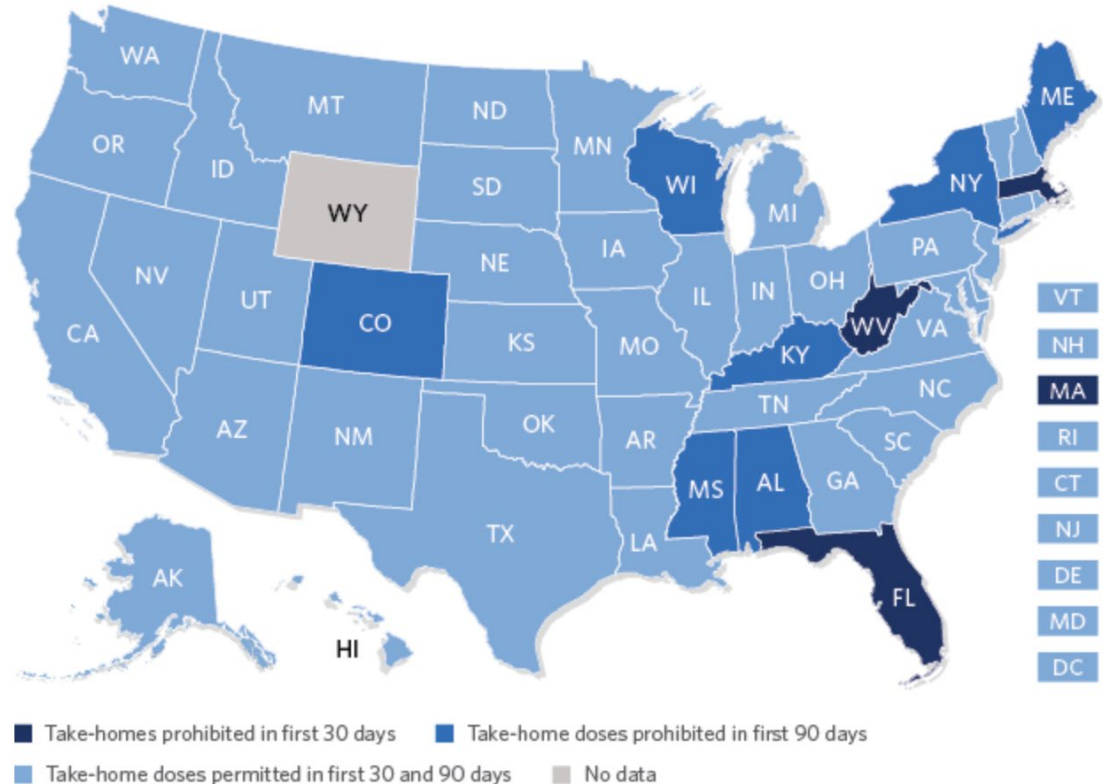


# Take-Home Doses

- Final rule makes COVID-19 flexibilities permanent
  - Removes “stable”/“less stable” terminology
    - Take-home doses based on the number of days in treatment
      - First 14 days: limited to 7 days of medication
      - 15-30 days: limited to 14 days of medication
      - After 31 days: up to 28 days of medications

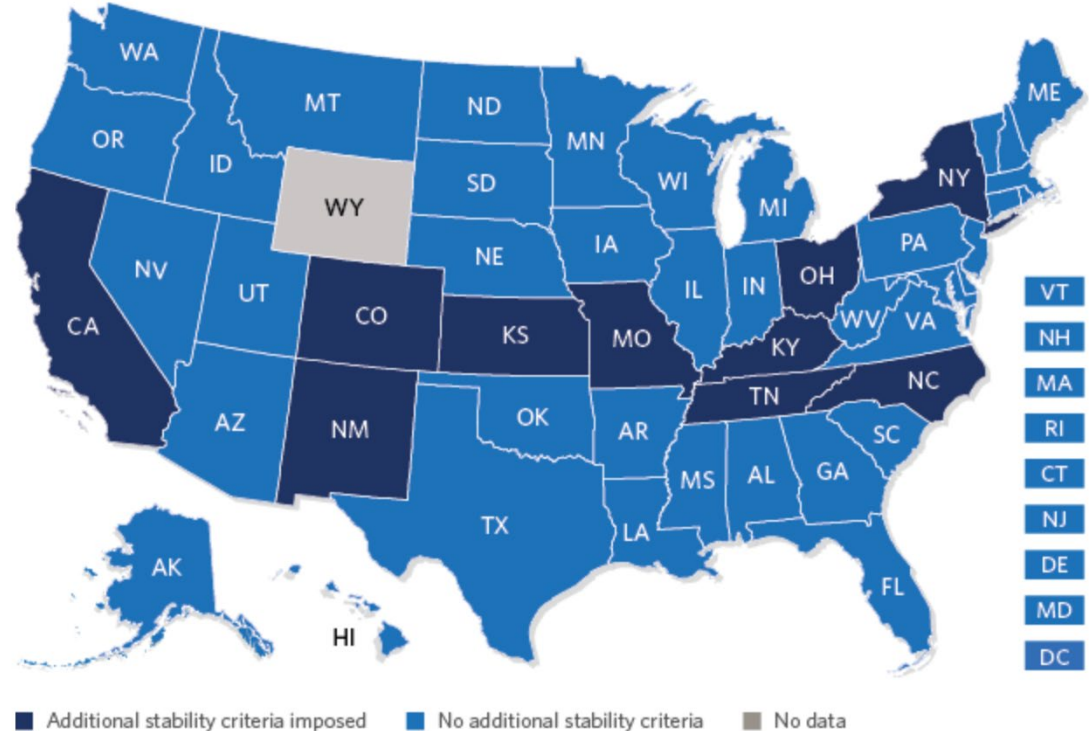
# State Laws Limiting Take-Home Medication

- Rules limiting take-home medications in the first 30 and 90 days of treatment as of June 1, 2021
- Reflects permanent rules in statutes or regulation
- Does not include federal waivers related to COVID-19, which likely expired in May 2023
- Wyoming = no OTPs or regulations



# State Stability Requirements for Take-Home Medication

- States with a definition of stability beyond the federal rule definition as of June 1, 2021
- Additional state stability criteria examples include demonstration of employment or attending school





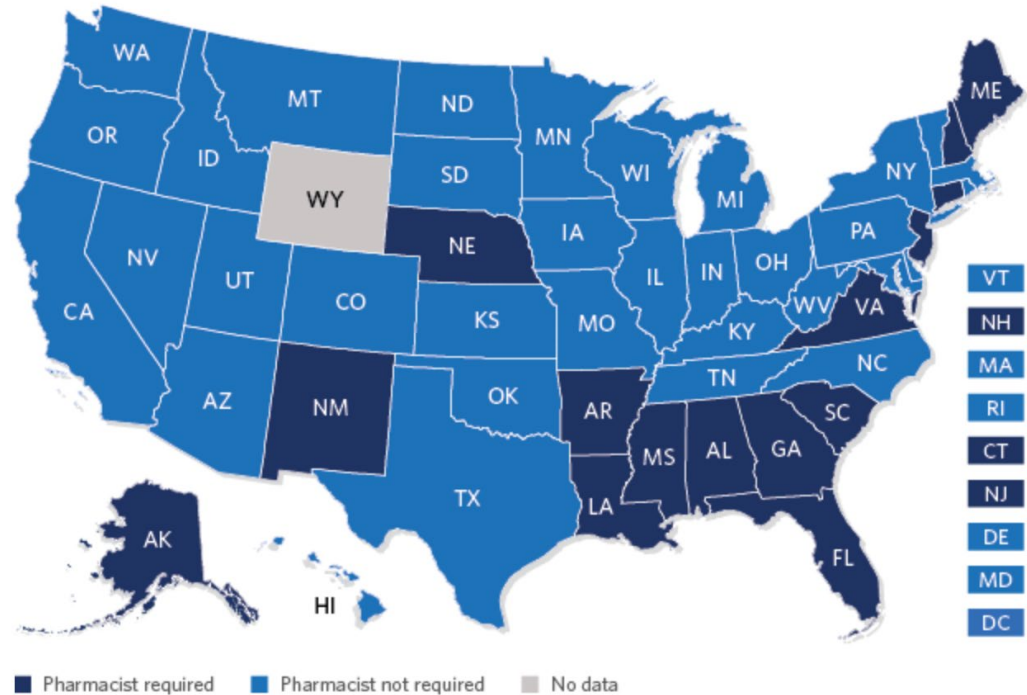
- Allows screening patients for initiation of buprenorphine via audio-only or audio-visual telehealth technology with provider discretion
  - Also allows for screening patients for the initiation of methadone via audio-visual telehealth under certain conditions
    - Goes beyond COVID-19 flexibilities
- Only applies to initial screening (in-person examination still required upon admission)
- Methadone must still be dispensed by OTP practitioners

# Scope of Practice

- Final rule includes any health care professionals licensed by the state to prescribe and dispense MOUD
  - Allows nurse practitioners and physician assistants to order MOUD for dispensing at the OTP **if consistent with the state law**
  - Need to know state scope of practice laws for NPs & PAs:
    - Dispensing/Prescribing authority
    - Supervision requirements
    - Collaboration agreements
  - Similar barriers for other health care professionals licensed by the state to prescribe and dispense MOUD

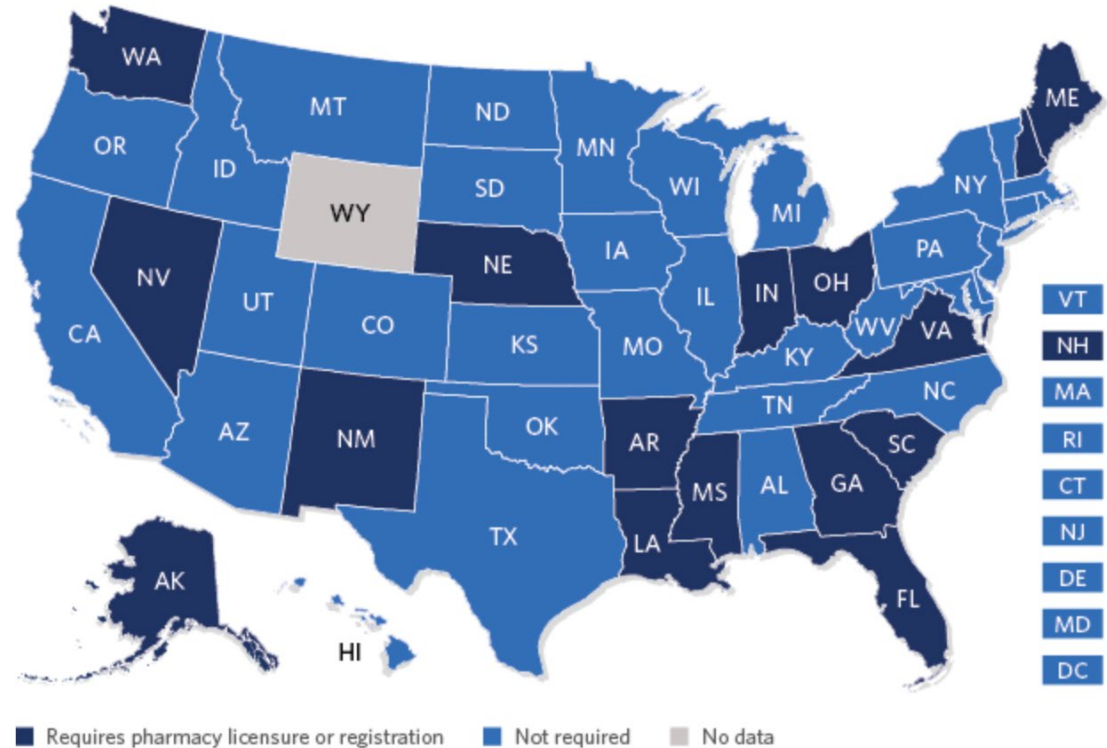
# States Requiring Pharmacist Services

- States requiring OTPs to hire a pharmacist or consultant pharmacist as of June 1, 2021
- Not required by federal law



# State Pharmacy License or Registration Requirements

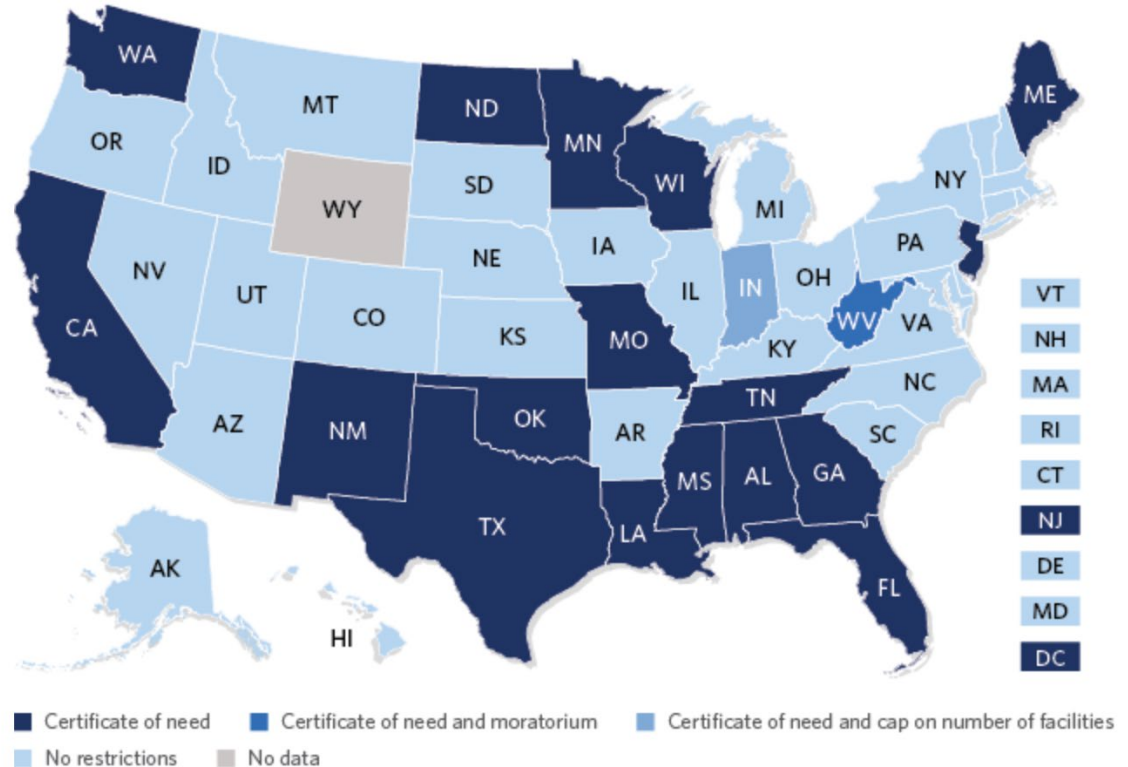
- States requiring pharmacy licensure or registration for new OTPs as of June 1, 2021
- Not required by federal law



- Improving monitoring to uphold quality standards at OTPs
  - Reporting time frames
  - Follow-up on OTP implementation of corrective measures
  - Communication with SAMHSA
- Allows for continuity of operations if compliance issues arise
  - Extend time for OTPs to take corrective actions

# State Restrictions on New OTPs

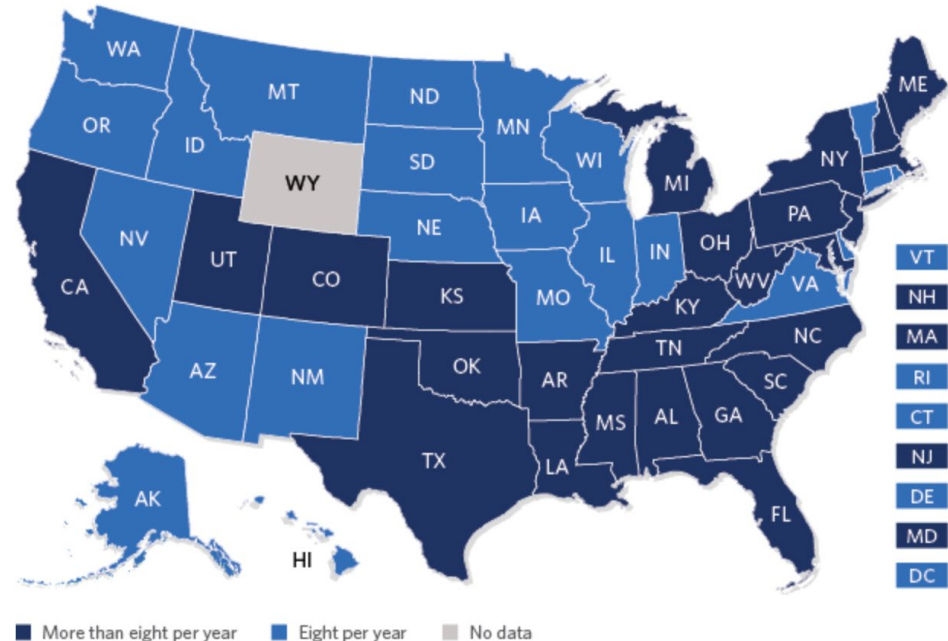
- States with barriers to opening new OTPs as of June 1, 2021
- Certificate of need = legal document demonstrating need for new facility



# Other State Law Barriers Remain

- Zoning restrictions
- Business hours
- Medication unit authorization
- Government ID requirement
- Set counseling schedules
- X-Waiver language
- **Increased frequency of drug screenings**

**26 States Require More Drug Screenings Than Federally Mandated**  
States requiring more than 8 drug screens per year as of June 1, 2021



# Resources

- PDAPS.org
- Pew Overview of Opioid Treatment Program Regulations by State:  
<https://www.pewtrusts.org/en/research-and-analysis/issue-briefs/2022/09/overview-of-opioid-treatment-program-regulations-by-state>
- Andraka-Christou B, Saloner B, Gordon AJ, Totaram R, Randall-Kosich O, Golan M, Stein BD. Laws for expanding access to medications for opioid use disorder: a legal analysis of 16 states & Washington D.C. Am J Drug Alcohol Abuse. 2022 Jul 4;48(4):492-503. doi: 10.1080/00952990.2022.2082301.

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