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State Opioid Treatment Program Regulations Put Evidence-Based Care Out of Reach for Many

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."[1] 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.[2]

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 to existing research and verifying results with state officials.

Comparison to existing research

Pew compared the findings to previously conducted reviews of OTP regulations.[3] 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.[4] 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

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.

Table A1

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?
	Cap on new OTPs	Limits access to care	Does the state set a limit on the number of new OTPs that can open?
	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 prohibited	Limits access to care	Does the state prohibit the operation of 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?
	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?
	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?
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 A2

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 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.
	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 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 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.
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))?
	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.

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[1] Jackson et al., “Characterizing Variability”; Prescription Drug Abuse Policy System, Requirements for Licensure and Operations of Medications for Opioid Use Disorder Treatment, through Aug. 1, 2020, https://pdaps.org/datasets/medication-assisted-treatment-licensure-and-operations-1580241579.
[2] American Society of Addiction Medicine, “COVID-19 - National and State Health Guidance,” https://www.asam.org/quality-care/clinical-guidelines/covid/national-and-state-guidance.
[3] Jackson et al., “Characterizing Variability”; Prescription Drug Abuse Policy System, Requirements for Licensure and Operations of Medications for Opioid Use Disorder Treatment.
[4] Substance Abuse and Mental Health Services Administration, “State Opioid Treatment Authorities,” https://www.samhsa.gov/medication-assisted-treatment/sota.