



The Pew Charitable Trusts

Overview of Opioid Treatment Program Regulations by State

Restrictive rules put evidence-based medication treatment out of reach for many

The Pew Charitable Trusts

Michael Caudell-Feagan, *executive vice president and chief program officer*

Kil Huh, *government performance*

Sara Dube, *behavioral health programs*

Project team

Sheri Doyle, *senior manager*

Frances McGaffey, *associate manager*

Vanessa Baaklini, *senior associate*

Kamren Gilbard, *associate*

External reviewers

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Overview

Opioid treatment programs (OTPs) are the only health care facilities that can offer patients all three forms of FDA-approved medication for opioid use disorder (OUD): methadone, buprenorphine, and injectable extended-release naltrexone.¹ But Pew found that nearly all states have rules governing OTPs that are not based in evidence and in turn limit access to care or worsen patient experience.²

These rules governing the establishment, operation, and provision of care at OTPs exist at both the federal and state levels: The federal government establishes baseline requirements for OTPs, and states layer additional requirements on top of them.³ Although debate over the future of federal methadone regulation is ongoing, **state policymakers have the opportunity to act now** to improve access to this medication and the quality of OTP services, as well as remove rules that go beyond federal restrictions and limit access to care.⁴

This chartbook examines OTP regulations across all 50 states and the District of Columbia as of June 2021 in two areas:

Access to care: Regulations that affect the ease with which patients access care at OTPs, such as dictating whether one is located close to where they live or work, whether services are available at convenient times, or whether patients must obtain a government ID to start treatment.

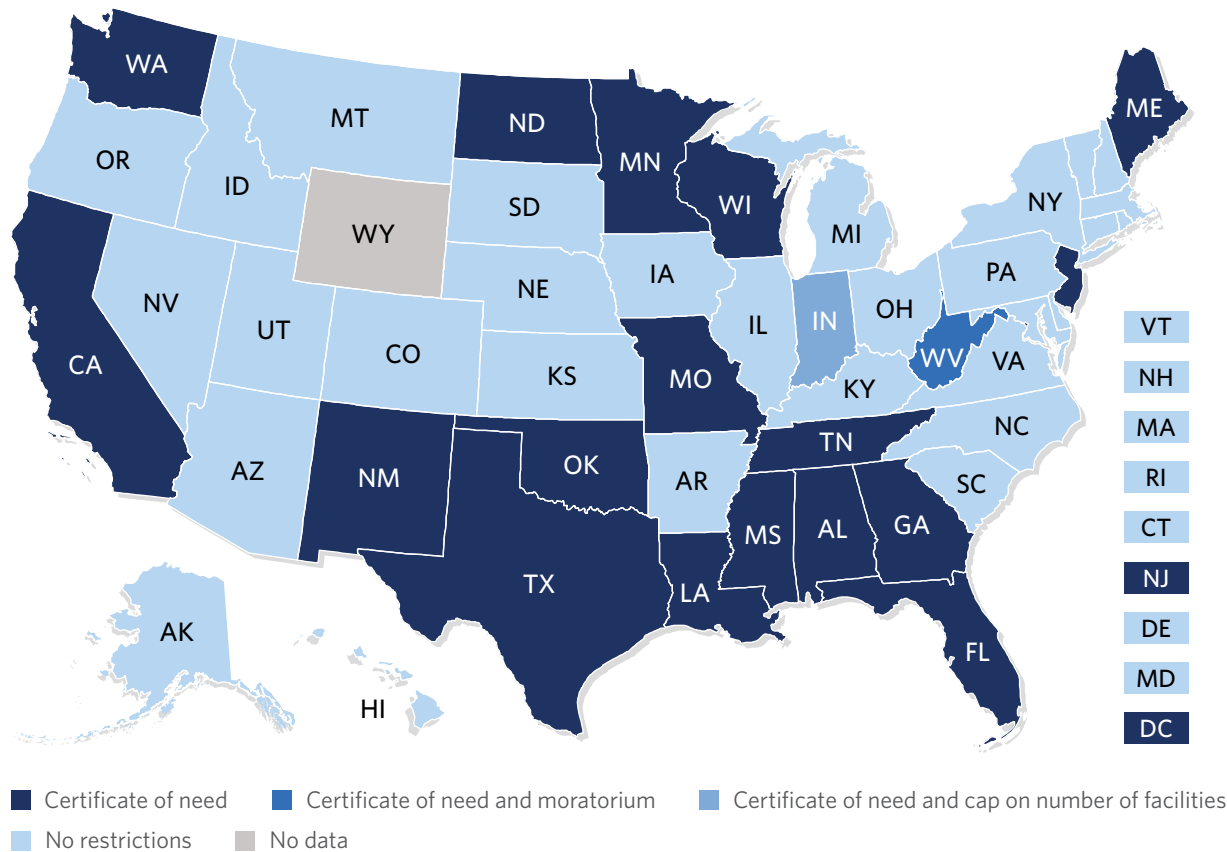
Patient experience: Rules that affect how patients receive care, such as whether they receive medication to take at home or if they have to go to the clinic every day. State regulations can help or hinder access to high-quality, evidence-based care that is aligned with federal rules and tailored to meet patients' needs.

Methadone is offered only in OTPs, which is one reason they are critical to reducing overdose deaths and providing lifesaving addiction treatment. State policymakers should review these rules and, where needed, revise them so that residents with OUD can access high-quality, lifesaving treatment.

Figure 1

19 States and the District of Columbia Impose Barriers on Opening New OTPs

Restrictions on new OTPs as of June 1, 2021



Notes: Wyoming has no data because the state has no OTPs or related regulations. A certificate of need is a legal document demonstrating the need for a new facility.

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Access to care

OTPs are not available in many communities. As of 2018, 80% of counties in the U.S., representing nearly a quarter of the population, had no OTPs.⁵ Even when a facility is nearby, patients may have challenges accessing care if services aren't available at convenient times or patients must show a government ID to receive methadone.

How states choose to regulate OTPs plays a role in how great these access challenges are.

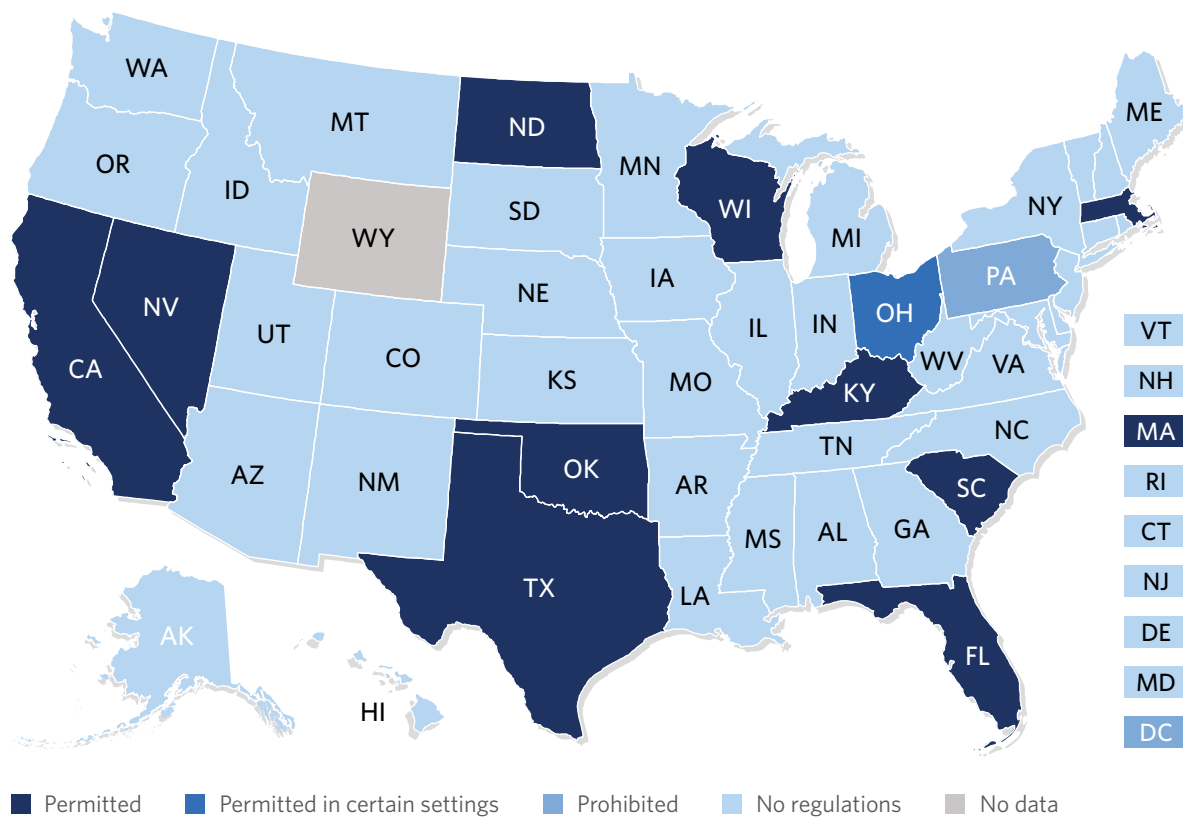
Restrictions on new OTPs

Nineteen states and the District of Columbia restrict providers from opening new OTPs in some way:

All 20 require a certificate of need, a legal document demonstrating that there is a need for a new facility. And Indiana limits the number of new facilities that can open.

West Virginia is the most restrictive state, with a legal moratorium disallowing new OTPs.

Figure 2
Medication Units Are Not Authorized in All States
 Medication-unit related regulations as of June 1, 2021



Medication units

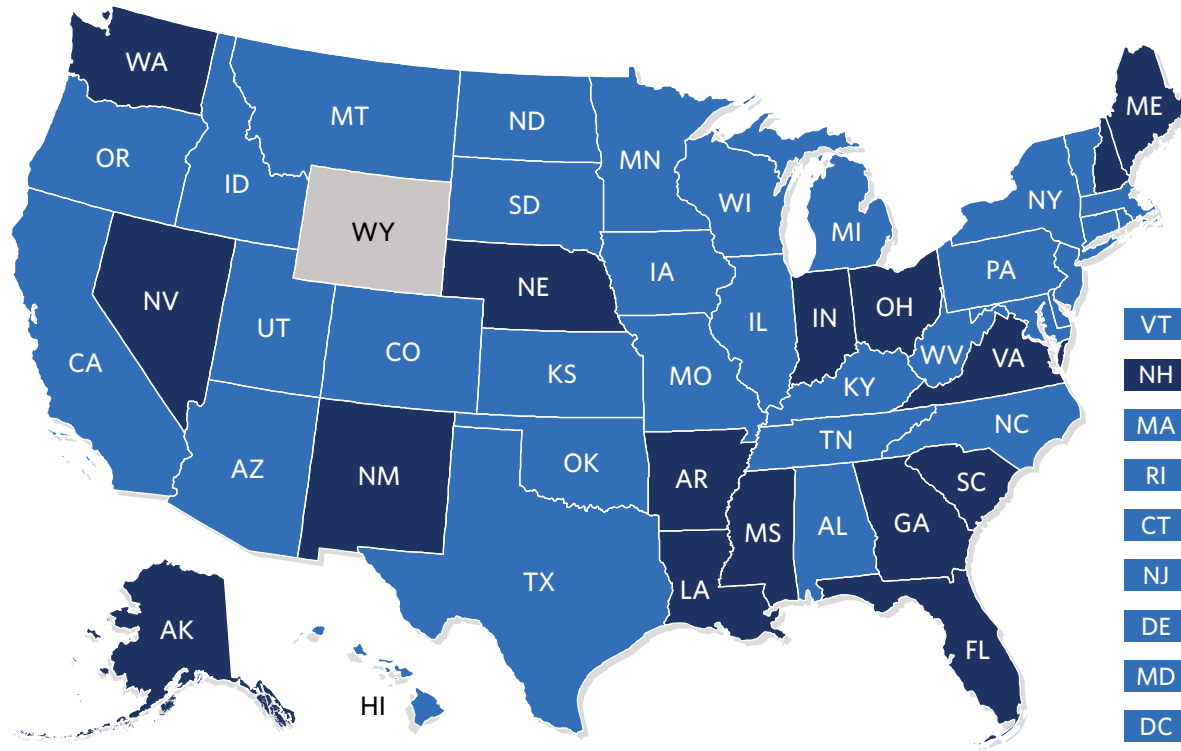
Conversely, allowing OTPs to open medication units—locations that may offer dosing and urine screens and are affiliated with an existing OTP—can make treatment more convenient for patients who receive methadone by expanding the locations where they can receive care.⁶

Eleven states explicitly permit medication units, while one—Pennsylvania—prohibits them. Ohio specifically allows medication units to operate in homeless shelters, jails, prisons, local boards of public health, community health centers, residential treatment providers, small counties, and counties in Appalachia.⁷

Note: Wyoming has no data because the state has no OTPs or related regulations.

Figure 3

16 States Require OTPs to Obtain a Pharmacy License or Registration Regulations as of June 1, 2021



■ Requires pharmacy licensure or registration ■ Not required ■ No data

Note: Wyoming has no data because the state has no OTPs or related regulations.

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Pharmacy-related barriers

Requiring pharmacy licensure or registration

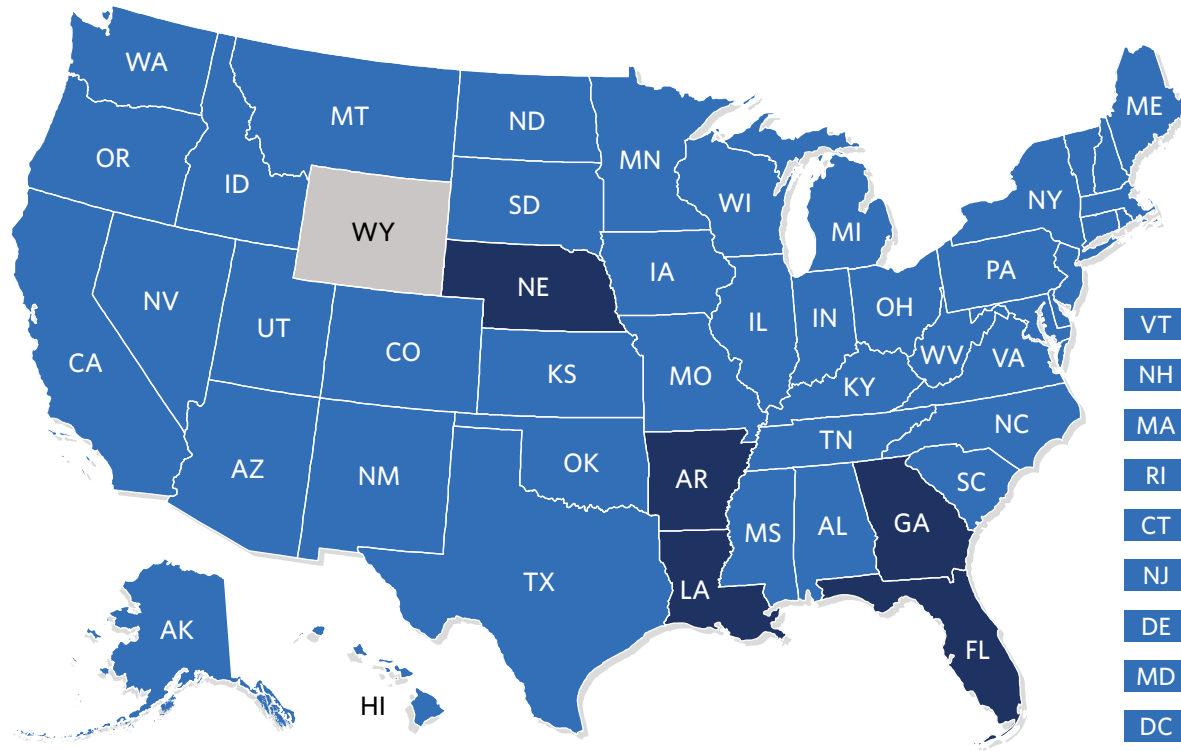
Another barrier to establishing new OTPs mandates that they be licensed or registered as pharmacies. This is not required by federal law.⁸

Sixteen states have these rules.

Figure 4

5 States Apply Pharmacy Regulations to OTPs

Regulations as of June 1, 2021



■ General pharmacy regulations applied to OTPs ■ Not applied ■ No data

Note: Wyoming has no data because the state has no OTPs or related regulations.

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Applying general pharmacy regulations to OTPs

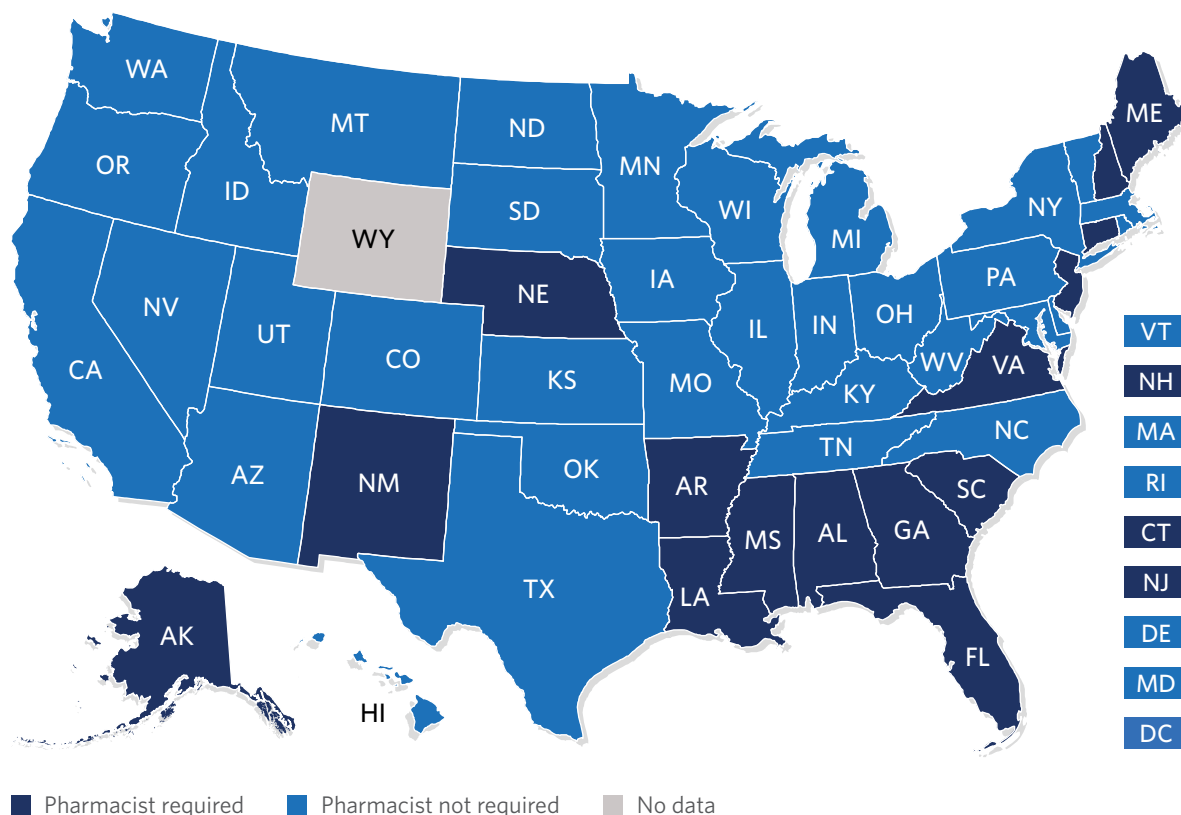
States that require OTPs to follow their general pharmacy regulations—which apply to a neighborhood drugstore that fills prescriptions for many medications that are used for multiple conditions—make establishing new OTPs even more challenging.

Five states apply general pharmacy regulations to OTPs.

Figure 5

15 States Require Pharmacist Services in OTPs

Regulations mandating that a pharmacist be employed at OTPs or a consultant pharmacist used as of June 1, 2021



Requiring pharmacist services

Federal law allows methadone administration by a variety of licensed health care professionals including registered nurses, licensed practical nurses, or other health care professionals who are otherwise authorized to dispense opioids.⁹

However, 15 states require OTPs to hire a pharmacist or a consultant pharmacist, who provides guidance on the appropriateness and safety of medication use.¹⁰

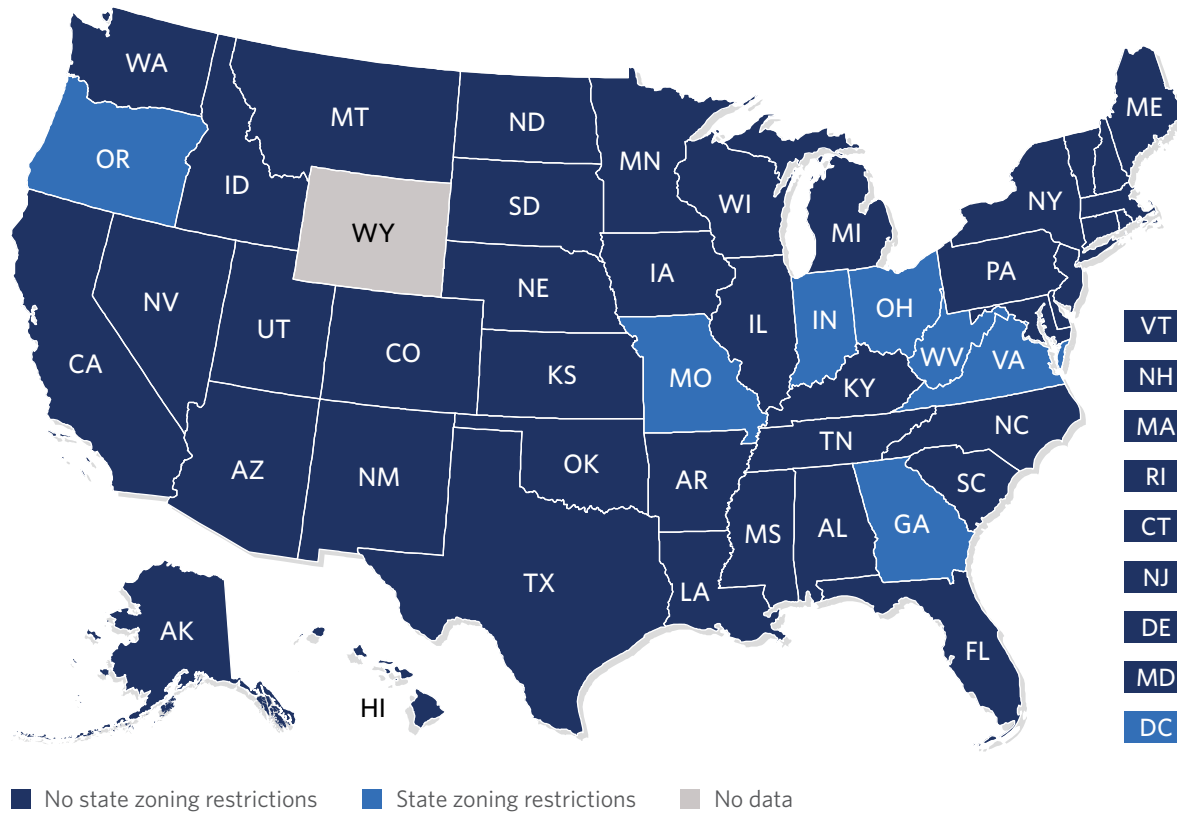
Note: Wyoming has no data because the state has no OTPs or related regulations.

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Figure 6

State Zoning Restrictions Can Limit Access to Care

Restrictions on where OTPs can operate as of June 1, 2021



Note: Wyoming has no data because the state has no OTPs or related regulations.

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Zoning

State zoning restrictions

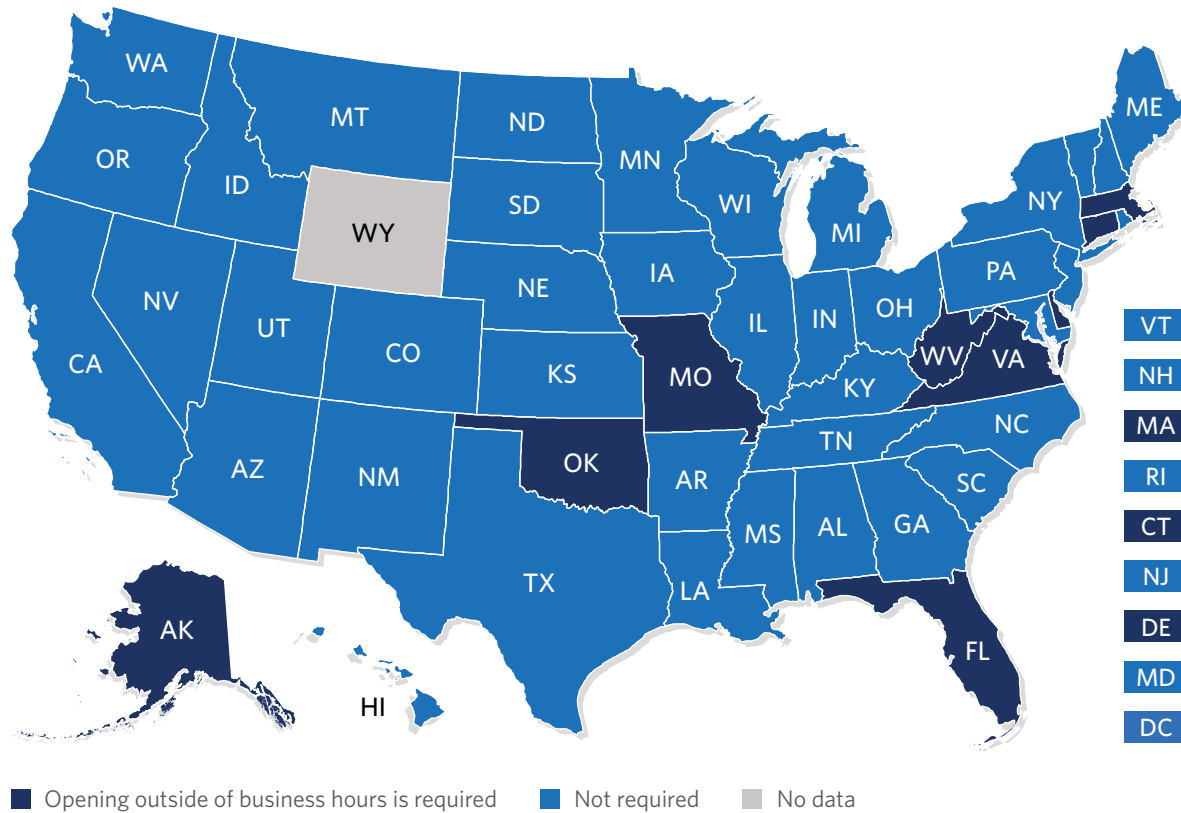
Restrictions on where an OTP can operate, beyond those that apply to other medical facilities, is not considered to be best practice.¹¹

Seven states and the District of Columbia have these rules. However, in the District, the regulation *supports* access to care because OTPs are required to be located near public transportation.

Figure 7

Being Open Outside of Typical Business Hours Helps Patients Access OTP Care

Rules as of June 1, 2021



Note: Wyoming has no data because the state has no OTPs or related regulations.

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Hours of operation

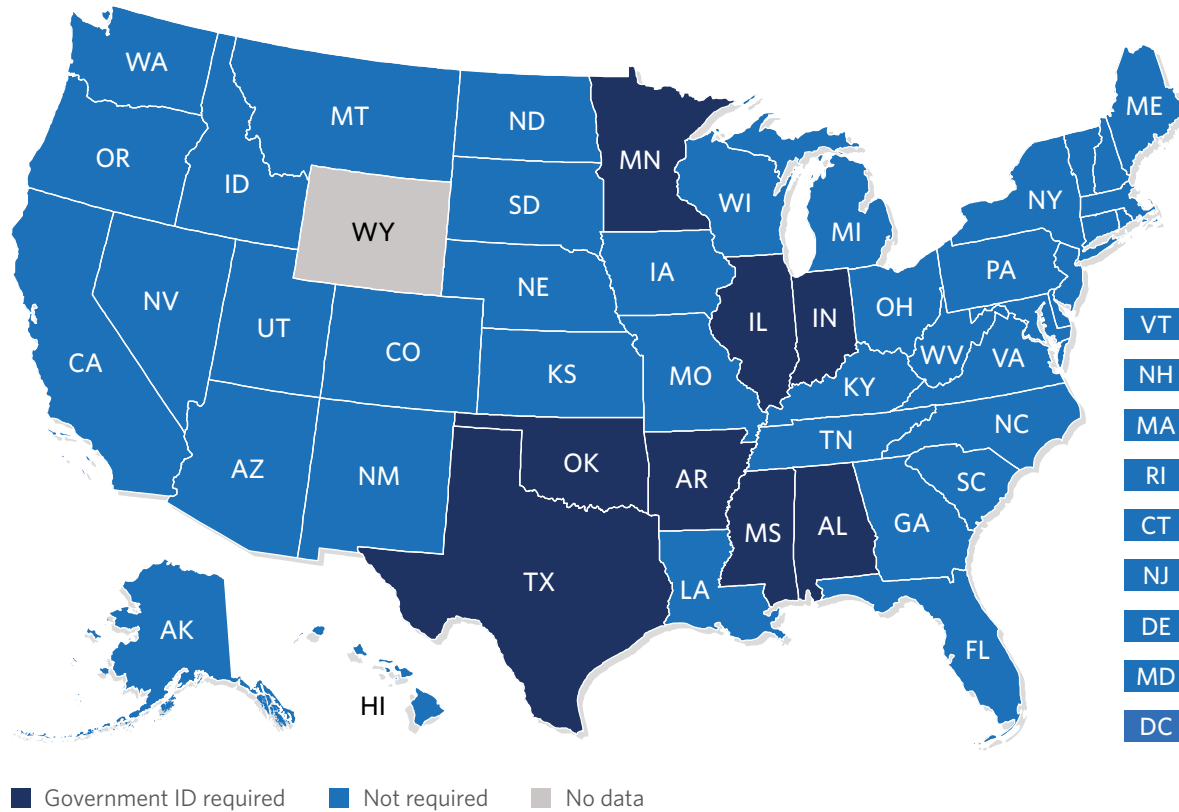
Requiring OTPs to be open outside of regular business hours (e.g., outside of 8 a.m.-5 p.m.) provides flexibility for clients who may find it difficult to go to the clinic each day due to other responsibilities such as work or family obligations.¹²

Nine states require OTPs to be open outside of business hours.

Figure 8

8 States Require a Government ID to Access OTP Treatment

Rules as of June 1, 2021



Note: Wyoming has no data because the state has no OTPs or related regulations.

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Government ID

Some people—including undocumented immigrants, people who have been incarcerated, people experiencing homelessness, and many other populations—face challenges in obtaining an ID.¹³ Requiring a client to show government ID to be admitted to an OTP can be a barrier to care.

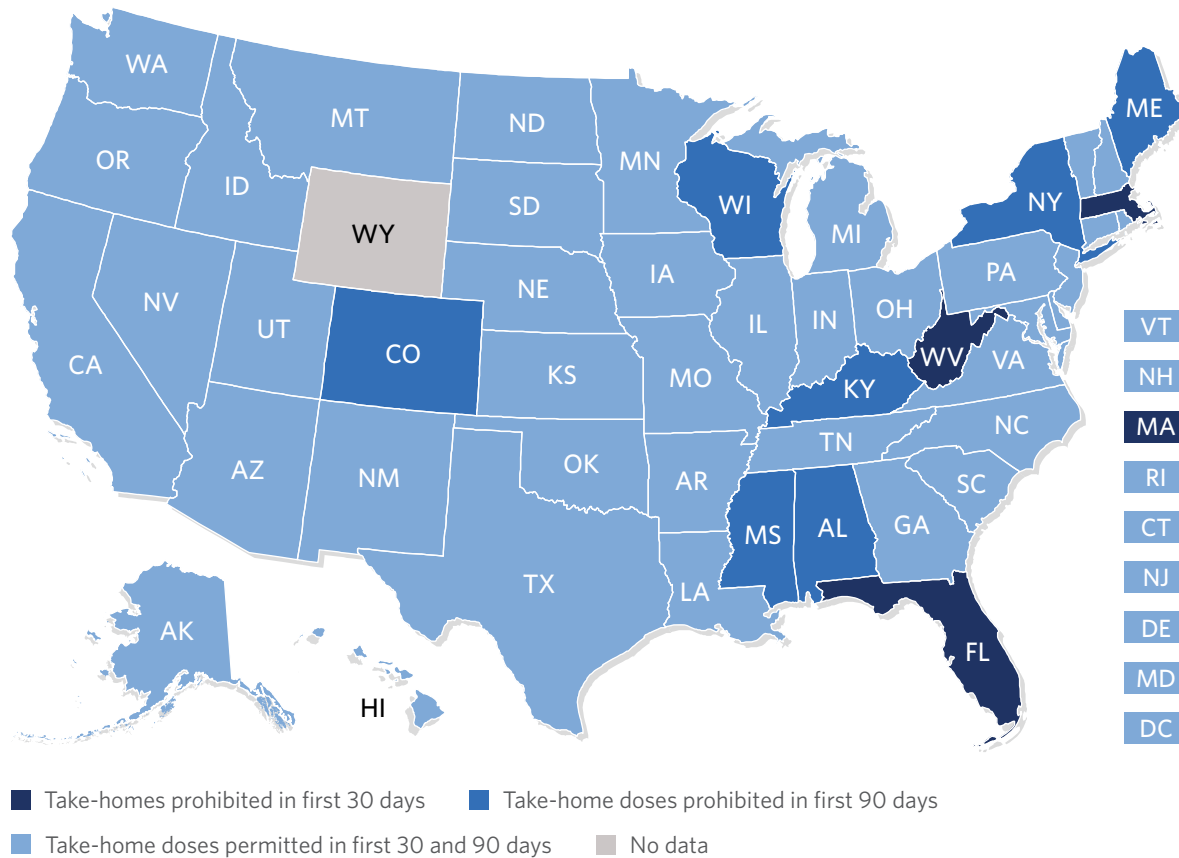
Eight states have this requirement.

Conversely, California allows OTPs to provide patient identification cards that include the individual's photo, a unique identifier, and a physical description.¹⁴ This allows the OTP to verify the patient's identity before dispensing methadone without requiring a government ID.

Figure 9

State Laws Limiting Take-Home Medication Reduce Patient Flexibility

Rules limiting take-home medication in the first 30 and 90 days of treatment as of June 1, 2021



Notes: Wyoming has no data because the state has no OTPs or related regulations.

Many states implemented a federal waiver to allow additional take-home doses during the COVID-19 public health emergency.¹⁵ This analysis is limited to permanent rules in statute or regulation and does not reflect these temporary changes.

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Patient experience

Federal rules already dictate the frequency of urine drug screens and whether patients can receive take-home methadone—a supply of medication for opioid use disorder that allows patients to avoid having to go to the clinic each day—as well as other aspects of OTP care.

When states add additional rules, they further constrain providers from offering individualized, high-quality care that meets their patients' needs.

Eligibility for take-home doses

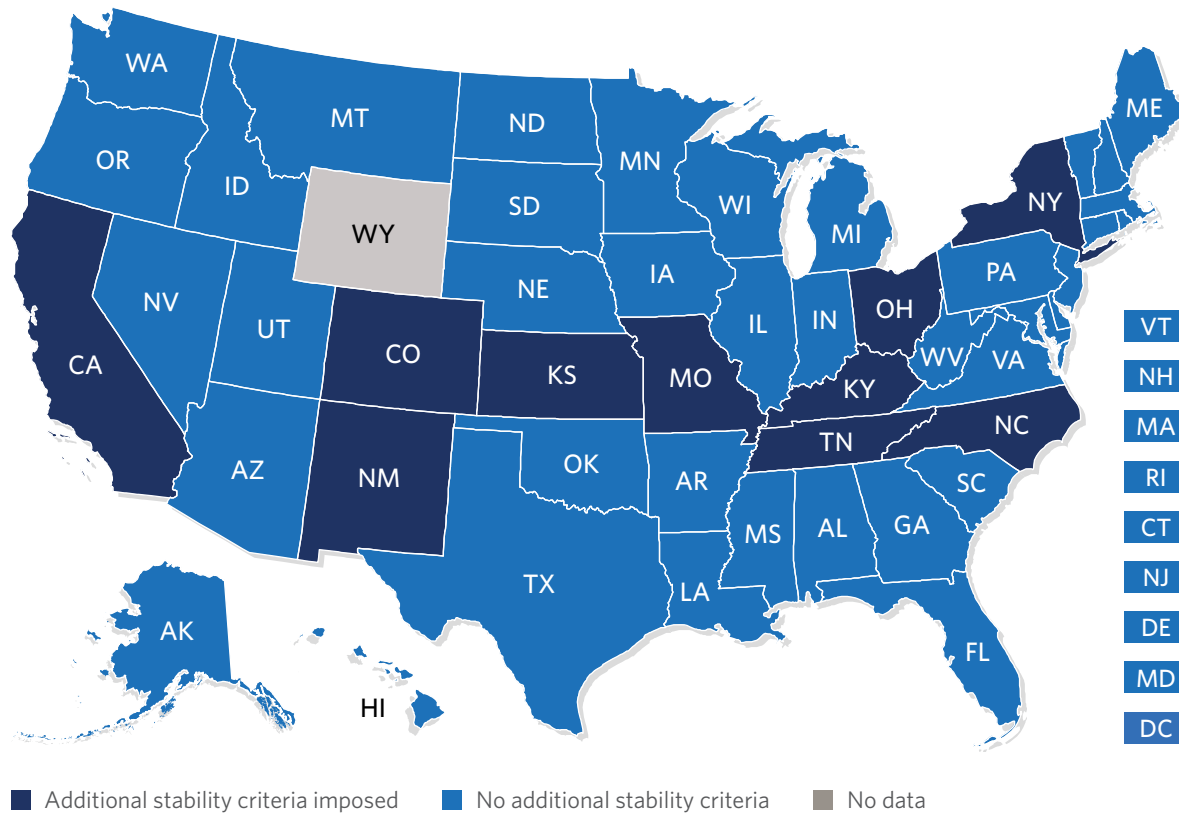
Before the COVID-19 public health emergency, federal rules allowed a single take-home dose per week in the first 90 days of treatment if patients met specific stability criteria.¹⁶ This requirement has not been permanently changed, and only temporary flexibilities have been granted as of April 2022.¹⁷

Ten states go beyond federal rules by prohibiting take-home doses in the first 30 days of treatment. Of these, seven states prohibit this practice during the full first 90 days of care.

Figure 10

State Stability Requirements Make It Harder to Obtain Take-Home Medication

States with a definition of stability beyond what is described in federal rules as of June 1, 2021



Note: Wyoming has no data because the state has no OTPs or related regulations.

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Additional stability criteria

Federal rules require that patients meet eight stability criteria to receive take-home doses:

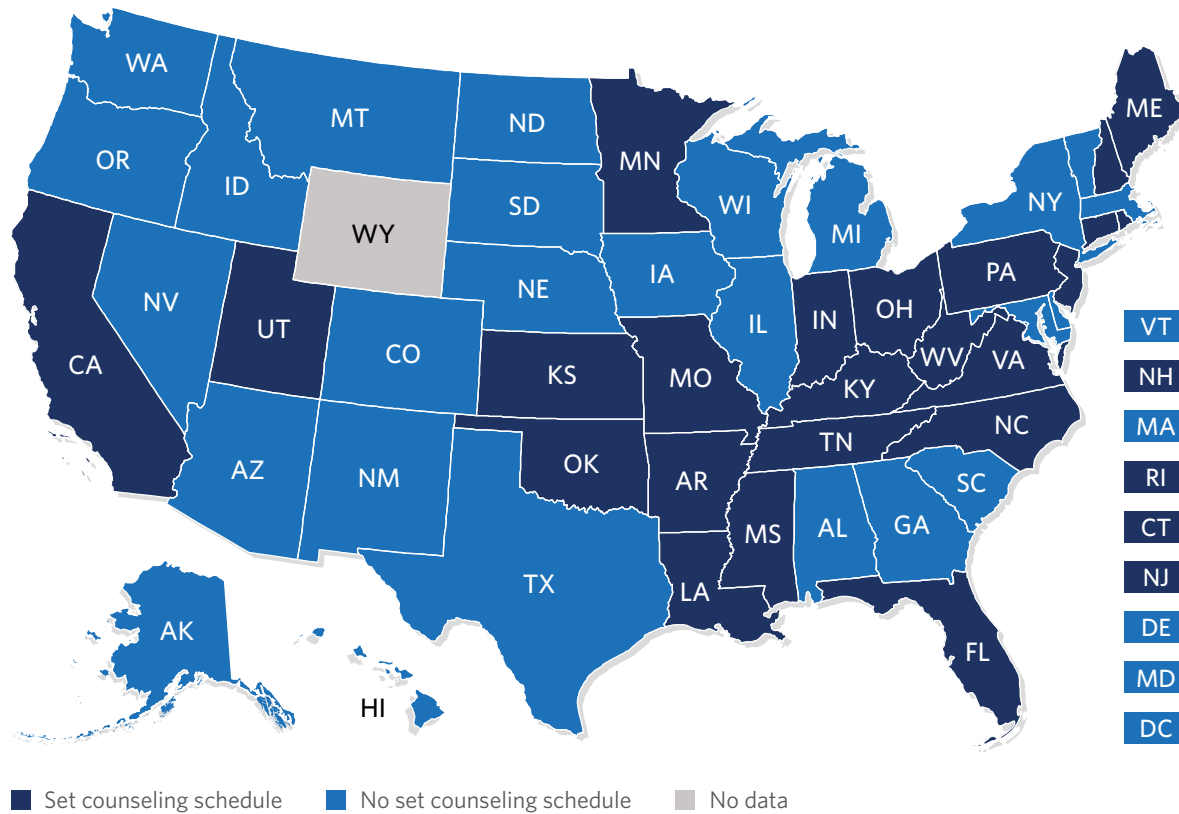
- Absence of recent abuse of drugs (opioid or non-narcotic), including alcohol.
- Regularity of clinic attendance.
- Absence of serious behavioral problems at the clinic.
- Absence of known recent criminal activity, e.g., drug dealing.
- Stability of the patient's home environment and social relationships.
- Length of time in comprehensive maintenance treatment.
- Assurance that take-home medication can be safely stored within the patient's home.
- Whether the rehabilitative benefit the patient derived from decreasing the frequency of clinic attendance outweighs the potential risks of diversion.¹⁸

Ten states impose additional stability criteria. For example, Missouri also requires that patients "demonstrate a level of stability as evidenced by ... employment, actively seeking employment, or attending school if not retired, disabled, functioning as a homemaker, or otherwise economically stable."¹⁹

Figure 11

Nearly Half of States Have a Set Counseling Schedule, Rather Than Individualized Treatment

States that specify a set counseling schedule based on time in treatment or other factors, as of June 1, 2021



Note: Wyoming has no data because the state has no OTPs or related regulations.

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Inflexible counseling requirements

Requiring clients to participate in a set counseling schedule (e.g., a minimum number or length of sessions) to stay in treatment or receive take-home medication is not in line with federal regulations, and strict counseling requirements can reduce retention in treatment.²⁰

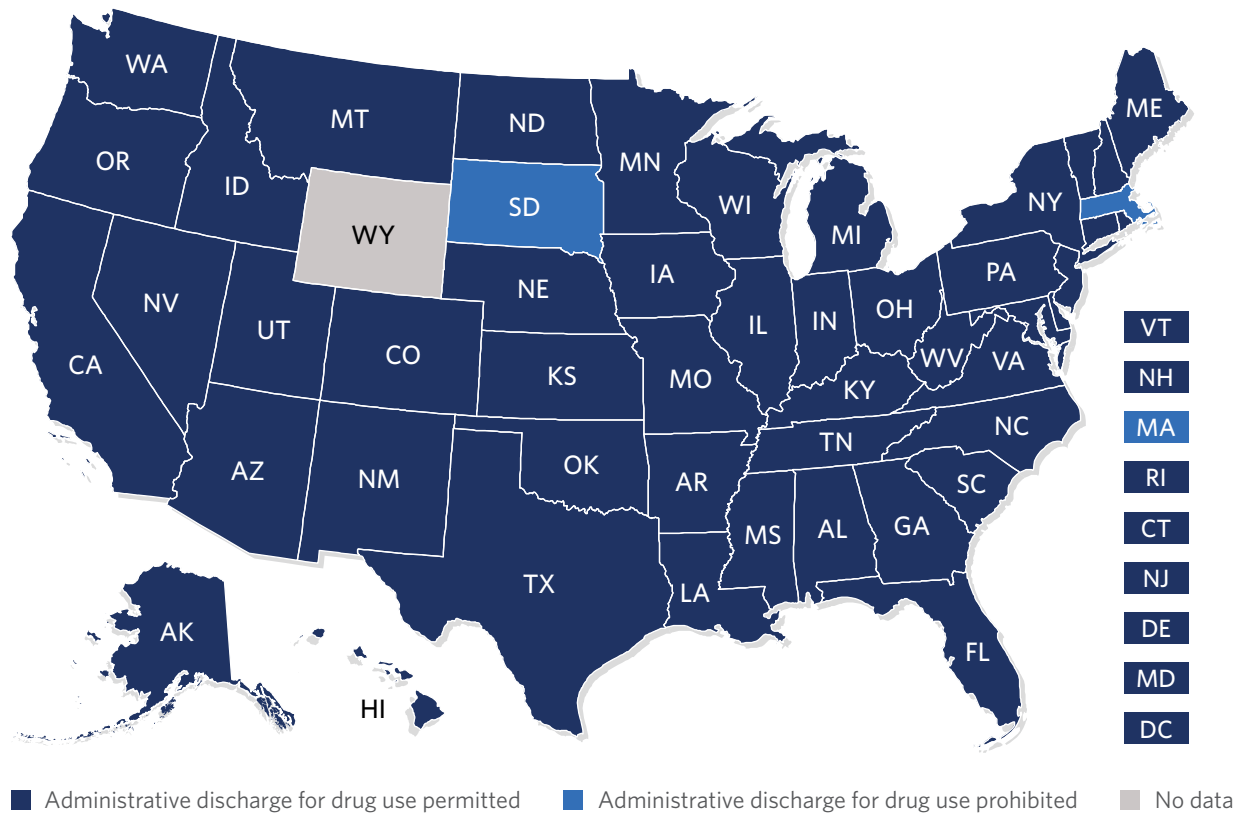
Twenty-three states impose a set counseling schedule. These rules can be tied to eligibility for take-home medication. In Oklahoma, for example, patients move through five phases of treatment based on time in treatment and compliance with program rules, including participation in a set number of individual and group counseling sessions per phase. Each phase provides more take-home doses.²¹

These rules are not aligned with evidence, which shows that medication for opioid use disorder can be effective without counseling.²²

Figure 12

Terminating Care Because of Continued Drug Use Is Common, Despite Being Against Federal Guidelines

Regulations allowing for administrative discharge as of June 1, 2021



Notes: Wyoming has no data because the state has no OTPs or related regulations.

Administrative discharge is the practice of terminating clients for violating program rules.

Regulations are interpreted as permitting administrative discharge if: 1) it is explicitly permitted, even if the regulation states that it should not be the sole reason for discharge, 2) the state grants broad discretion to programs to terminate services, or 3) there is no prohibition on administrative discharge for this reason.

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Forcing people to leave treatment for violating program rules

It's common for people who use opioids to also use multiple substances as well as return to opioid use, even among people on medications for opioid use disorder (MOUD).²³ Although federal guidelines and recommendations list neither as a reason to end medication treatment and research supports that continuing MOUD is safer than suddenly stopping treatment, some programs "administratively discharge"—or terminate—clients because of continued drug use.²⁴

Only Massachusetts and South Dakota prohibit administrative discharge for not being abstinent.

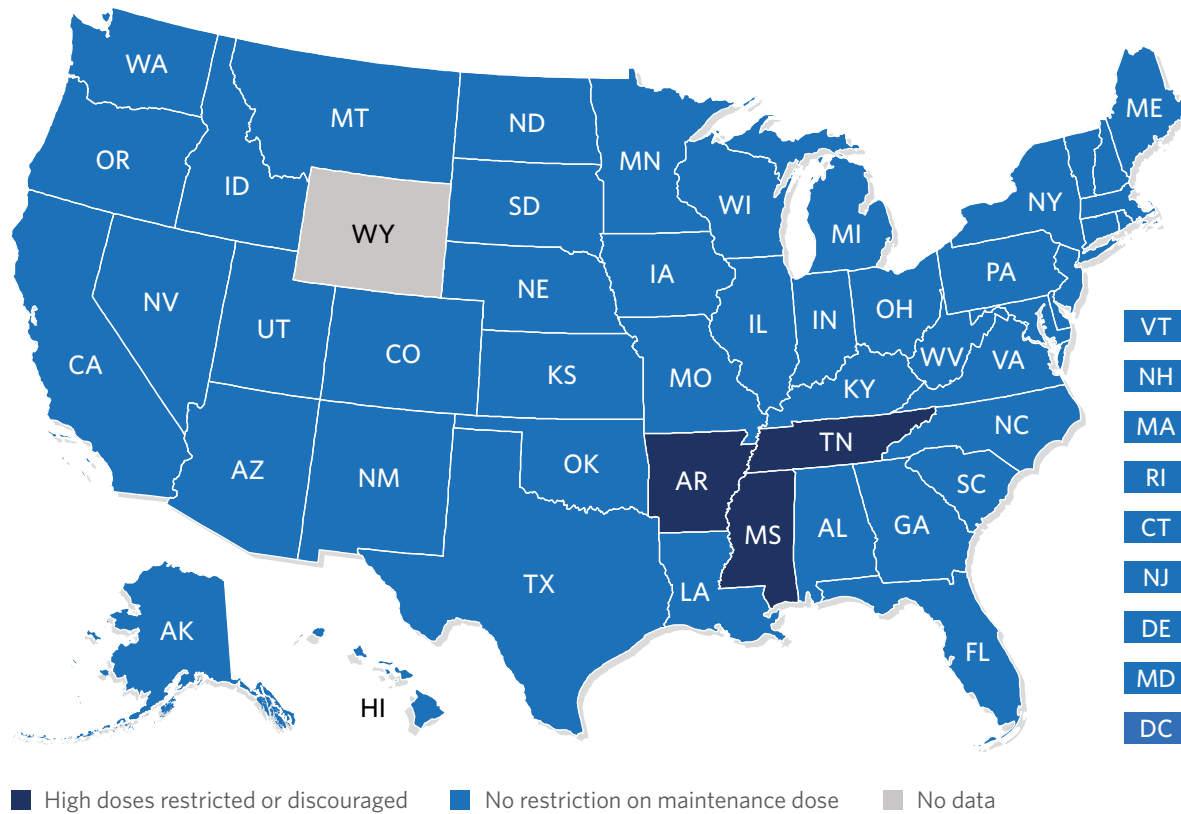
All states allow administrative discharge for missed methadone doses, although federal guidelines recommend reassessing patients who miss more than four methadone doses rather than terminating their treatment.²⁵

All states also allow administrative discharge for nonparticipation in counseling or other ancillary services, even though the American Society of Addiction Medicine says the decision to decline these services should not affect a patient's ability to obtain MOUD.²⁶

Figure 13

3 States Make It More Difficult for Patients to Get the Dose Level They Need

States that restrict or discourage high maintenance doses as of June 1, 2021



Notes: Wyoming has no data because the state has no OTPs or related regulations.

A restriction is defined as always prohibiting certain dose levels or requiring State Opioid Treatment Authority approval to exceed a certain amount. Restrictions on initial doses are excluded.

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Restricting medication dosage

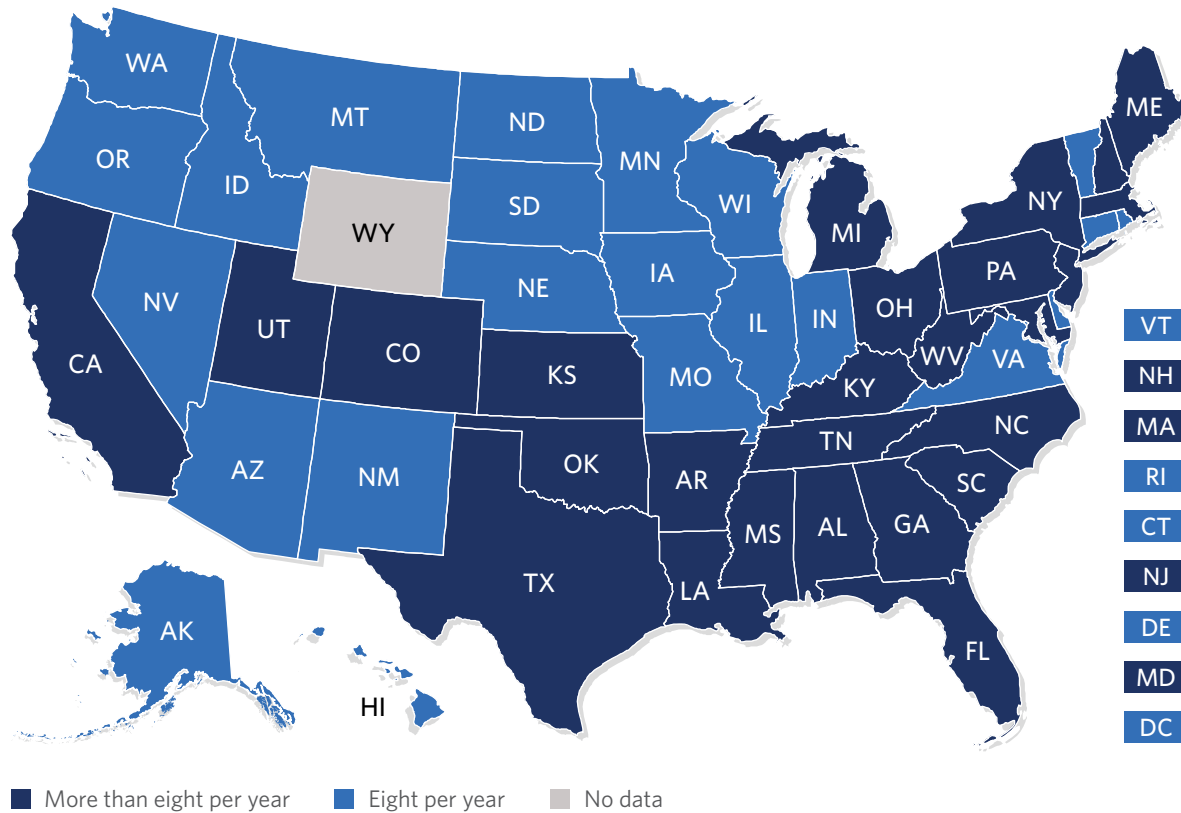
Doses that are too low may not effectively reduce drug cravings or use.²⁷ Restricting or discouraging higher doses of medication may cause patients to discontinue treatment. This restriction is also not aligned with federal guidelines or evidence, as higher doses can lead to greater reductions in drug use among patients with OUD.²⁸

Three states have these rules.

Figure 14

26 States Require More Drug Screenings Than Federally Mandated

States requiring more than 8 drug screens per year as of June 1, 2021



Note: Wyoming has no data because the state has no OTPs or related regulations.

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Urine drug screenings

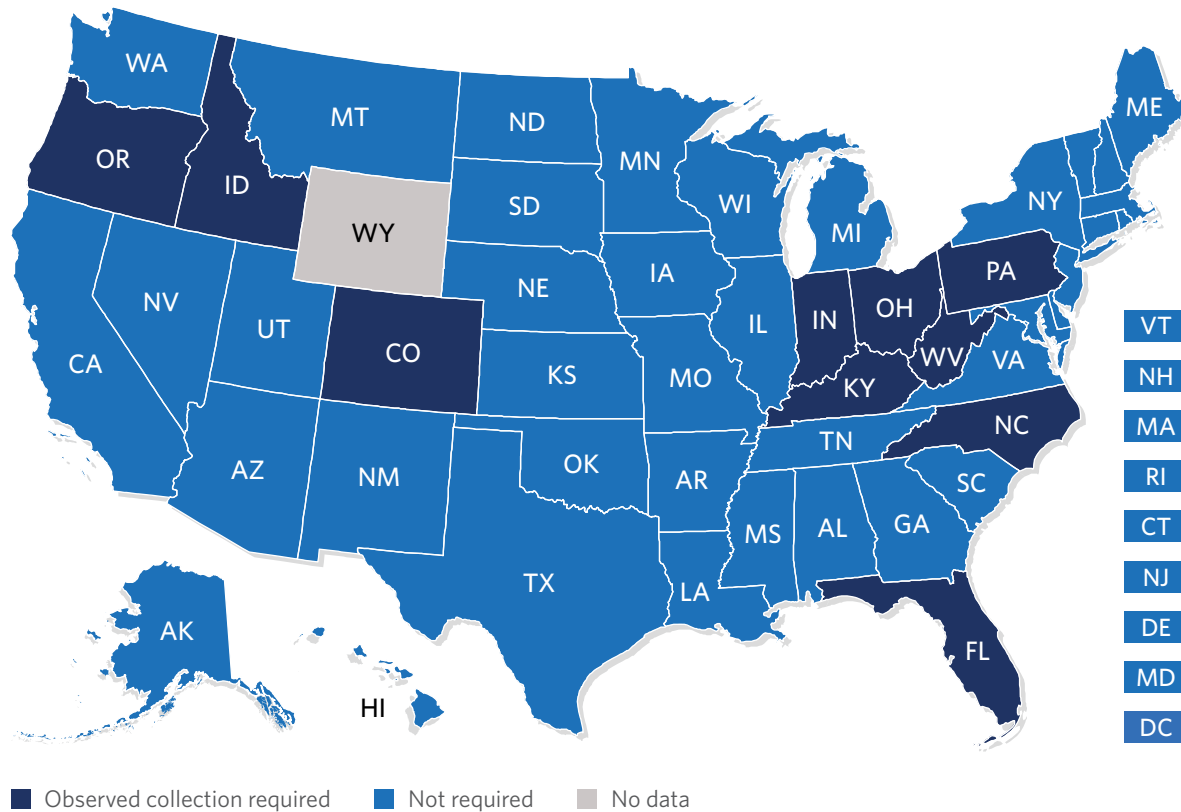
Requiring additional tests

Federal rules require eight drug tests per year.²⁹ Requiring additional tests places a burden on patients and, according to preliminary research, may not be as necessary for patient safety as once thought, and may also raise the cost of treatment.³⁰

Twenty-six states require more than eight annual drug screenings.

Figure 15

Requiring Observed Urine Collection Can Be Embarrassing for Clients Rules as of June 1, 2021



Notes: Wyoming has no data because the state has no OTPs or related regulations.

States are included if they generally require observation for all urine collections, rather than only in cases when diversion or continued drug use is suspected.

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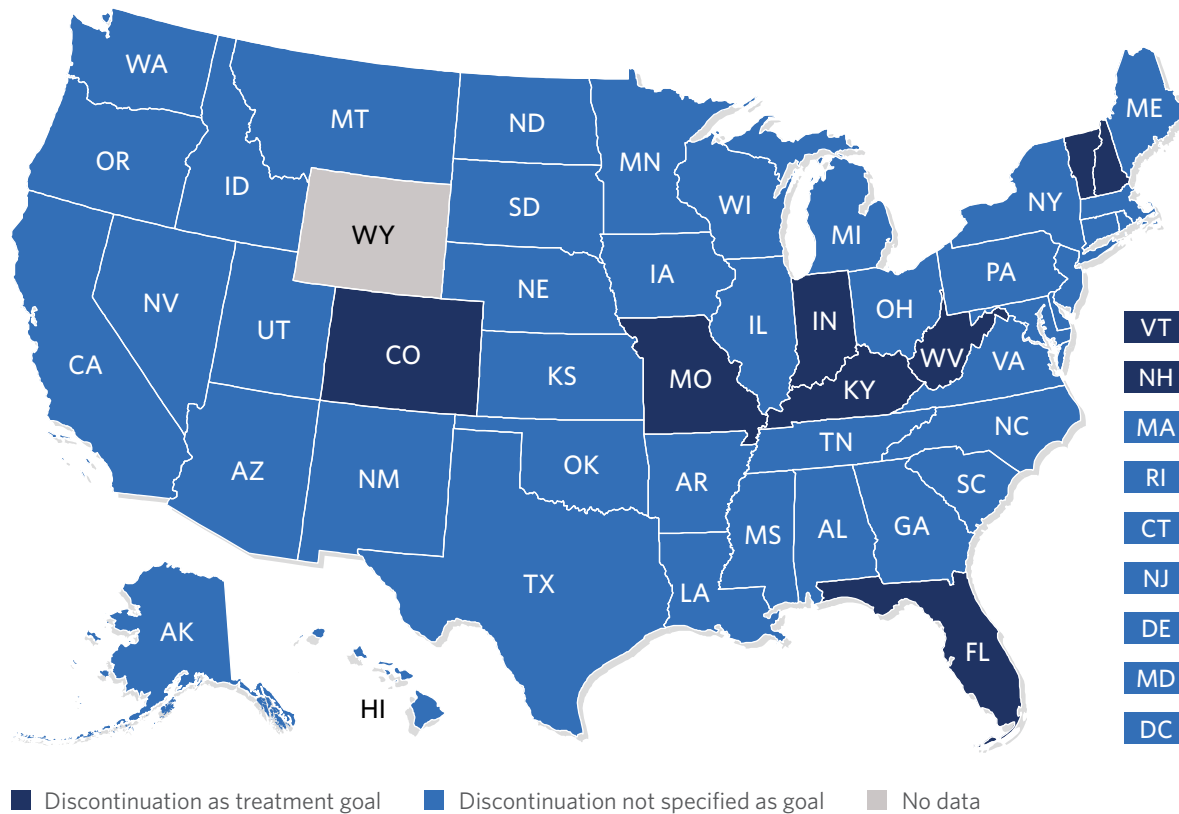
Observing urine specimen collection

Ten states have rules requiring OTPs to observe patients during urine sample collection, which can be embarrassing and degrading for clients.³¹ According to one, “I don’t like somebody looking at me, or behind me ... it’s not a very pleasant experience for anybody. Actually, I think it’s undignified, and I feel it’s wrong.”³²

Figure 16

Long-Term Treatment Leads to Better Outcomes, but 8 States Encourage Discontinuation

Rules as of June 1, 2021



Notes: Wyoming has no data because the state has no OTPs or related regulations.

States are included if they explicitly define discontinuation as the treatment goal or require clients to be offered withdrawal management at regular intervals.

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Establishing a treatment goal not based in evidence

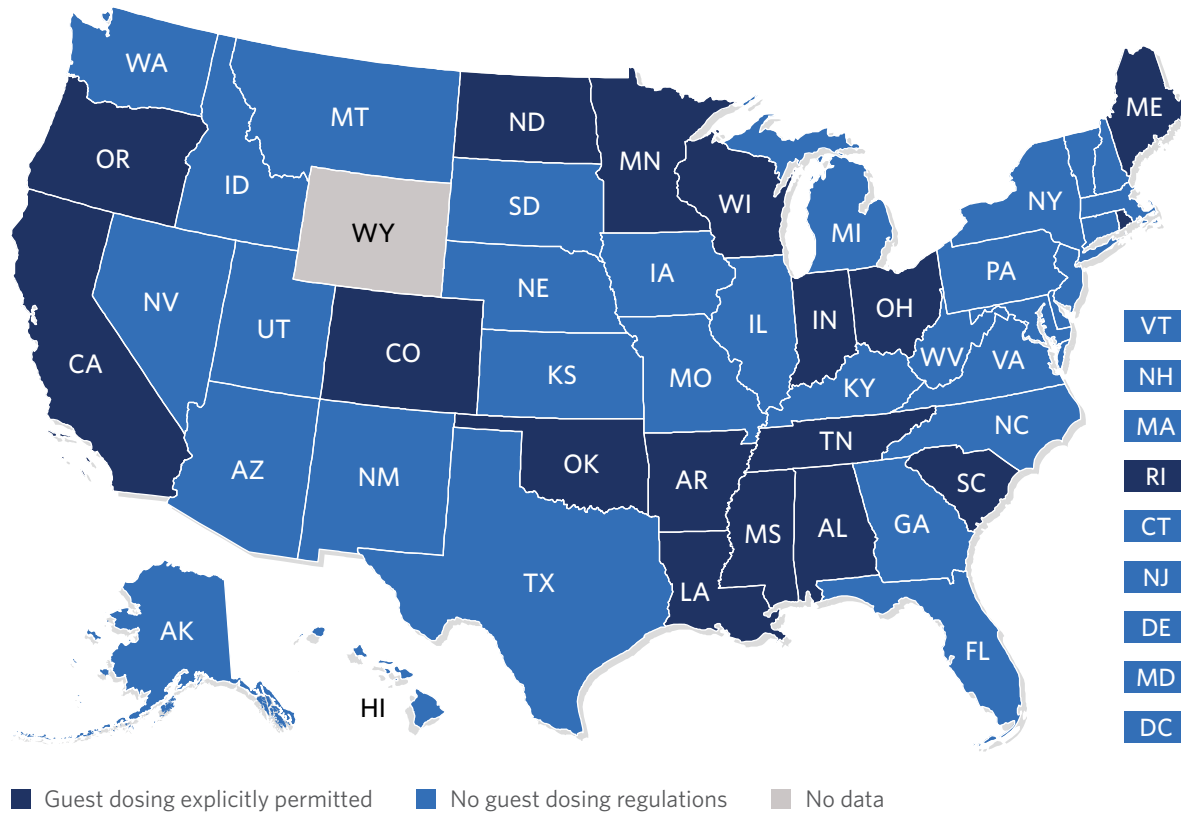
Evidence supports that long-term treatment can be more beneficial for patients in terms of overdose risk, employment, health, and criminal justice involvement; according to the American Society of Addiction Medicine, “There is no recommended time limit for pharmacological treatment with methadone.”³³

But eight states have rules that establish discontinuation as the goal of treatment. These regulations may encourage providers and patients to stop treatment when doing so is not necessary and can increase overdose death.³⁴

Figure 17

Guest Dosing Allows OTP Patients to Travel

Rules as of June 1, 2021



Note: Wyoming has no data because the state has no OTPs or related regulations.

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Allowing patients flexibility while traveling

Although other regulations can worsen patient experience, states can also improve it through regulations.

Explicitly allowing guest dosing—that is, temporarily getting methadone from an OTP other than the one at which someone is a patient—is one way to help. This provides flexibility for patients who are traveling.³⁵

Seventeen states have rules that explicitly allow this practice, though it may still be permitted in states without these regulations.

Conclusion

Data shows that many states make it harder for OTP patients to access and remain in treatment in a variety of ways.

As overdose deaths continue to climb, state policymakers should review these rules and make changes so that more people get the lifesaving treatment provided in these settings.

Methodology

Identifying regulatory language

Pew reviewed both statutes and administrative codes for the District of Columbia and all states, except for Wyoming, using Lexis. Wyoming was excluded because the state does not have any OTPs or related regulations.

Initial citations were drawn from Jackson et al. (2020) and the Prescription Drug Abuse Policy System “Requirements for Licensure and Operations of Medications for Opioid Use Disorder Treatment.”³⁶ In addition to these sources, Pew reviewed the section of statutes providing rule-making authority to the agency that promulgated regulations in the administrative code. If either regulations or statutes referred to Board of Pharmacy oversight, Pew also examined the relevant sections of administrative code produced by that body.

Data represents state rules codified in statute and administrative code as of June 2021. It does not reflect any temporary changes such as executive orders or policy statements states may have issued due to the COVID-19 pandemic.³⁷

Coding

Pew developed an initial list of codes based on a review of the OTP federal guidelines and literature on best practices. Using NVivo, the research team that has years of OUD research and policy expertise initially coded five states. The regulations for each state were independently coded by two members of the research team. Pew then held a coding meeting to discuss our findings and refine the codebook, and then recoded these states. The research team then conducted a test of inter-rater reliability, which ensures consistency in coding among research team members, resolved coding discrepancies, and refined the codebook further. Pew then coded five additional states, held another coding meeting, and finalized the codebook. (See Appendix)

Quality control

Pew conducted two quality control steps—comparing our findings with existing research and verifying results with state officials.

Comparison with existing research

Pew compared the findings with previously conducted reviews of OTP regulations.³⁸ In most cases, disagreement between Pew’s findings and these publications were due to differences in definition or because regulations had been updated since those reviews were conducted. If we identified an error based on these comparisons, we updated our data.

Verification with state opioid treatment authorities (SOTAs)

Between June and August 2021, Pew sent the results of each jurisdiction's regulatory review to their state opioid treatment authority, or SOTA, the official charged with overseeing OTPs. These officials were identified by a list maintained by the Substance Abuse and Mental Health Services Administration.³⁹ For Wyoming, Pew contacted the deputy administrator of the Behavioral Health Division because the state does not have a SOTA.

Each SOTA was asked to verify whether Pew's interpretation of their state's OTP rules was correct, and if it was not, to provide updated information.

After sending multiple reminders to each official, Pew received responses from all but 12 states (Delaware, Kansas, Mississippi, Missouri, New Hampshire, New York, Rhode Island, Tennessee, Utah, Vermont, Washington, and Wisconsin). If the SOTA disagreed with the research team's findings, Pew either updated the research or explained the decision not to. In those cases where we did not update our findings, those discrepancies were either due to differences in definitions or because updated regulatory language was not in effect until after June 1, 2021, our cutoff date.

Appendix: Codebook

Table A.1

Theme: Access to OTP Services

Area of regulation	Regulation	Impact	Description
Restrictions on new OTPs	Moratorium in place	Limits access to care	Does the state prohibit the licensing and operation of any new OTPs?
Restrictions on new OTPs	Cap on new OTPs	Limits access to care	Does the state set a limit on the number of new OTPs that can open?
Restrictions on new OTPs	Certificate of need required	Limits access to care	Does the state require a certificate of need (CON) for new facilities? States are interpreted to require a CON if programs are required to demonstrate need prior to approval, even if the exact term "certificate of need" is not used.
Medication units	Medication units permitted	Supports access to care	Does the state permit the operation of medication units? States are only coded as permitting medication units if their regulations specifically authorize them.
Medication units	Medication units prohibited	Limits access to care	Does the state prohibit the operation of medication units?
Medication units	Restrictions on medication unit settings	Limits access to care	Does the state place restrictions on where and how medication units can operate (e.g., only in specific facilities such as federally qualified health centers, hospitals, etc.)?
Pharmacy	Pharmacy licensure or registration required	Limits access to care	Does the state require a license from or registration with the Board of Pharmacy to operate an OTP?
Pharmacy	General pharmacy regulations applied to OTPs	Limits access to care	If licensure with the Board of Pharmacy is required, does the state require the OTP to comply with the state's general pharmacy regulations?
Pharmacy	Pharmacist services required	Limits access to care	Does the state require the employment of a pharmacist at OTPs or the use of a consultant pharmacist?
Zoning	State zoning restrictions	Limits access to care	Does the state place restrictions on where an OTP can operate?

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Area of regulation	Regulation	Impact	Description
Hours of operation	Requirements to be open outside of regular business hours	Supports access to care	Does the state explicitly require the OTP to be open any time outside of regular business hours (e.g., outside of 8 a.m.-5 p.m.)? Excludes dosing by appointment only outside of regular business hours.
Government ID	Government ID required to access treatment	Limits access to care	Does the state require a patient to have a government ID to be admitted?

Table A.2

Theme: Patient experience

Area of regulation	Regulation	Impact	Description
Take-home medication	Take-home medication prohibited in the first 30 days	Worsens patient experience	Does the state prohibit take-home medications in the first 30 days of treatment? Only states with an explicit prohibition in this time period are included.
Take-home medication	Take-home medication prohibited in the first 90 days	Worsens patient experience	Does the state prohibit take-home medications in the first 90 days of treatment? Only states with an explicit prohibition in this time period are included.
Take-home medication	Additional stability criteria for take-home medication	Worsens patient experience	Does the state have a specific definition of “stability” for take-home medication beyond what is described in federal regulations? See 42 C.F.R. § 8.12(h)(4)(i).
Administrative discharge	Administrative discharge permitted for continued drug use	Worsens patient experience	Does the state permit administrative discharge for continued use of illicit drugs (whether discovered through positive urine drug screen, self-report, or other means)? Regulations are interpreted as permitting administrative discharge if: 1) it is explicitly permitted, even if the regulation states that it should not be the sole reason for discharge, 2) the state grants broad discretion to programs to terminate services, or 3) there is no prohibition on administrative discharge for this reason.
Administrative discharge	Administrative discharge permitted for missed dose	Worsens patient experience	Does the state permit administrative discharge for missed dosing appointments? Regulations are interpreted as permitting administrative discharge if: 1) it is explicitly permitted, even if the regulation states that it should not be the sole reason for discharge, 2) the state grants broad discretion to programs to terminate services, or 3) there is no prohibition on administrative discharge for this reason.
Administrative discharge	Administrative discharge permitted for nonparticipation	Worsens patient experience	Does the state permit administrative discharge for nonparticipation in the treatment plan (e.g., not attending counseling or group sessions)? Regulations are interpreted as permitting administrative discharge if: 1) it is explicitly permitted, even if the regulation states that it should not be the sole reason for discharge, 2) the state grants broad discretion to programs to terminate services, or 3) there is no prohibition on administrative discharge for this reason.
Counseling	Set schedule for counseling sessions	Worsens patient experience	Does the state specify a set counseling schedule with a minimum number of sessions based on time in treatment or other factors? This includes requiring a set schedule to receive take-home medications.

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Area of regulation	Regulation	Impact	Description
Medication dosing	Medication dose level restrictions	Worsens patient experience	Does the state restrict or discourage high maintenance doses? A restriction is defined as always prohibiting certain dose levels or requiring SOTA approval to exceed a certain amount. Restrictions on initial doses are excluded.
Drug testing	Additional drug tests required	Worsens patient experience	Does the state require drug testing more frequently than federal rules (at least eight per year - see 42 C.F.R § 8.12(f)(6))?
Drug testing	Observed collection of urine samples required	Worsens patient experience	Does the state have a blanket requirement that OTPs observe urine specimen collections?
Guest dosing	Guest dosing allowed	Improves patient experience	Does the state explicitly permit guest dosing? This includes the concept of being able to temporarily get methadone from an OTP other than the one at which someone is a client, even if the state does not use the term "guest dosing."
Treatment goal	Discontinuation of medications as a goal for treatment	Worsens patient experience	Does the state establish the discontinuation of medications for opioid use disorder as the goal of treatment? This includes states that require clients to be offered withdrawal management at regular intervals.

Endnotes

- 1 The Pew Charitable Trusts, "Medications for Opioid Use Disorder Improve Patient Outcomes" (2020), <https://www.pewtrusts.org/en/research-and-analysis/factsheets/2020/12/medications-for-opioid-use-disorder-improve-patient-outcomes>.
- 2 The Pew Charitable Trusts, "Improved Opioid Treatment Programs Would Expand Access to Quality Care" (2022), <https://www.pewtrusts.org/-/media/assets/2022/03/improve-opioid-treatment-programs-to-expand-access.pdf>.
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For further information, please visit:

pewtrusts.org

Contact: Erin Davis, communications manager

Email: edavis@pewtrusts.org

Project website: pewtrusts.org/substancemisuse

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