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Revised Regulations for Opioid Treatment Programs: Establishing a Baseline to Measure Progress Over Time

SAMHSA
Substance Abuse and Mental Health Services Administration

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Executive Summary

Part 8 of Title 42 of the Code of Federal Regulations (CFR), *Medications for the Treatment of Opioid Use Disorder* (commonly referred to as 42 CFR part 8 or Part 8), contains the federal regulations that establish the standards for services provided in opioid treatment programs (OTPs), which are specialized facilities certified to provide treatment for individuals with opioid use disorder (OUD). These regulations ensure the safe and effective use of medications such as methadone and buprenorphine (also referred to as medications for opioid use disorder [MOUD])* for the treatment of individuals with OUD, as well as other services OTPs are required to offer patients with OUD.

In February 2024, the Department of Health and Human Services (HHS) and the Substance Abuse and Mental Health Services Administration (SAMHSA) published a substantial revision of the 42 CFR part 8 regulations, updating them for the first time in more than 20 years. To allow time for OTPs to prepare for the revisions and states/territories to review their regulations, SAMHSA set the effective date as April 2, 2024, and the compliance date as October 2, 2024. To help states/territories with adoption, SAMHSA released the revised Federal Guidelines for Opioid Treatment Programs in December 2024.

The revisions increase access to lifesaving, evidence-based MOUD; allow OTPs more flexibility in creating patient-centered care plans; and enhance individualized care, with the goal of increased retention in care. Furthermore, they promote practitioner discretion, remove stigmatizing or outdated language, and reduce barriers to patients receiving care. Changes to 42 CFR part 8 address essential aspects of effective treatment in OTPs according to OTP practitioners and patients. Additionally, the changes reflect an OTP accreditation and treatment environment that has evolved over the past 20 years.

* Naltrexone, an opioid receptor antagonist, is not classified as a controlled medication and is not regulated. See Medications for the Treatment of Opioid Use Disorder, 42 CFR part 8 (2024). https://www.federalregister.gov/documents/2024/02/02/2024-01693/medications-for-the-treatment-of-opioid-use-disorder

This report seeks to establish a baseline for how states/territories and OTPs are adopting and implementing the revised regulations across the following 13 elements of the rule:

1. Elimination of the 1-year opioid addiction history requirement for admission
2. Elimination of the admissions requirement for two documented instances of unsuccessful treatment for people under age 18
3. Access to medication without making it contingent on counseling attendance
4. Updated criteria for take-home doses of methadone
5. Take-home doses of methadone from the first week of treatment under certain conditions
6. Patient screening for the initiation of methadone via audiovisual telehealth
7. Patient screening for the initiation of buprenorphine via audio-only or audiovisual telehealth
8. Medical screening by practitioners external to the OTP
9. Use of drug testing as a data point to inform clinical and medical decision-making (e.g., take-home doses, discharge plan)
10. Nurse practitioners can order MOUD for dispensing at the OTP if consistent with state law
11. Physician assistants can order MOUD for dispensing at the OTP if consistent with state law
12. The use of medication units, which can be brick-and-mortar outposts or mobile units, to expand the reach of OTPs
13. Treatment of comorbidities

A subset of members of the National Association of State Alcohol and Drug Agency Directors (NASADAD) and the American Association for the Treatment of Opioid Dependence (AATOD) provided data for this report. These members represent input from 46 State Opioid Treatment Authorities (SOTAs), which are the designated entities for overseeing OTPs within their states, and 241 individual OTP representatives.

Challenges to fully implementing all elements include mindset change in the OTP, financial issues, and state non-adoption of changes.

The revision of 42 CFR part 8 has the potential to improve access to needed care and promote health through approaches designed to enhance patient-centered care in OUD management. OUD treatment, including medication, overdose education and prevention practices, counseling/psychotherapy, and contingency management, is associated with significant cost savings, health benefits, and reduced mortality.[1]

This report provides a time-specific baseline as of February 2025 regarding the extent to which states/territories have adopted and OTPs have implemented key changes in the revised regulations. The results in this report do not imply noncompliance or unwillingness to accept the changes in 42 CFR part 8; rather, they are a snapshot of the progress of states/territories and OTPs in implementing practice changes based on local needs.

Key Findings

Regarding Changes to 42 CFR part 8, as of February 2025

SOTA Responses (n = 46)

- **37%** of states/territories have adopted all the changes (*n* = 17)
- **63%** of states/territories have adopted more than three-quarters of the changes (*n* = 29)
- **85%** of states/territories have adopted more than half of the changes (*n* = 39)
- **89%** of states/territories have adopted more than a quarter of the changes (*n* = 41)
- **4%** of states/territories have not adopted any of the changes (*n* = 2)

OTP Responses (n = 241)

- **2%** of OTPs have implemented all the changes (*n* = 6)
- **34%** of OTPs have implemented at least three-quarters of the changes (*n* = 82)
- **71%** of OTPs have implemented at least half of the changes (*n* = 171)
- **93%** of OTPs have implemented at least a quarter of the changes (*n* = 223)
- **2%** of OTPs have not implemented any of the changes (*n* = 6)

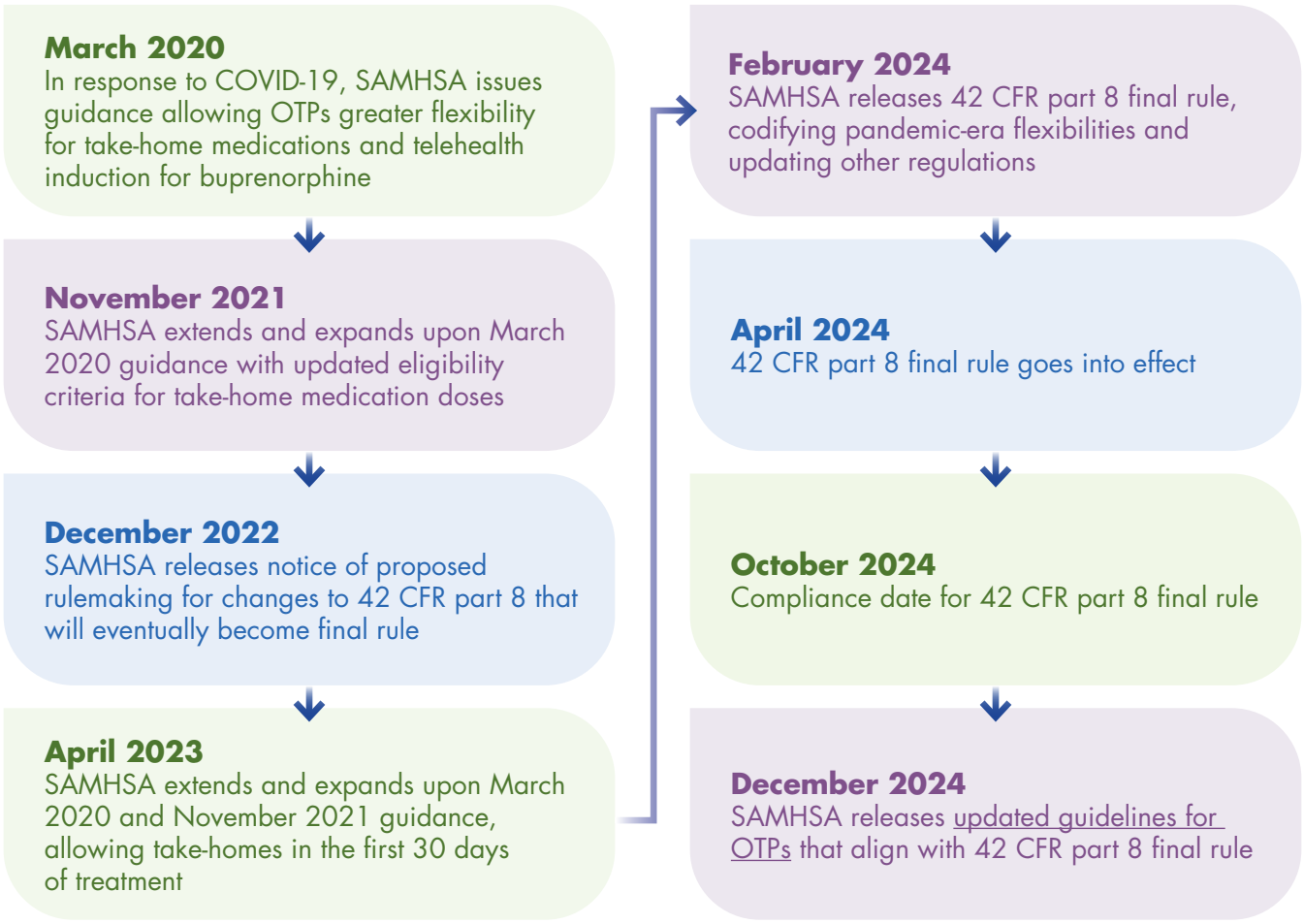
CHAPTER 1

Introduction

Since 2001, Part 8 of Title 42 of the Code of Federal Regulations (42 CFR part 8) has included the federal regulations that establish the standards regarding services provided in opioid treatment programs (OTPs). The rule also regulates processes for OTP accreditation and certification. The regulations ensure the safe and effective use of medications such as methadone and buprenorphine* in treating individuals with opioid use disorder (OUD) and delineate the range of other services patients can expect to access in an OTP. In February 2024, after a period of public notice and comment, the Substance Abuse and Mental Health Services Administration (SAMHSA) published significant revisions to 42 CFR part 8, representing the first substantive change to the regulations in over 20 years.

The 2024 revisions permanently incorporated some of the temporary flexibilities introduced during the COVID-19 public health emergency. For example, in 2020, SAMHSA issued federal guidance allowing greater flexibility with take-home doses of methadone and the use of telehealth to initiate buprenorphine treatment. These temporary flexibilities had positive effects on patient care and safety.[2,3]

Exhibit 1. Brief Timeline of Recent OTP-Related Regulatory Policy Changes



*Naltrexone, an opioid receptor antagonist, is not classified as a controlled medication and is not regulated. See Medications for the Treatment of Opioid Use Disorder, 42 CFR part 8 (2024). https://www.federalregister.gov/documents/2024/02/02/2024-01693/medications-for-the-treatment-of-opioid-use-disorder

Opioid Treatment Programs

A subset of OTPs and State Opioid Treatment Authorities (SOTAs) provided data for this report. OTPs:

Provide medications for opioid use disorder (MOUD), such as methadone and buprenorphine

May also provide counseling as well as screening and education on infectious diseases, such as HIV

Must be certified by SAMHSA and accredited by an independent, SAMHSA-approved accrediting body

Must also be licensed in their state and registered with the Drug Enforcement Administration (DEA)

State Opioid Treatment Authorities

SOTAs are state employees who:

Serve as liaisons between OTPs in their state and the Single State Agency overseeing drug treatment in that state, SAMHSA, and other government agencies, such as the DEA

Link OTPs to other state agencies, such as Medicaid

Monitor OTPs' operations to ensure quality and regulatory compliance

Provide guidance to OTPs on how to navigate any discrepancies between state and federal regulations. For example, in response to temporary changes implemented during the COVID-19 pandemic, SOTAs provided written and video guidance on federal and state flexibilities, as well as resources on issues such as staff safety, operational procedures, oversight, and billing practices, to align with new models of service delivery.[4]

The Compliance Landscape

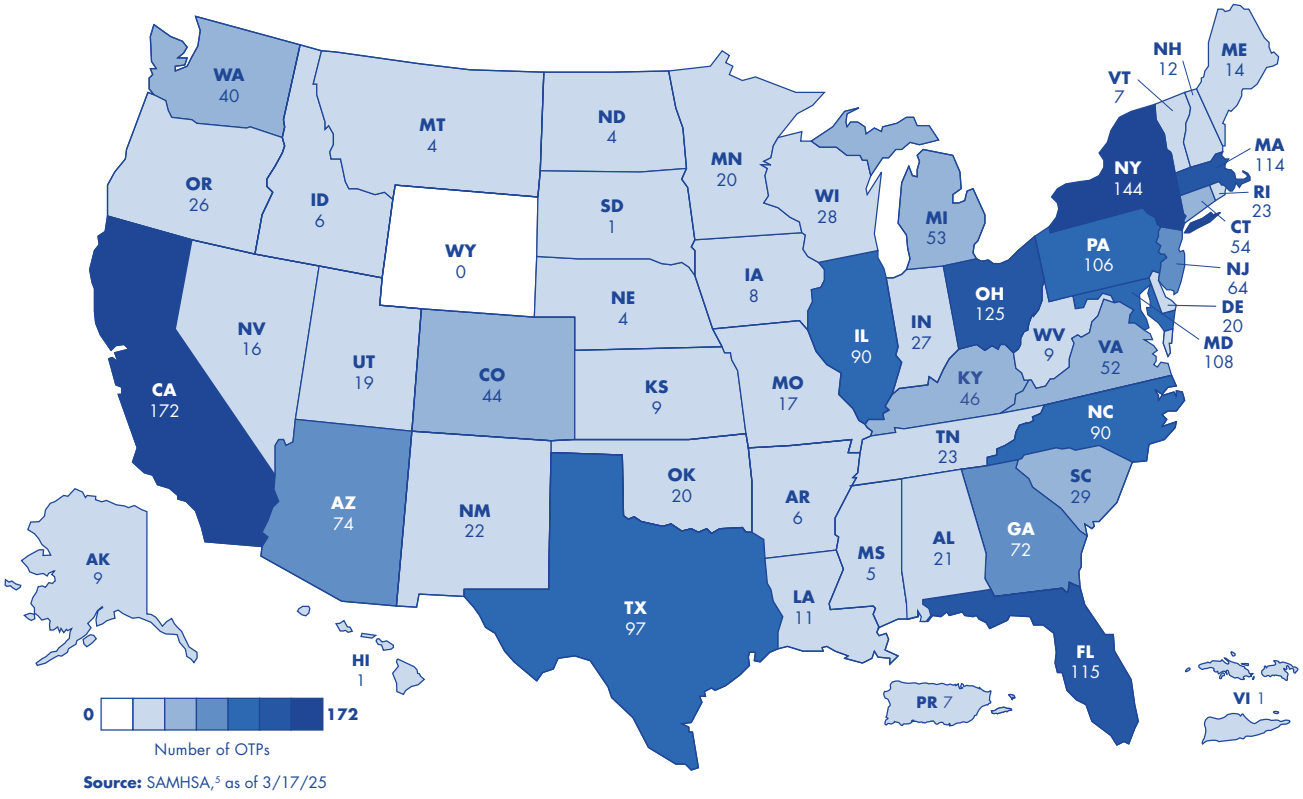
Regulations at both the federal and state levels set standards for OTP service provision. This means OTPs must consider several factors as they implement changes.

- Federal regulations in 42 CFR part 8 establish a national set of parameters for OUD treatment in OTPs. States/territories may opt to have stricter, but not more lenient, requirements than those delineated in the federal regulations.
- OTPs must adhere to the stricter state/territory requirement if it differs from the federal regulation.

Adoption of telehealth initiation of methadone serves as an example of how this interplay between federal and state regulations impacts OTPs and patients. Even though the revised federal regulations allow for this, if state/territory rules do not permit it, the OTP cannot implement this service delivery method.

There are 52 SOTAs in the United States across 49 states, the District of Columbia, Puerto Rico, and the Virgin Islands who provide guidance to the more than 2,000 OTPs in U.S. states/territories (see Exhibit 2). For a more comprehensive description of the role of SOTAs, see the Role of the State Opioid Treatment Authority by the National Association of State Alcohol and Drug Agency Directors.

Exhibit 2. Number of OTPs by State/Territory



Source: SAMHSA,[5] as of 3/17/25

Report Purpose and Rationale

The purpose of this report is to provide a baseline, or initial understanding, of the extent to which states/territories have adopted and OTPs have implemented practice changes to align with the revised federal regulations found in 42 CFR part 8. It explores key barriers and facilitators to adoption and implementation. By capturing adoption and implementation at baseline, future work can track progress and determine longer-term outcomes associated with the regulation changes.

Report Research Questions

Among States/Territories

- To what extent have states/territories adopted elements of the regulations?
- Which elements have higher and lower adoption rates?
- To what extent might increases in adoption rates occur over time?

Among OTPs

- To what extent have OTPs implemented elements of the regulations?
- Which elements have higher and lower implementation rates?
- To what extent might increases in implementation rates occur over time?

Among Both States/Territories and OTPs

- To what extent do state/territory adoption and OTP implementation rates align with each other?

CHAPTER 2

Methodology

Between December 2024 and February 2025, the National Association of State Alcohol and Drug Agency Directors (NASADAD) and the American Association for the Treatment of Opioid Dependence (AATOD) invited a subset of their members to respond to a NASADAD survey of State Opioid Treatment Authorities (SOTAs) and an AATOD survey of their membership, respectively. Forty-six SOTAs and 241 opioid treatment programs (OTPs) provided responses on the adoption and implementation of the 13 key elements of Part 8 of Title 42 of the Code of Federal Regulations (42 CFR part 8), as outlined in this report. Explanations of why some states had not adopted or will not adopt certain elements were provided by individual SOTAs, when applicable.

NASADAD

represents state substance use disorder agencies in all 56 U.S. states/territories. Of these, 52 jurisdictions (49 states, the District of Columbia, Puerto Rico, and the Virgin Islands) have designated SOTAs. NASADAD invited all SOTAs to submit responses for this report.

AATOD

represents a membership of 1,400 OTPs across 29 states, with some OTPs having multiple members from the same OTP. For this report, AATOD reached out to approximately 600 member OTPs in good standing (defined as those adhering to the association's Canon of Ethics) to share responses on the implementation of the revised regulations.

Both NASADAD and AATOD distributed survey instruments via email, asking members about a selection of the regulatory changes. Each OTP submitted only one response. Both organizations followed up with nonrespondents to improve response rates.

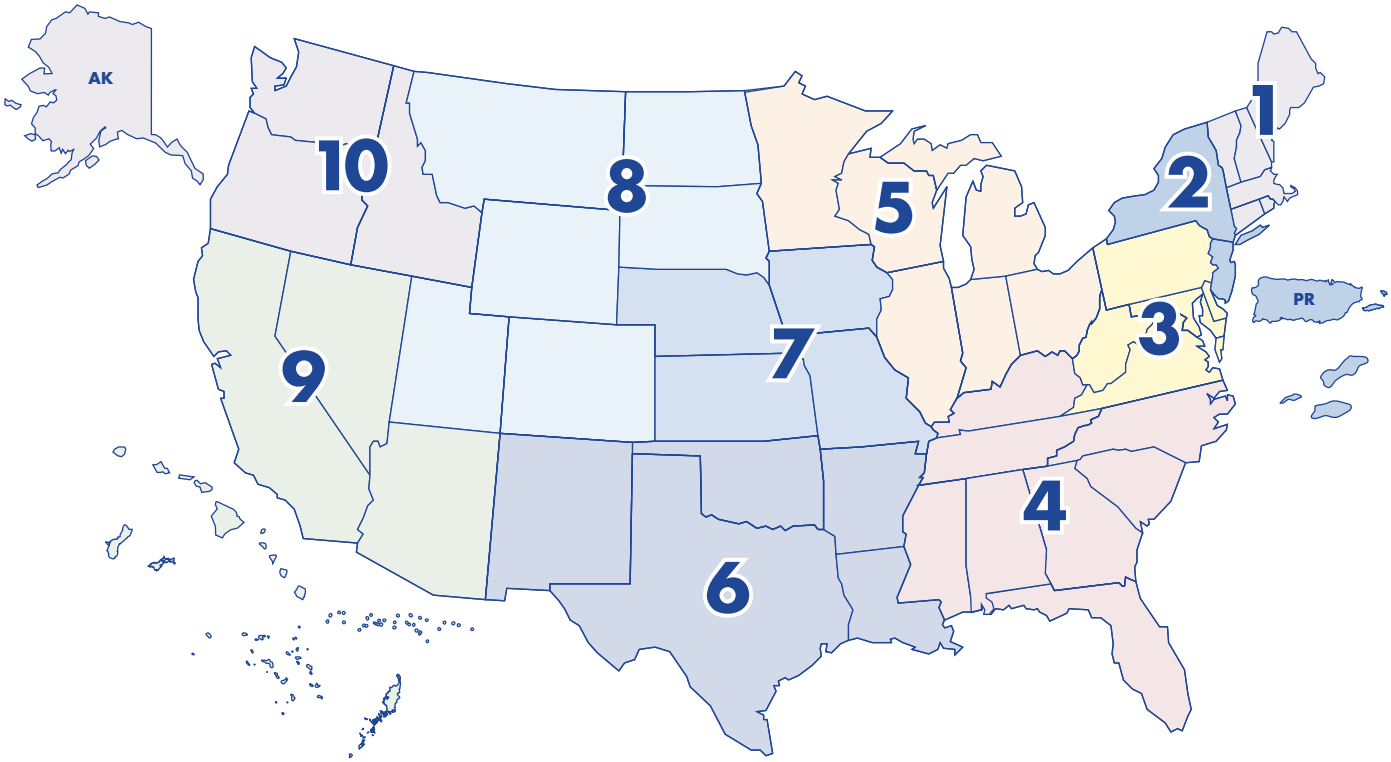
Exhibit 3. Regulation Elements for Which SOTAs and OTPs Provided Responses

Changes to 42 CFR Part 8 Included in This Baseline Report

1. Elimination of the 1-year opioid addiction history requirement for admission
2. Elimination of the admissions requirement for two documented instances of unsuccessful treatment for people under age 18
3. Access to medication without making it contingent on counseling attendance
4. Updated criteria for take-home doses of methadone
5. Take-home doses of methadone from the first week of treatment under certain conditions
6. Patient screening for the initiation of methadone via audiovisual telehealth
7. Patient screening for the initiation of buprenorphine via audio-only or audiovisual telehealth
8. Medical screening by practitioners external to the OTP
9. Use of drug testing as one data point, rather than a sole determinant, to inform clinical and medical decision-making (e.g., take-home doses, discharge plan)
10. Nurse practitioners can order MOUD for dispensing at the OTP if consistent with state law
11. Physician assistants can order MOUD for dispensing at the OTP if consistent with state law
12. Use of medication units as extensions of the OTP to deliver methadone and associated services
13. Treatment of comorbidities

To protect the anonymity of NASADAD members, this report presents SOTA responses by Department of Health and Human Services (HHS) region. Exhibit 4 presents a map of the 10 HHS regions as of February 2025.

Exhibit 4. HHS Regions



HHS Regions

1. Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, and Vermont
2. New Jersey, New York, Puerto Rico, and the Virgin Islands
3. Delaware, District of Columbia, Maryland, Pennsylvania, Virginia, and West Virginia
4. Alabama, Florida, Georgia, Kentucky, Mississippi, North Carolina, South Carolina, and Tennessee
5. Illinois, Indiana, Michigan, Minnesota, Ohio, and Wisconsin
6. Arkansas, Louisiana, New Mexico, Oklahoma, and Texas
7. Iowa, Kansas, Missouri, and Nebraska
8. Colorado, Montana, North Dakota, South Dakota, Utah, and Wyoming
9. Arizona, California, Hawaii, Nevada, American Samoa, Commonwealth of the Northern Mariana Islands, Federated States of Micronesia, Guam, Marshall Islands, and Republic of Palau
10. Alaska, Idaho, Oregon, and Washington

This report presents descriptive analyses of responses to the NASADAD survey of SOTAs and the AATOD survey of their membership. Most results are reported as frequencies or means and are organized in the following order: SOTA responses, OTP responses, and combined results.

CHAPTER 3

42 CFR Part 8 Adoption and Implementation

State Opioid Treatment Authority Responses

Of 52 State Opioid Treatment Authorities (SOTAs), 46 provided responses, yielding a SOTA response rate of 88 percent.

All the elements of Part 8 of Title 42 of the Code of Federal Regulations (42 CFR part 8) covered in this report had state- and territory-level adoption rates at or above 65 percent. However, adoption varied across the 13 elements.

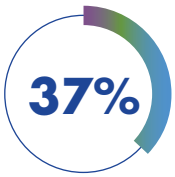
The revised 42 CFR part 8 final rule permanently incorporated flexibilities provided by the Substance Abuse and Mental Health Services Administration (SAMHSA) during the COVID-19 public health emergency. These flexibilities included take-home medication doses in the first week under certain conditions, expanded criteria for take-home medication doses,[6] and telehealth screening for buprenorphine.[7] Based on responses provided by SOTAs in this report, state adoption rates for these permanently incorporated flexibilities stand at:

80%
adopted take-home medication doses from the first treatment week

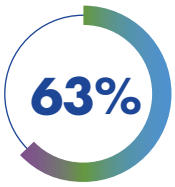
75%
updated their methadone take-home criteria

78%
adopted telehealth screening for buprenorphine initiation

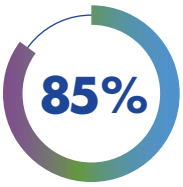
Key Findings From SOTA Survey



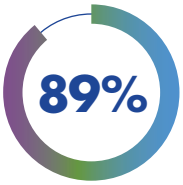
of states/territories have adopted all of the changes (*n* = 17)



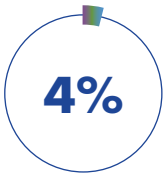
of states/territories have adopted more than three-quarters of the changes (*n* = 29)



of states/territories have adopted more than half of the changes (*n* = 39)



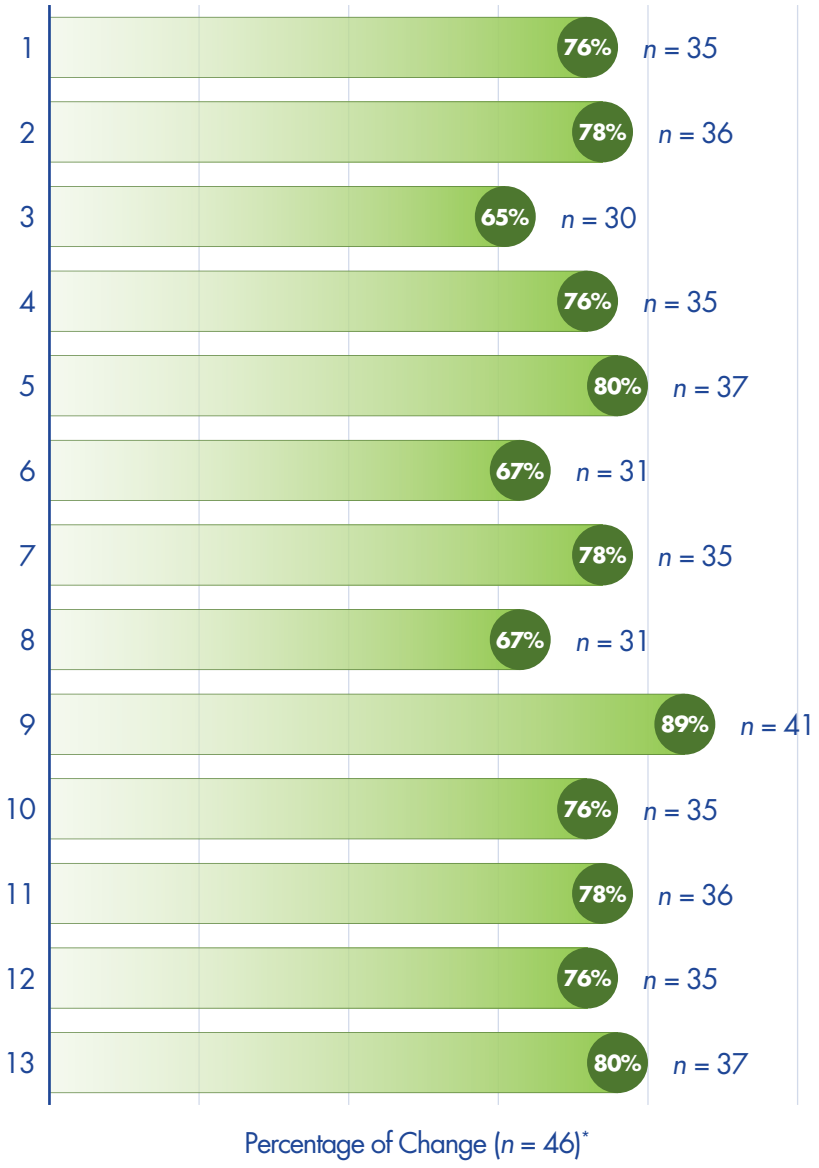
of states/territories have adopted more than a quarter of the changes (*n* = 41)



of states/territories have not adopted any of the changes (*n* = 2)

SOTA Adoption of Elements in 42 CFR Part 8

Exhibit 5. Rates of SOTA Adoption of Each Element of 42 CFR Part 8 (*N* = 46)



*Note: One state did not respond regarding element 7.

Rule elements are as follows: **1** = Elimination of the 1-year opioid addiction history requirement for admission; **2** = Elimination of the admissions requirement for two documented instances of unsuccessful treatment for people under age 18; **3** = Access to medication without making it contingent upon counseling attendance; **4** = Updated criteria for take-home doses of methadone; **5** = Take-home doses of methadone from the first week of treatment under certain conditions; **6** = Patient screening for the initiation of methadone via audiovisual telehealth; **7** = Patient screening for the initiation of buprenorphine via audio-only or audiovisual telehealth; **8** = Medical screening by practitioners external to the OTP; **9** = Use of drug testing as one data point, rather than a sole determinant, to inform clinical and medical decision-making (e.g., take-home doses, discharge plan); **10** = Nurse practitioners can order MOUD for dispensing at the OTP if consistent with state law; **11** = Physician assistants can order MOUD for dispensing at the OTP if consistent with state law; **12** = Use of medication units as extensions of the OTP to deliver methadone and associated services; **13** = Treatment of comorbidities.

Most Frequently Adopted Elements by SOTAs

1. Using **drug testing** to inform clinical decision-making (89%; *n* = 41)[#9]
2. Allowing patients to receive **take-home** doses of methadone from the first week of treatment (80%; *n* = 37)[#5]
3. Treating other medical and psychiatric **comorbidities** (e.g., hepatitis C, depression, HIV, sexually transmitted infections) in the opioid treatment program (OTP) (80%; *n* = 37)[#13]

Least Frequently Adopted Elements by SOTAs

1. Separating **medication receipt** from receipt of counseling (65%; *n* = 30)[#3]
2. Screening for methadone initiation using **audiovisual telehealth** methods (67%; *n* = 31)[#6]
3. Allowing **practitioners external to the OTP** to conduct admissions examinations (67%; *n* = 31)[#8]

Number of Elements Adopted According to Region

On average, states/territories have adopted 9.9 elements out of 13 (SD = 3.8), with a median adoption count of 12 (IQR = 5). Two states have adopted no changes, whereas 17 states/territories have adopted all 13 changes.

SOTAs from states/territories across all 10 Department of Health and Human Services (HHS) regions provided responses. Exhibit 6 details the number of states/territories that responded from each region.

Exhibit 6. Number of States/Territories Responding, by Region

HHS region	Number of states/territories responding
1	5 of 6 (83%)
2	3 of 4 (75%)
3	6 of 6 (100%)
4	8 of 8 (100%)
5	6 of 6 (100%)
6	5 of 5 (100%)
7	2 of 4 (50%)
8	4 of 5 (80%)
9	4 of 4 (100%)
10	3 of 4 (75%)

Region 10 adopted the most changes on average, with a mean and median of 13 changes adopted (SD = 0; IQR = 0). Conversely, Region 6 adopted the fewest changes on average, with a mean of 7.6 (SD = 3.2) and a median of 7 (IQR = 5.5) changes adopted.

Exhibit 7. Region-Level Adoption of Each 42 CFR Part 8 Element

	Regulation elements (1–13)												
HHS region	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**
1	100%	100%	80%	100%	100%	80%	80%	60%	80%	80%	80%	60%	80%
2	100%	100%	33%	67%	67%	33%	67%	33%	100%	33%	67%	100%	67%
3	83%	83%	67%	67%	67%	67%	83%	83%	83%	83%	67%	67%	67%
4	50%	50%	38%	50%	63%	63%	63%	63%	75%	63%	75%	63%	88%
5	67%	67%	67%	67%	67%	83%	83%	67%	83%	83%	83%	83%	83%
6	40%	60%	60%	80%	80%	40%	40%	40%	100%	40%	40%	60%	80%
7	100%	100%	50%	100%	100%	50%	50%	50%	100%	100%	100%	100%	50%
8	75%	75%	75%	100%	100%	75%	100%	75%	100%	100%	100%	100%	100%
9	100%	100%	100%	75%	100%	75%	100%	100%	100%	100%	100%	75%	75%
10	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%

Regulation elements are as follows: 1 = Elimination of the 1-year opioid addiction history requirement for admission; 2 = Elimination of the admissions requirement for two documented instances of unsuccessful treatment for people under age 18; 3 = Access to medication without making it contingent upon counseling attendance; 4 = Updated criteria for take-home doses of methadone; 5 = Take-home doses of methadone from the first week of treatment under certain conditions; 6 = Patient screening for the initiation of methadone via audiovisual telehealth; 7 = Patient screening for the initiation of buprenorphine via audio-only or audiovisual telehealth; 8 = Medical screening by practitioners external to the OTP; 9 = Use of drug testing as one data point, rather than a sole determinant, to inform clinical and medical decision-making (e.g., take-home doses, discharge plan); 10 = Nurse practitioners can order MOUD for dispensing at the OTP if consistent with state law; 11 = Physician assistants can order MOUD for dispensing at the OTP if consistent with state law; 12 = Use of medication units as extensions of the OTP to deliver methadone and associated services; 13 = Treatment of comorbidities.

Non-Adoption of Elements

If a state/territory had not adopted an element of 42 CFR part 8 at the time of the assessment, the SOTA could indicate the reason by choosing one of four categories. Exhibit 8 presents the current status of state/territory adoption or reason for non-adoption, by element.

Exhibit 8. Further Information on Non-Adoption, by Element

		Reason for decision			
Element (*N* = SOTAs indicating non-adoption)		**In process, *n* (%)**	**Under consideration, *n* (%)**	**No capacity, *n* (%)**	**No plans to implement, *n* (%)**
1	Elimination of the 1-year opioid addiction history requirement for admission (*N* = 11)	5 (45%)	6 (55%)	0 (0%)	0 (0%)
2	Elimination of the admissions requirement for two documented instances of unsuccessful treatment for people under age 18 (*N* = 10)	2 (20%)	5 (50%)	0 (0%)	3 (30%)
3	Access to medication without making it contingent upon counseling attendance (*N* = 16)	3 (19%)	6 (38%)	1 (6%)	6 (38%)
4	Updated criteria for take-home doses of methadone (*N* = 11)	5 (45%)	5 (45%)	0 (0%)	1 (9%)
5	Take-home doses of methadone from the first week of treatment under certain conditions (*N* = 9)	4 (44%)	3 (33%)	0 (0%)	2 (22%)
6	Patient screening for the initiation of methadone via audiovisual telehealth (*N* = 15)	6 (40%)	8 (53%)	1 (7%)	0 (0%)

Reason for decision					
Element (*N* = SOTAs indicating non-adoption)		**In process, *n* (%)**	**Under consideration, *n* (%)**	**No capacity, *n* (%)**	**No plans to implement, *n* (%)**
7	Patient screening for the initiation of buprenorphine via audio-only or audiovisual telehealth (*N* = 10)	4 (40%)	5 (50%)	1 (10%)	0 (0%)
8	Medical screening by practitioners external to the OTP (*N* = 15)	4 (27%)	10 (67%)	0 (0%)	1 (7%)
9	Use of drug testing as one data point, rather than a sole determinant, to inform clinical and medical decision-making (e.g., take-home doses, discharge plan) (*N* = 5)	2 (40%)	2 (40%)	0 (0%)	1 (20%)
10	Nurse practitioners can order MOUD for dispensing at the OTP if consistent with state law (*N* = 11)	1 (9%)	7 (64%)	1 (9%)	2 (18%)
11	Physician assistants can order MOUD for dispensing at the OTP if consistent with state law (*N* = 10)	2 (20%)	7 (70%)	0 (0%)	1 (10%)
12	Use of medication units as extensions of the OTP to deliver methadone and associated services (*N* = 11)	3 (27%)	5 (45%)	1 (9%)	2 (18%)
13	Treatment of comorbidities (*N* = 9)	1 (11%)	7 (78%)	0 (0%)	1 (11%)

Note: One SOTA indicated element 7 was not being implemented but did not provide a reason or details.

Opioid Treatment Program Responses

OTP providers submitted 241 complete responses from an AATOD survey that was sent to approximately 600 OTPs.The email asked that only one representative respond from each OTP. The report excluded 65 responses that were less than 25 percent complete. In total, 241 OTPs across 39 states/territories provided responses, yielding an OTP response rate of approximately 40 percent (see Exhibit 9).

Key Findings from Responding OTPs (*N* = 241)

2% of OTPs have implemented all the changes (*n* = 6)

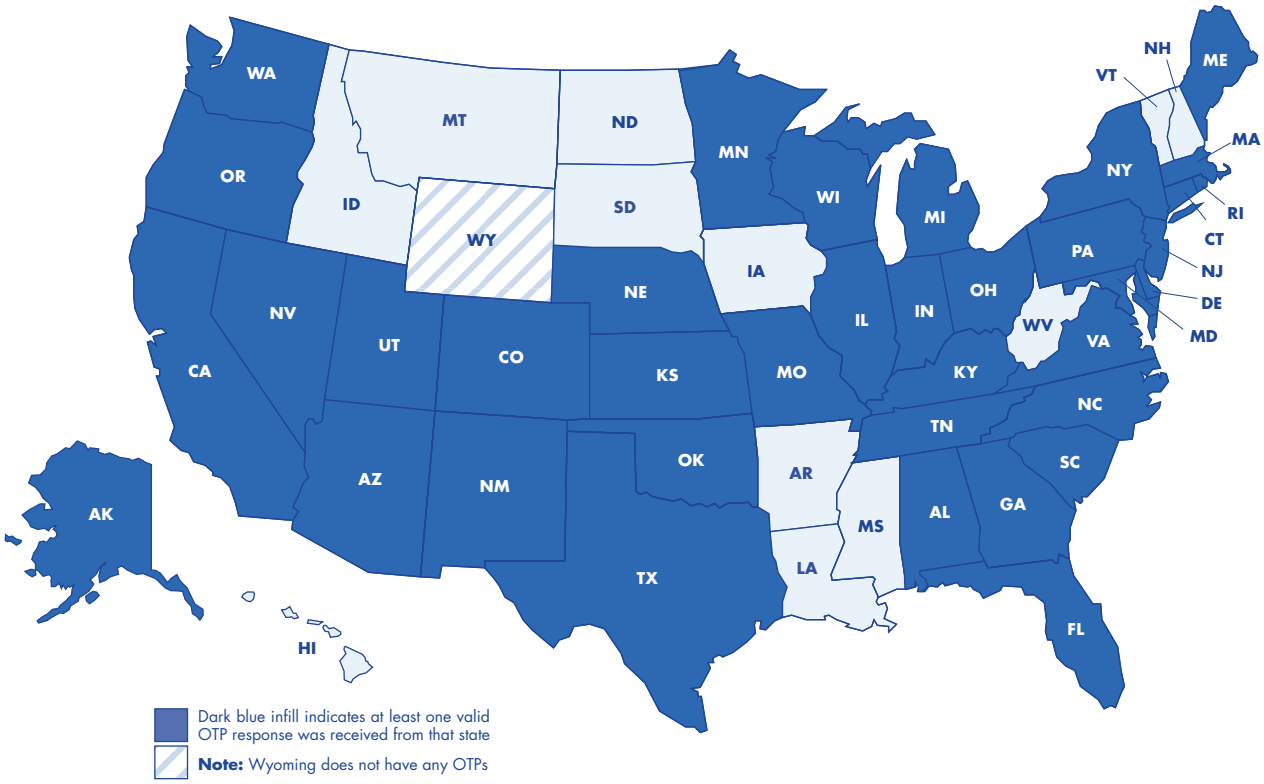
34% of OTPs have implemented at least three-quarters of the changes (*n* = 82)

70% of OTPs have implemented more than half of the changes (*n* = 169)

92% of OTPs have implemented more than a quarter of the changes (*n* = 221)

2% of OTPs have not implemented any of the changes (*n* = 6)

Exhibit 9. States/Territories with at Least One Valid OTP Response



Other than "Use of medication units as extensions of the OTP to deliver methadone and associated services," all assessed elements of 42 CFR part 8 had OTP implementation rates at or above 45 percent. There was some variation in implementation across the 13 elements.

Some components of 42 CFR part 8 had previously been adopted during the COVID-19 public health emergency. Those include:

- Take-home medication doses in the first week[6]
- Expanded criteria for take-home medication doses[6]
- Telehealth screening for buprenorphine initiation[7]

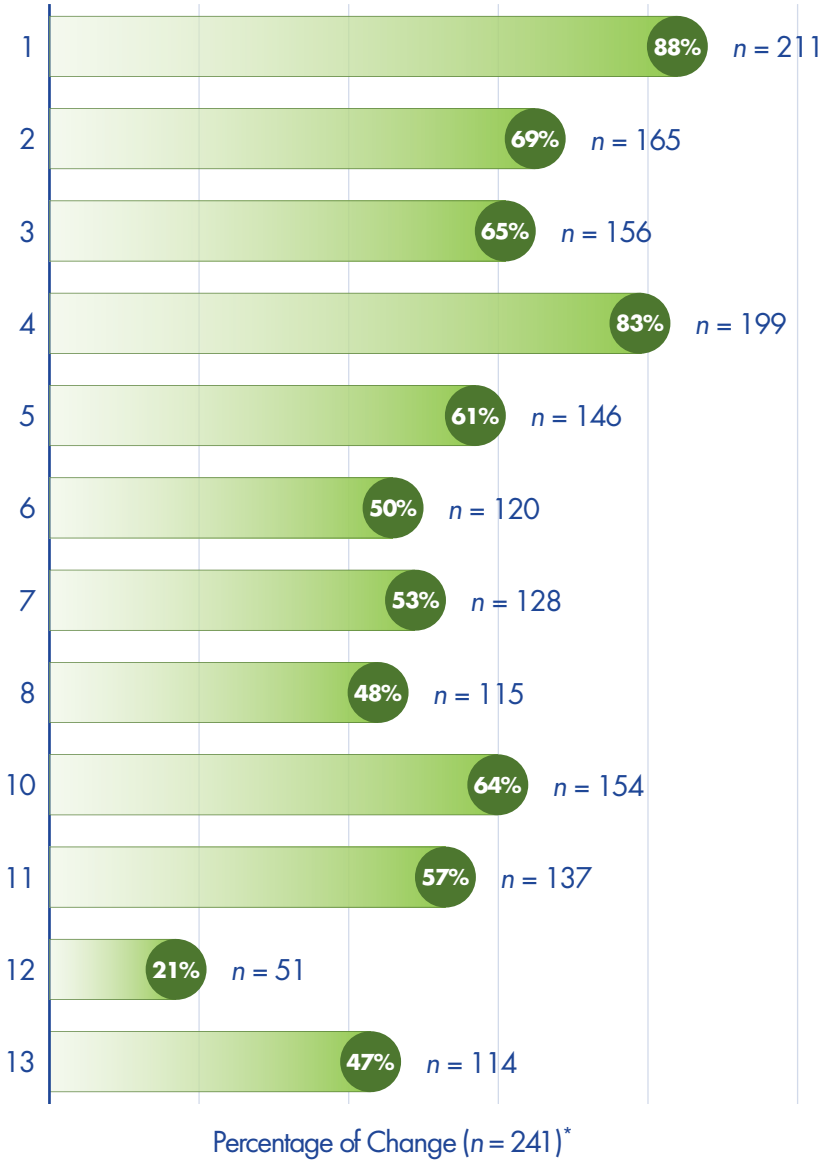
Despite previous experience with these components, OTPs implemented these elements at roughly the same rate as other elements that were not allowed during the public health emergency:

61%
adopted the use of take-home medication doses from the first treatment week

83%
updated their methadone take-home criteria

53%
adopted telehealth screening for buprenorphine initiation

Exhibit 10. OTP Implementation of 42 CFR Part 8 (*N* = 241)



*Note: Only 240 OTPs responded regarding elements 1, 2, 7, or 11. Additionally, OTPs were not asked about element 9 due to a programming error in the survey.

Rule elements are as follows: 1 = Elimination of the 1-year opioid addiction history requirement for admission; **2** = Elimination of the admissions requirement for two documented instances of unsuccessful treatment for people under age 18; **3** = Access to medication without making it contingent upon counseling attendance; **4** = Updated criteria for take-home doses of methadone; **5** = Take-home doses of methadone from the first week of treatment under certain conditions; **6** = Patient screening for the initiation of methadone via audiovisual telehealth; **7** = Patient screening for the initiation of buprenorphine via audio-only or audiovisual telehealth; **8** = Medical screening by practitioners external to the OTP; **9**† = Use of drug testing as one data point, rather than a sole determinant, to inform clinical and medical decision-making (e.g., take-home doses, discharge plan); **10** = Nurse practitioners can order MOUD for dispensing at the OTP if consistent with state law; **11** = Physician assistants can order MOUD for dispensing at the OTP if consistent with state law; **12** = Use of medication units as extensions of the OTP to deliver methadone and associated services; **13** = Treatment of comorbidities.

†OTPs were not asked about element 9 due to a programming error in the survey.

Most Frequently Implemented Elements by OTPs

1. Eliminating the **1-year opioid addiction history** requirement for admission (88%; *n* = 211)[#1]
2. Using updated criteria for **take-home doses** of methadone (83%; *n* = 199)[#4]
3. Removing the requirement for **two documented instances** of unsuccessful treatment for individuals under age 18 (69%; *n* = 165)[#2]

Least Frequently Implemented Elements by OTPs

1. Using **medication units** as an OTP extension to deliver methadone services (21%; *n* = 51)[#12]
2. Treating **other medical and psychiatric comorbidities** in the OTP (47%; *n* = 114)[#13]
3. Allowing **practitioners external to the OTP** to conduct admissions examinations (48%; *n* = 115)[#8]

Comparing SOTA and OTP Findings

Exhibit 11. Comparison of State/Territory and OTP Rates for Adopting/Implementing Each 42 CFR Part 8 Element in This Report

Element		State/territory adoption rate (*N* = 46)	OTP implementation rate (*N* = 241)
1	Elimination of the 1-year opioid addiction history requirement for admission	76%	88%
2	Elimination of the admissions requirement for two documented instances of unsuccessful treatment for people under age 18	78%	69%
3	Access to medication without making it contingent upon counseling attendance	65%	65%
4	Updated criteria for take-home doses of methadone	76%	83%
5	Take-home doses of methadone from the first week of treatment under certain conditions	80%	61%
6	Patient screening for the initiation of methadone via audiovisual telehealth	67%	50%
7	Patient screening for the initiation of buprenorphine via audio-only or audiovisual telehealth	76%	53%
8	Medical screening by practitioners external to the OTP	67%	48%

Element		State/territory adoption rate (*N* = 46)	OTP implementation rate (*N* = 241)
9	Use of drug testing as one data point, rather than a sole determinant, to inform clinical and medical decision-making (e.g., take-home doses, discharge plan)	89%	N/A*
10	Nurse practitioners can order MOUD for dispensing at the OTP if consistent with state law	76%	64%
11	Physician assistants can order MOUD for dispensing at the OTP if consistent with state law	78%	57%
12	Use of medication units as extensions of the OTP to deliver methadone and associated services	76%	21%
13	Treatment of comorbidities	80%	47%

Note: Elements 1, 2, 7, and 11 each had one nonresponse from OTP providers.

*OTPs did not respond regarding element 9 due to a programming error in the survey.

CHAPTER 4

Looking Ahead

Since the publication of the revised Part 8 of Title 42 of the Code of Federal Regulations (42 CFR part 8) in February 2024, State Opioid Treatment Authorities (SOTAs) and opioid treatment programs (OTPs) have begun to adopt and implement the updated regulations. Although it often takes time for states/territories to adopt federal regulatory changes and incorporate them into routine practice, the process of implementation is underway:

37% of states/territories have adopted all13 elements analyzed in this report

34% of OTPs have implemented at least three quarters of the elements

71% of OTPs have implemented at least half of the elements

Of the five states/territories that have implemented three or fewer elements to date, two states/territories are in the process of implementing 80 percent or more of their currently non-adopted elements. One state has no plans to implement over half the elements.

Across all states/territories, most elements of 42 CFR part 8 included in this baseline assessment are under consideration (55%) or in process (28%). Thus, a follow-up study would likely show increased adoption, as states/territories may need more time to undertake processes such as receiving input from interested parties, drafting legislation, modifying regulations, and seeking legal review from regulatory bodies. States/territories indicated that capacity is not a driving force in the lack of adoption; indeed, only 3 percent of the changes remain unadopted due to capacity issues. Additionally, states/territories reported no plans to adopt 12 percent of the changes.

Benefits and Complexities of Adoption or Implementation

States/territories and OTPs shared insights on the benefits and complexities of adopting and implementing the updated regulations in follow-up conversations. They also discussed the factors that helped facilitate these changes and opportunities to increase uptake.

Benefits

Although states/territories can impose stricter standards than delineated in 42 CFR part 8—and OTPs in those areas are required to follow these regulations—OTPs that have implemented changes reported experiencing perceived benefits. These include the following:

More patients and new patients, as well as increasing numbers of take-home medication doses

Improved patient experiences that feel more respectful and supportive and consider patient needs

Stabilization of current patients through take-home medications

Expanded access for patients to treatment at OTPs that have created satellite offices in more rural areas

Increased patient retention resulting from higher doses available at induction and additional take-home opportunities

Increased access to care through telehealth for patients who are incarcerated, hospitalized, or from large states

Streamlined processes at clinics due to allowing nurse practitioners and physician assistants to work at the top of their scope of practice

"We've had a steady increase [in admissions] since our change in regulations, since the new take-home schedule. I could almost link it on a timeline."

—OTP representative, Oklahoma

Facilitators

According to responding states/territories and OTPs, the following factors have supported the adoption and implementation of elements in the revised 42 CFR part 8:

Preexisting infrastructure

Some states/territories and OTPs already had protocols and processes in place due to the COVID-19 pandemic flexibilities.

Pre-implementation training

This includes online sessions and in-person meetings with OTPs to create buy-in for the anticipated changes.

Champions

OTPs that have made the changes can share best practices and the effects of the changes with other OTPs contemplating implementation.

Consistent communication

This includes communication via listservs or regular clinic visits, as well as open discussions between SOTAs and OTPs with opportunities to ask questions. SOTAs can reduce OTP concerns by clearly explaining the reason for the changes and fostering honest discussions of concerns.

State/territory guidance documents developed for OTPs

These include training curricula and guides, checklists, and job aids on how to implement changes.

State waivers

Some states have granted waivers to existing OTP regulations, allowing the immediate implementation of all or some of the revised provisions in 42 CFR part 8. Waivers allow states time to revise their current OTP regulations, or in some cases, enact new legislation and regulations to better align with Part 8.

"I think it's been a positive—100 percent for the patients . . . I do know that patients are feeling much more treated like human beings than they have in years past."

—OTP representative, Ohio

Opportunities

SOTAs and OTP representatives mentioned several opportunities to increase uptake of the regulation changes:

Unbundled payment strategies

Moving to a fee-for-service model to cover medication would help offset costs for take-home doses and other expenses related to keeping locations open. This form of compensation may make OTP providers more likely to order more take-home doses.

Funding diversification

One state has applied for Centers for Medicare & Medicaid Services funding for OTPs and other county substance use disorder treatment facilities to expand co-occurring programming. The SOTA suggested that this approach would likely be a bigger factor than regulatory changes in spurring the expansion of satellite offices.

New provider pipeline

Current OTP providers are retiring, and the changes to healthcare provider education requirements will give OTPs the opportunity to hire a new generation of providers who may bring fresh perspectives and be less tied to traditional approaches. These new providers will enter the field with updated standards and practices as their baseline.

Partnerships with clinics

Some OTPs are working to create satellite offices in partnership with Federally Qualified Health Centers to expand their reach.

Complexities for Full Adoption and Implementation

When discussing the complexities of adopting and implementing changes, OTP representatives and SOTAs frequently mentioned **mindset change** and **finances**.

Mindset change is difficult for organizations or practitioners who have been applying a specific approach to opioid use disorder (OUD) treatment. According to SOTAs, many OTP providers who are hesitant about the new approach have begun implementing changes only after having one-on-one conversations with their SOTA to help them understand the benefits of the changes.

Driving mindset change among OTPs involves finding ways to:

- **Enhance counseling skills** to motivate patients to attend counseling if OTPs can no longer require patients to attend counseling in exchange for medications.
- **Move from a standardized, one-size-fits-all approach** to one that requires individualized clinical decision-making.
- **Accept different levels of practitioners,** such as nurse practitioners or physician assistants newly working in the field.

> "It's having a positive effect in reducing stigma and the treatment culture . . . making it more patient centered and certainly implementing the idea of the shared decision-making process in a more concrete and systemic way. "
>
> —OTP representative, Connecticut

Finances have also created challenges in adopting the revised rule.

- **Reimbursement rates and mechanisms, including those through Medicaid, do not support the larger number of take-home doses.** Reimbursements are based either on a bundled rate or per-patient interaction, and OTP providers do not receive more funding for the doses they send home with the patient.
- **Financial decisions are leading some organizations to require clients to attend in person to maximize payments.** In the past, OTPs in some states/territories have been paid an all-inclusive daily rate. If patients do not visit the clinic as frequently under the revised regulations, OTPs may be paid less per patient. This approach has been a disincentive to increasing take-home doses, particularly among for-profit companies in states/territories with this type of financing model.
- **OTPs providing more holistic care for chronic disease are not always reimbursed for that care,** such as the treatment of hepatitis C. OTPs perceive that limited reimbursement for delivery to facilities that prohibit the patient from leaving the premises, such as the Department of Corrections or sober living facilities, may make medication continuity more difficult to sustain. To move to a more comprehensive treatment system, all parties would need to resolve billing concerns.

Other complexities include:

Conflicting requirements

Oftentimes, OTPs and SOTAs must navigate perceived conflicting sets of rules, requirements, and processes, such as licensing board standards or corporate and state policies.

Concerns about liability, confidentiality, and equipment

Many clinics and clinicians are concerned about their liability in providing take-home medications, particularly when initiating treatment. Similarly, telehealth interactions require HIPAA-compliant systems, but OTPs have questions about security and how to confirm whether a system is fully compliant.

Supply-chain challenges

Though telehealth could benefit many individuals in rural areas, OTPs must first resolve challenges with acquiring consistent supplies of methadone for these regions. Inconsistencies in implementation across different OTPs could worsen existing differences in access and quality of care.

Additional costs for mobile units

Mobile units need Drug Enforcement Administration-mandated security, specialized parking (e.g., fenced areas), maintenance, gas, and trained drivers. Moreover, they increase insurance rates, are not currently rolled into Medicaid reimbursement rates, and underutilize staff, who may spend a large portion of the day driving to provide care to only a handful of patients.

Limitations

This report has several limitations. First, it is not a comprehensive assessment of all changes included in 42 CFR part 8. The report assessed the adoption of 13 changes in 42 CFR part 8; this brevity was intentional to limit OTP and SOTA response burden.

Moreover, the report includes data from 241 OTPs, which represents a fraction of the more than 2,000 OTPs across U.S. states/territories. Given the limited response rate, the findings may not accurately reflect the experiences of all OTPs. In addition, OTPs were not asked about one of the changes due to a programing error in the survey.

Finally, the report discusses data from SOTAs and OTPs only and does not include information from other important interested parties, such as patients with OUD and Medicaid agencies. Future work should include a broader range of populations and more in-depth qualitative data collection to assess nuances that may be missed in quantitative data.

Conclusion

The revisions to 42 CFR part 8 mark a significant regulatory shift. These changes have the potential to improve access to care and advance health outcomes for people with OUD through more patient-centered treatment approaches. Research shows that combining medications for OUD with overdose education, prevention practices, counseling/psychotherapy, and contingency management leads to substantial health benefits and cost savings, including lives saved.[1]

Financing systems, particularly reimbursement rates, play a critical role in the extensive implementation of any clinical practice. Current financial policies often favor more frequent in-person clinic visits, which may discourage the adoption of more flexible care models. As Medicaid reimbursement policies evolve, they are likely to influence the adoption of key elements in the revised regulations, especially those involving take-home medication doses and the integration of care for other physical and mental health conditions and chronic diseases.

This report offers a baseline snapshot, as of February 2025, of how widely states have adopted and OTPs have implemented changes included in the revised regulation. While these data highlight current progress, many factors influence adoption and implementation. Ongoing study is needed to fully understand these influences. Reassessment in 2 to 5 years, along with analysis of Medicaid, Medicare, and commercial claims data, can provide deeper insights into the impact of the regulations on patient care and access to lifesaving OUD treatment.

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