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Federal Guidelines for Opioid Treatment Programs

SAMHSA
Substance Abuse and Mental Health Services Administration

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Contents

Foreword

Title 42 of the Code of Federal Regulations (42 CFR) part 8 sets the standards for services provided in opioid treatment programs (OTPs) and regulates processes related to their certification and accreditation. The original regulations, published in 2001, shifted administrative responsibility and oversight of OTPs from the Food and Drug Administration (FDA) to the Substance Abuse and Mental Health Services Administration (SAMHSA) to allow for greater clinical judgment in the treatment of opioid use disorder (OUD) and to streamline regulatory oversight over OTPs.

Although the 2001 rules reduced the scope of FDA regulations that had been in place since 1972, many of the original restrictive requirements of 42 CFR part 8 remained substantially unaltered—until the COVID-19 pandemic. That historic public health emergency necessitated the implementation of significant changes in the provision of OTP-related care to ensure the health and safety of patients and staff. Those changes included flexibilities in the provision of take-home doses of methadone and in the use of telehealth technology to initiate buprenorphine.

The effect of those flexibilities has been significant and, on the whole, positive for patients and providers. [1] The experience also refuted stigma-based fears of mass medication diversion and related harms. Feedback from multiple stakeholder groups, backed by research, urged continuation of the flexibilities. At the same time, the ongoing opioid crisis called for expansion of OUD treatment and a more person-centered approach to care to enhance engagement and retention in treatment. In 2022, the process of revising 42 CFR part 8 began, and the revised final rule was published on February 2, 2024.

The revised 42 CFR part 8 rule eliminates outdated content; removes stigmatizing language; clarifies several key aspects of treatment; expands integration of harm reduction, recovery services, and other evidence-based practices into the OTP; and enhances the OUD treatment workforce by incorporating additional health professionals as practitioners who can order and manage methadone and other medications in OTPs in accordance with the scope of their practices and state and tribal law. Among other things, the updated rule clarifies the availability of methadone treatment in correctional facilities that hold a Drug Enforcement Administration–registered hospital/clinic and treat OUD as an adjunct to a primary health condition and elucidates the range of services that can be provided in both brick-and-mortar medication units and mobile units.

Critically, the 2024 regulations emphasize treating patients within the context of their full lives. The field has long promoted the value of patient-centered care, but the revisions operationalize this value by revising admissions criteria, lowering barriers to care by expediting screening for treatment, and incorporating a "whole-life" approach to patient assessments. The revisions also promote shared decision-making between the patient and practitioner, reinforcing respect for patients and the key role they play in their individualized care plans. For many OTPs, these changes call for a transformation of the culture of care and treatment provision in OTPs.

The 2024 *Federal Guidelines for Opioid Treatment Programs* (the Guidelines) describe the opportunities provided by the revised regulations and ways those revisions can be implemented, and they clarify the application of clinical judgment in carrying out OTP regulatory standards. The Guidelines incorporate recent research to provide a strong science-to-treatment foundation. The Guidelines also reflect the insights of a panel of experts, as less prescriptive regulations lend themselves to more use of the art of medicine, a focus on patient engagement, and truly individualized care than may have occurred previously in some OTPs. In these ways, the Guidelines support SAMHSA's mission to

lead public health and service delivery efforts that promote mental health, prevent substance misuse, and provide treatments and supports to foster recovery while ensuring equitable access and better outcomes.

SAMHSA thanks the expert panelists for the expertise, dedication, and collaboration they brought to this process and expresses gratitude for each person who contributed time and expertise to the development and finalization of these Guidelines. SAMHSA hopes the recommendations ultimately improve access to and the experience of care, increase support of patients' engagement in care and recovery efforts, and empower practitioners within OTPs to use their best clinical judgment to treat people with OUD with the dignity, respect, and highest quality of care they deserve.

Document History and Development Process

To fully understand the context for the development of the 2024 *Federal Guidelines for Opioid Treatment Programs* (the Guidelines), it is helpful to review how guidance related to opioid treatment program (OTP) regulations for the addiction treatment field has evolved over the years. In 1993, the Substance Abuse and Mental Health Services Administration's (SAMHSA) Center for Substance Abuse Treatment (CSAT) and the American Methadone Treatment Association (now named the American Association for the Treatment of Opioid Dependence—AATOD), in conjunction with the American Society of Addiction Medicine's Committee on Methadone Treatment, developed Treatment Improvement Protocol (TIP) 1, *State Methadone Treatment Guidelines*.[2] Several factors drove the development of TIP 1, including increased rates of HIV, the appearance of drug-resistant tuberculosis, and worsening polydrug use; an economy affected by recession; and a need for a richer mix of comprehensive services and enhanced program accountability. The document was intended to serve as suggestions of best practices for state policy officials and "methadone maintenance treatment providers," as OTP providers were then called. This TIP provided an overview of effective, evidence-based therapeutic techniques for methadone maintenance treatment of opioid use disorder (OUD).

Between 1996 and 1999, in anticipation of the shift in oversight of OTPs from the Food and Drug Administration to SAMHSA, CSAT created federal guidelines by following a development process similar to the process used for TIP 1. The resulting federal guidelines extrapolated from multiple sections of 42 CFR part 8 and provided additional interpretation, guidance, and explanation of how to apply the delineated rules. SAMHSA convened two meetings of expert panelists who provided input on guidelines content and conducted field reviews and obtained clearances from other federal agencies and the U.S. Office of Management and Budget. In 2001, SAMHSA published the first edition of the *CSAT Guidelines for the Accreditation of Opioid Treatment Programs* (CSAT Guidelines).

In 2005, following several years of experience implementing certification and accreditation standards for OTPs, advancements in the field, and new research to support updates to evidence-based practices for treating OUD, SAMHSA convened another expert panel to update the 2001 CSAT Guidelines. SAMHSA subsequently published the updated edition of the OTP Guidelines in 2007. As policies, research, and practices continued to evolve, SAMHSA once again revised the OTP guidelines in 2015. In this update, SAMHSA reinterpreted the regulations in the then-current context of OUD, healthcare delivery, and public health issues.

In 2022, several factors led SAMHSA to propose revisions to Title 42 of the Code of Federal Regulations (42 CFR) part 8, including the present opioid and overdose crisis driven by the lethality and availability of non-methadone synthetic opioids, lessons learned from the COVID-19 pandemic, and efforts to improve access to medications for the treatment of OUD (MOUD). The proposed revisions, released in December 2022, were significant and reflected a paradigm shift, and their implementation required explanation and guidance. As a result, SAMHSA convened an expert panel in 2023 and charged them with providing input for another revision of the CSAT Guidelines that would align with the revised 42 CFR part 8.

This diverse group of experts contributed to the development of these revised Guidelines. The panel members, who have extensive knowledge and expertise in OUD treatment services, include OTP medical directors; addiction medicine physicians; addiction psychiatrists; OTP program sponsors and directors; directors of single state agencies; state opioid treatment authorities; representatives of accreditation bodies; individuals with lived and living experience of substance use disorders (SUDs), including OUD,

who currently or previously utilized MOUD; policy leaders; peer engagement and outreach specialists; accreditation specialists; physician assistants; and nurse practitioners.

In 2024, SAMHSA disseminated a draft document to the field for review and comments and subsequently revised the Guidelines before final publication. The Guidelines have been edited, organized, and formatted in accordance with Federal Plain Language Guidelines (see Public Law 111-274, Plain Writing Act of 2010).

Key Revisions in This Update

These Guidelines continue the paradigm shift toward patient-centered care in SUD treatment that began with the pioneers of methadone treatment for OUD, Drs. Vincent Dole and Marie Nyswander, in the 1960s. The Guidelines clarify a need for increased access to quality care that is patient-centered, trauma informed, and culturally responsive. Additionally, these Guidelines aim to increase patient engagement and retention in MOUD by recognizing that SUDs are chronic medical conditions and that people with SUDs respond to treatment and services that meet them where they are.

The 2015 CSAT Guidelines and the 2024 Guidelines have key differences. The 2015 CSAT Guidelines were written to update the 2007 edition in light of changes and evolution of the field. The revised 42 CFR part 8 rule, published in 2024, made the most substantive changes to the prior regulations in over 20 years. These Guidelines are intended to provide guidance on the revised rule, including guidance on critical changes in take-home methadone dose protocols that were initiated during the COVID-19 public health emergency. Additional content in the 2024 Guidelines includes discussions on the use of telehealth in OUD treatment, changes intended to expand access to treatment, and challenges related to treating patients who receive MOUD in the era of high-potency synthetic opioids, primarily illegally made fentanyl.

Audiences for This Update

This document primarily addresses OTP staff. However, its content is also meant to serve as a resource to a range of stakeholders, including patients, non-OTP clinicians, emergency department personnel, justice-involved individuals and justice-related staff, peer support and recovery community members, community leaders, healthcare administrators, and state regulatory agencies. It is important to note that, in most instances, these guidelines are not requirements but rather offer a patient-centered framework, recommendations, and best practices for how to interpret and apply the final rule to diverse populations.

Publication Information

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Introduction

Background and Context

In October 2017, the opioid crisis that began with prescription opioids was declared a public health emergency (PHE), and the declaration has been regularly renewed as the crisis has evolved from prescription opioids to heroin and now to illegally made fentanyl and polysubstance use. [3] During the COVID-19 pandemic, substance misuse worsened, overdose deaths increased, and needed public health measures related to COVID-19 reduced access to in-person care. [4] Many people experienced financial hardships and limited access to substance use disorder (SUD) treatment services.

Opioid treatment program (OTP) services directly address the opioid crisis by providing evidence-based, life-saving medications for the treatment of opioid use disorder (MOUD) in combination with other counseling and related services to support remission and recovery from opioid use disorder (OUD). Whereas all OTPs dispense and administer methadone, which is one type of MOUD, many also offer buprenorphine and naltrexone, the other two types of MOUD approved by the Food and Drug Administration (FDA) for OUD treatment. In 2001, there were approximately 900 OTPs; by the end of 2023, the number grew to 2,115. As of May 2024, the Substance Abuse and Mental Health Services Administration (SAMHSA) has certified 2,151 OTPs across virtually all U.S. states and territories, and several operated by Tribal Nations.

The onset of the COVID-19 pandemic in early 2020 created an environment for rapid change, affecting how OTPs provided MOUD and accompanying services. Protecting the public's health, promoting social distancing, and preserving patient and staff safety within healthcare settings called for different approaches in OTP treatment practices. Given these needs, SAMHSA issued regulatory exemptions in March 2020 that provided flexibilities in the provision of take-home doses of methadone and in the use of telehealth to initiate buprenorphine. These flexibilities, which allowed continued treatment of OUD while reducing direct patient contact with OTP staff, represented the first substantial change to OTP treatment and medication delivery standards in more than 20 years.

Patients, OTPs, and state authorities generally supported the medication take-home flexibility. [5, 6, 7] A growing body of research has shown that this flexibility eliminates requirements that promote stigma and discourage people from accessing treatment in OTPs. Patients reported that increased take-home medication doses left them feeling more respected as responsible individuals. [8, 9] State authorities reported that patients and OTPs appreciated the flexibilities associated with the expanded take-home medication policies. A literature review of 40 studies in the United States, Canada, and England found that increased take-home medication policies for both methadone and buprenorphine improved treatment retention and satisfaction among patients while showing no significant increases in medication-related overdoses or increased use of illicit substances. [10, 11, 12, 13]

In April 2020, SAMHSA further expanded its COVID-19 PHE-related flexibilities by exempting OTPs from the Title 42 of the Code of Federal Regulations (42 CFR) § 8.12(f)(2) requirement to perform an in-person physical evaluation for any patient receiving treatment with buprenorphine. This exemption applied if a program physician, primary care physician, or other authorized healthcare professional under the supervision of a program physician determined that an adequate evaluation of the patient could be accomplished via telehealth, including audio-only platforms. The duration of this exemption was specifically tied to the period of the national COVID-19 PHE, but the exemption did not include the use of telehealth for the initiation of methadone. Considering the escalating overdose crisis and an

increasing need to reach remote and underserved communities, making telehealth flexibility permanent has been identified as of paramount importance by stakeholders and policymakers. [14]

Further, the flexibilities that began in early 2020 formed the context for the revised 42 CFR part 8. On June 28, 2021, the Drug Enforcement Administration (DEA), the federal agency within the U.S. Department of Justice that registers OTPs, introduced guidance to facilitate adding a mobile component to an existing OTP registration [15] and waived any obligation for OTP mobile medication units to separately register remote locations where they dispense controlled MOUD (Volume 86 of the *Federal Register* page 33861 [86 FR 33861]). On September 21, 2021, SAMHSA also released guidance on mobile and brick-and-mortar medication units and on the expansion of allowable services that an OTP could offer in these extension locations. More information about this expansion is available on SAMHSA's Statutes, Regulations, and Guidelines webpage.

Each of these flexibilities and policies represented a significant change to the treatment standards in OTPs. Coupled with a national overdose crisis, the shifting landscape warranted revision to the federal OUD treatment standards in 42 CFR part 8. The final revised regulations promote and facilitate collaboration and coordination of care. They integrate harm reduction principles to reduce the risk of overdose and to prevent transmission of HIV, viral hepatitis, and sexually transmitted infections. The revised rules also make treatment more accessible by eliminating restrictive admissions criteria, expand the workforce by incorporating additional healthcare practitioners who can order and manage methadone and buprenorphine, and include other revisions that improve treatment and foster engagement and retention of patients in care.

These *Federal Guidelines for Opioid Treatment Programs* (the Guidelines) explain how OTPs can implement changes that align with federal regulations in the context of the current environment. The changes in 42 CFR part 8 are significant: They make the COVID-19 flexibilities permanent, and they update OTP standards based on evidence. The revised 42 CFR part 8 rule also supports OTPs in providing equitable and evidence-based care. It aligns with the seminal 2022 U.S. Department of Health and Human Services (HHS) Overdose Prevention Strategy and is reiterated in the 2024 National Drug Control Strategy, both of which call for increasing access to and uptake of evidence-based treatments for SUDs and the revision of the federal OTP regulations.

Introduction to OTPs

OTPs are federally certified, registered, and accredited entities that provide comprehensive services for people with OUD and other related SUDs, and related physical and mental health conditions, through a multidisciplinary team of dedicated healthcare professionals. OTPs dispense and administer methadone, and increasingly also buprenorphine and naltrexone, the three categories of MOUD. They play a critical role in OUD treatment by offering lifesaving medications that can lower the risk of opioid-related overdoses and overdose-related deaths, treat opioid withdrawal, and stabilize individuals with OUD. OTPs also offer medical care and non-pharmacological behavioral health services such as counseling and other interventions, peer support, care management, and referrals to community recovery organizations where patients can find additional recovery supports. The range of services is influenced by state and federal financing policies, including the requirements for receiving bundled payments.

Providing a range of treatment services demonstrates that OUD treatment is not one-size-fits-all, and each patient's needs are unique. Care is determined on an individual basis, with practitioners using their clinical judgment and a shared decision-making process to help patients identify and achieve their treatment goals (e.g., relief from withdrawal symptoms, reduction in substance use, abstinence, stable

housing, gainful employment, family reunification, improvements in overall health and quality of life). The care incorporates support and flexibility (e.g., medication take-home schedules, individualized counseling sessions, peer support) that empower patients to remain engaged in care for as long as they want to participate. [16] This approach aligns closely with the patient-centered care model, which encourages practitioners to deliver services that: [17]

- Convey empathy.
- Provide value to patients.
- Support patient autonomy in making informed treatment decisions.
- Help patients achieve their individual recovery goals.

Understanding the Role of MOUD in Supporting Recovery

In the same way that medications can be used to treat long-term, chronic health conditions, such as hypertension, diabetes, or even depression, medications can also be used to treat OUD. For some people, short-term use of methadone or buprenorphine for withdrawal management purposes may be helpful, but short-term withdrawal management by itself is associated with extremely high recurrence and overdose risks. [18] The reduction in mortality and the increased recovery benefits associated with MOUD are enhanced when these medications are part of a long-term, chronic disease management plan that supports people with OUD taking their medication for as long as it helps them. [19, 20, 21]

Methadone and buprenorphine are long-acting opioid medications that, when taken daily, substantially reduce cravings for short-acting opioids. [22] These medications have a lower risk profile than non-prescribed opioids (e.g., heroin, fentanyl), are effective for the treatment of OUD, and are approved by the FDA as first-line strategies for treating people with OUD. [23] Studies show that the use of MOUD helps improve treatment retention and outcomes for patients with OUD [24] and significantly reduces the risk of an opioid overdose. [25] Additionally, MOUD can be used with or without other interventions. Alone, MOUD has been shown to effectively reduce the risk of opioid-related overdose; in combination with counseling, peer support, and other services, MOUD helps improve physical and mental health and fosters recovery. [26]

Despite the effectiveness of MOUD in reducing opioid-related disease and death, OTP services are underused. This can be attributed to: [27]

- Stigma: Persistent stigma surrounding substances, substance use, OUD, and the use of agonist medications for treatment creates a barrier to seeking care. [28, 29, 30]
- Knowledge gaps for patients and providers: Misconceptions about MOUD, medication effectiveness, and accessibility deter both patients and providers from pursuing OTP services. [31, 32, 33]
- Treatment barriers: Insurance coverage limitations, geographic access disparities and transportation obstacles, and the requirements of some OTPs (e.g., daily attendance, limited hours for dosing) make access challenging. [34, 35, 36]
- Previous negative treatment experiences: Prior adverse experiences with the healthcare system, including specialty addiction treatment programs, lead to mistrust of OTPs.

The revised 42 CFR part 8 rule, described in these Guidelines, helps address some of these barriers by:

- Ensuring practitioners have the knowledge required to feel comfortable managing methadone in particular and referring to or providing care in OTPs.
- Ensuring healthcare professionals working as part of a multidisciplinary team in an OTP understand how to support the culture change envisioned in and made possible by the revised regulations.

- Eliminating requirements that contribute to stigma.
- Addressing concerns about regulatory interpretation and logistics that contribute to compliance issues.

Federal Regulations Guiding OTPs

The regulations in 42 CFR part 8 are authorized under Title 21 of the United States Code, section 823(h), and establish the procedures by which the Secretary of the U.S. Department of Health and Human Services ("the Secretary") and HHS delegates determine whether a program is qualified to dispense opioid agonist medications, such as methadone, for the treatment of OUD. To provide services, OTPs must successfully complete the certification and accreditation process and meet other requirements outlined in 42 CFR part 8. All of 42 CFR part 8 contains rules related to the operation and regulation of OTPs.

Most importantly, methadone is a Schedule II controlled medication governed by the Controlled Substances Act (CSA); buprenorphine is a Schedule III controlled medication. The CSA establishes federal drug policy for regulating the manufacturing, importing, possession, use, and distribution of controlled substances, including controlled medications. The CSA requires that methadone be dispensed or administered (but not prescribed) to people with OUD through OTPs, with few exceptions. In addition, given that methadone and buprenorphine are controlled medications, OTPs are subject to additional DEA requirements intended to prevent diversion. All staff working in OTPs should have familiarity with the DEA regulations related to medication safety and security, documentation of medication administration, use of telehealth services for ordering medications, and operation of mobile units, for example, and how the focus and scope of DEA's regulations differ from those established in 42 CFR part 8. [37]

The federal regulations delineated in the revised 42 CFR part 8 describe a minimum acceptable standard for the operation of OTPs. They are not intended to provide clinical or medical guidelines; rather, they promote a whole-person approach to care, advance individualized services, and support patient well-being and safety.

Regulatory Changes to the Treatment of OUD

SAMHSA has revised 42 CFR part 8 to increase access to services, reflect practitioner autonomy, and ensure a patient-centered approach to care. Several key changes to the regulations include:

- **Recognition of the effect of high potency synthetic opioids (HPSO) other than methadone, such as fentanyl, in the illicit drug supply.** Practitioners treating OUD and the OTPs in which they practice must continually adapt to evolving patterns of substance use, including changes to the drug supply. In recent years, the United States has seen rapid increases in overdose deaths involving illicitly manufactured HPSOs and other opioid analogs. Changes to 42 CFR part 8 respond to the significant rise in overdose deaths related to these synthetic opioids by expanding access to care and promoting engagement in OTP services—while also maintaining oversight and accreditation activities. The changes also highlight that overdose from HPSOs is a public health concern that providers must be aware of and account for as they make clinical decisions in the care of people with OUD. [38] Consequently, the revised rule promotes the provision of harm reduction activities in OTPs, including distribution of naloxone, other opioid overdose reversal medications, and drug checking supplies (e.g., fentanyl and xylazine test strips) to patients.

- **Revised criteria for admission to treatment.** To remove barriers to medication access and to add protections for at-risk groups, the revised rule reinforces priority treatment for people who are pregnant and eliminates the requirement that patients have an opioid addiction history of 1 year or longer to be eligible for treatment. The revised rule also removes the requirement that people younger than age 18 must have two documented instances of unsuccessful attempts at withdrawal management or non-MOUD treatment to be eligible for MOUD treatment. Other access-related changes include allowing enrollment and initiation of medication upon an abbreviated screening medical evaluation, allowing (under certain conditions) screening examinations to be performed by practitioners outside the OTP, and allowing for electronic consent for treatment.
- **Increased flexibilities related to the provision of take-home medication doses.** In March 2020, in response to the COVID-19 pandemic, SAMHSA published exemptions allowing flexibilities in the provision of take-home doses of methadone. The exemptions allowed OTPs to dispense up to 28 days of take-home doses for patients who are stable in treatment and up to 14 take-home doses for patients who might benefit from more structured care if the OTP believed the patient could safely handle the quantity of take-home medication. Recognizing the evidence supporting the safety and efficacy of this flexibility, the revised rule makes take-home medication flexibilities permanent. These changes also give healthcare practitioners the discretion to determine, using a shared decision-making framework, the appropriate level of flexibility based on each patient's individual needs and progress, promoting a more personalized, responsive approach to treatment.
- **Expanded use of telehealth.** In April 2020, in response to the COVID-19 pandemic, SAMHSA made changes to exempt OTPs from requirements related to performing in-person physical evaluations for patients to be treated with buprenorphine. The revised rule makes permanent the criteria for initiating buprenorphine via audio-only or audio–visual telehealth technology when an OTP physician or authorized practitioner determines that an adequate evaluation of the patient can be accomplished via telehealth. Additionally, the revised rule allows for the initiation of methadone for new patients through the use of audio–visual telehealth when an authorized practitioner determines that an adequate evaluation of the patient can be accomplished via an audio–visual telehealth platform. [39]
- **Updated regulations pertaining to medication units.** In September 2021, SAMHSA released guidance on the establishment of services at mobile and brick-and-mortar medication units. The revised rule incorporates these allowances for all OTP services to be provided at these medication units, as long as space and privacy permit, enabling an even greater expansion of OTP reach.

To align with changes in the revised rule, phrasing and practices have been updated throughout these Guidelines. Culturally responsive, person-first language has replaced outdated terminology that perpetuates negative stereotypes. The Guidelines also incorporate evidence-based principles that focus on practitioner autonomy, shared decision-making, and individualized care. For example, the term *medications for the treatment of opioid use disorder* is used instead of *medication-assisted treatment* to reflect currently accepted medical terminology and more precisely describe the group of FDA-approved medications available for the treatment of OUD. Other components of treatment, including counseling, medical care, and psychiatric care, are named individually. Counseling, other treatment services, and recovery support services are therefore described as being provided in combination with medications for whole-person care. The term *detoxification* and the corresponding definition and standards for short- and long-term withdrawal treatment have been removed. The terms *withdrawal management* and *tapering from MOUD* have been added in reference to patients who seek withdrawal management or who want or need to reduce or discontinue MOUD. These language changes—in both the revised rule and the Guidelines—aim to create a more inclusive and supportive treatment environment; reflect a

growing understanding that OUD is a chronic, treatable condition; and emphasize that individuals seeking treatment deserve dignity and respect.

Principles and Themes of the Guidelines

The *Federal Guidelines for Opioid Treatment Programs* is not a legal document. Instead, it provides guidance and recommendations to OTPs for implementing requirements outlined in the revised 42 CFR part 8 rule. **These Guidelines are not intended to replace the judgment of healthcare practitioners and do not represent professional standards of care.** However, they are presented with the understanding that OTPs provide an essential medical service, and, thus, the care they deliver should be comparable to the medical care provided in other settings.

These Guidelines mark a critical shift in thinking about how to approach care for OUD by increasing access and removing barriers to OTP services and MOUD. The Guidelines align with SAMHSA's guiding principles: [40]

- **Behavioral health equity,** or the right to access high-quality and affordable healthcare services and supports for all populations.
- **Recovery,** a process of change through which individuals improve their health and wellness, live self-directed lives, and strive to reach their full potential.
- **Trauma-informed approaches,** which recognize and respond to the lasting adverse effects of traumatic experiences while promoting linkages to recovery and resilience for impacted individuals and families.
- **A commitment to data and evidence,** which helps public health officials, policymakers, community practitioners, and the public to understand mental health and substance use trends and how they evolve; inform the development and implementation of targeted evidence-based interventions; focus resources where needed most; and evaluate programs and policy success.

The Guidelines also are consistent with the 2022 HHS Overdose Prevention Strategy, which calls for increasing access to and uptake of evidence-based treatments for SUDs, [41] and with SAMHSA's Harm Reduction Framework, which emphasizes that when substance use is viewed on a continuum, incremental change can be made, allowing for risk reduction to better suit a person's own individual goals and motivations. [42]

As noted throughout, **the Guidelines place the patient at the center of all activities** and focus on treatment approaches that include the principles of harm reduction and encourage individualized pathways to recovery. This approach prioritizes the unique needs, preferences, and goals of each individual seeking treatment for OUD and recognizes that one-size-fits-all approaches are ineffective in addressing the complexities of addiction and recovery.

To promote a patient-centered approach, **the Guidelines emphasize easier access and more flexibility in providing services,** which enables patients to maintain jobs, attend to education, and more easily care for family while receiving treatment. By increasing access to OTP services, these changes help address barriers related to social determinants of health, which may include social injustice and racial inequity, unemployment, less education, lack of access to transportation, food insecurity, housing instability, and exposure to trauma. [43]

The Guidelines also encourage treatment environments that promote and sustain patient engagement, offering services that save and improve lives and supporting patients in achieving their goals. A key aspect of patient-centered care is the promotion of shared decision-making between the

patient and practitioner, reinforcing respect for the patient's values and preferences as they make decisions about their treatment. This collaborative process empowers patients to take an active role in their recovery, fostering a sense of autonomy and self-determination. By involving patients in treatment decisions, OTPs can improve engagement, adherence, and, ultimately, outcomes.

The Guidelines highlight the importance of clinical decision-making and practitioner discretion. At the heart of clinical decision-making is the principle of patient-centered care and shared decision-making, which improves outcomes and promotes long-term recovery from SUDs, including OUD. The revised rule recognizes the critical role of clinical decision-making and practitioner discretion in providing effective, individualized care within OTPs and empowers healthcare professionals to use their expertise and judgment in tailoring treatment to each patient's unique needs and goals.

The revised rule also recognizes the importance of practitioner discretion in determining and recommending the appropriate level of care and support for each patient. For example, the rule allows for flexibility in the provision of take-home doses of methadone (42 CFR § 8.12[i]). Rather than imposing rigid, one-size-fits-all dosing schedules, the rule gives practitioners the authority and responsibility to work with patients to determine the appropriate level of patient medication visits based on each patient's individual needs, progress, and stability. This discretion and engagement with a patient is at the heart of shared decision-making [44] and enables practitioners to respond to changes in a patient's circumstances and adjust treatment strategies accordingly. In this way, practitioners promote a more personalized, dynamic approach to care. The importance of clinical decision-making using a shared decision-making framework and practitioner discretion is further underscored by the revised rule's emphasis on evidence-based practices and continuous quality improvement (42 CFR § 8.12[c]). The rule requires OTPs to regularly assess patient outcomes and adjust treatment strategies based on the best available evidence. This approach recognizes that addiction treatment is a complex, evolving field and that practitioners must have the flexibility to adapt to new research and best practices.

It is important to note that clinical decision-making, shared decision-making, and practitioner discretion are not without bounds. The rule establishes clear standards for patient assessment, care planning, and medication administration, among other areas (42 CFR § 8.12). These standards provide a framework for ensuring that all patients receive a safe, consistent, high level of care while allowing for individualization based on each patient's unique needs and circumstances. By striking a balance between standardization and flexibility, the rule promotes a more effective, equitable system of care.

The Guidelines empower OTPs and practitioners to provide compassionate, comprehensive, holistic care that addresses the full range of an individual's needs. In addition to MOUD, OTPs must offer medical, counseling, vocational, educational, and other assessment and treatment services. This multidisciplinary approach acknowledges that addiction is a complex disease that affects all aspects of an individual's life and that recovery is multifaceted. By addressing co-occurring physical and mental conditions, social determinants of health, and other factors that contribute to substance use, OTPs can provide more effective, sustainable treatment.

Key Definitions and Terms

The revised Title 42 of the Code of Federal Regulations (42 CFR) part 8 rule includes updates to terminology, adding several new terms, such as *patient-centered care,* and removing stigmatizing language. The following terms include selected 42 CFR § 8.2 definitions and other key opioid treatment program (OTP)–related terms.

- **Adverse childhood experiences (ACEs)** are potentially traumatic events that occur in childhood (ages 0 to 17 years). Examples include experiencing violence, abuse, or neglect, witnessing violence in the home or community, or having a family member attempt or die by suicide. Also included are aspects of the child's environment that can undermine their sense of safety, stability, and bonding. This may include growing up in a household with a person with substance use or mental health issues, instability due to parental separation, or instability due to household members being in jail or prison. (About Adverse Childhood Experiences | Centers for Disease Control and Prevention)
- **Behavioral health equity** is the right to access high-quality and affordable healthcare services and supports for all populations, including Black, Hispanic/Latino, and Indigenous and Native American persons; Asian Americans and Pacific Islanders and other people of color; members of religious minority groups; lesbian, gay, bisexual, transgender, queer, intersex, asexual, Two Spirit, or other (LGBTQIA2S+) people; people with disabilities; people who live in rural areas; and people otherwise adversely affected by persistent poverty or inequality. (Behavioral Health Equity | Substance Abuse and Mental Health Services Administration [SAMHSA])
- **Behavioral health service** refers to any intervention carried out in a therapeutic context at an individual, family, or group level. Interventions may include structured, professionally administered clinical interventions (e.g., cognitive–behavioral therapy or insight-oriented psychotherapy) delivered in person or remotely via telehealth or telemedicine, which has been shown to facilitate treatment outcomes, or nonclinical interventions. See 42 CFR § 8.2.
- **Care coordination** is the organization of a patient's care across multiple health care providers. (Care Coordination | Healthcare.gov)
- **Care management** refers to sustained services that help a patient manage one or more chronic diseases, such as diabetes or cardiovascular disease. Care management may employ the use of case managers as part of overarching care coordination. (*Advisory:* Comprehensive Case Management for Substance Use Disorder Treatment | SAMHSA)
- **Care plan** is an individualized treatment or recovery plan that outlines attainable treatment and recovery goals that have been identified and agreed upon between the patient and the OTP clinical team and that specifies the services to be provided, as well as the proposed frequency and schedule for their provision. See 42 CFR § 8.2.
- **Case management** (not to be confused with care management) may vary by setting, but generally refers to a coordinated, individualized approach that links patients with appropriate concrete services to address their specific needs and help them achieve their stated goals. Case management typically provides the patient a single point of contact for arranging services and is often more time-limited than care management. (*Advisory:* Comprehensive Case Management for Substance Use Disorder Treatment | SAMHSA)
- **Certification** is the process by which the U.S. Department of Health and Human Services (HHS) Secretary determines that an OTP is qualified to provide opioid use disorder (OUD) treatment under federal OUD treatment standards. See 42 CFR § 8.2.

- **Certification application** is the application filed by an OTP for the purposes of obtaining certification from the Secretary, as described in 42 CFR § 8.11(b). See 42 CFR § 8.2.
- **Comprehensive treatment** is treatment that includes the continued use of medications for the treatment of OUD (MOUD) provided in conjunction with an individualized range of appropriate harm reduction, medical, counseling, mental health, and recovery support services. See 42 CFR § 8.2.
- **Continuity of care** is the degree to which a series of discrete healthcare events is experienced by people as coherent and interconnected over time and consistent with their health needs and preferences. (Continuity and Coordination of Care | World Health Organization)
- **Continuous medication treatment** means the uninterrupted treatment for OUD involving the dispensing and administration of MOUD at stable dosage levels for a period of more than 21 days.
- **Dispense** means to deliver a controlled medication to an ultimate user by, or pursuant to, the lawful order of, a practitioner, including the prescribing and administering of a controlled medication. See 42 CFR § 8.2.
- **Diversion control plan** is a set of documented procedures that reduce the possibility that controlled medications will be transferred or otherwise shared with others to whom the medication was not prescribed or dispensed. See 42 CFR § 8.2.
- **Harm reduction** refers to practical, evidence-based strategies, including overdose education; testing and intervention for infectious diseases, including counseling and risk mitigation activities forming part of a comprehensive, integrated approach to address HIV, viral hepatitis, sexually transmitted infections, and bacterial and fungal infections; distribution of opioid overdose reversal medications; linkage to other public health services; and connecting those who have expressed interest in additional support-to-peer services (see 42 CFR § 8.2). This definition refers to SAMHSA's definition of harm reduction as "a practical and transformative approach that incorporates community-driven public health strategies—including prevention, risk reduction, and health promotion—to empower people who use drugs (PWUD) and their families with the choice to live healthier, self-directed, and purpose-filled lives. Harm reduction centers the lived and living experience of PWUD, especially those in underserved communities, in these strategies and the practices that flow from them." (Harm Reduction Framework | SAMHSA).
- **Individualized dose** is the dose of a medication for OUD, ordered by an OTP practitioner and dispensed to a patient, that sufficiently suppresses opioid withdrawal symptoms with minimal to no adverse side effects. Individualized doses may also include split doses of a medication for OUD, where such dosing regimens are indicated. See 42 CFR § 8.2.
- **Long-term care facilities** mean those facilities that provide rehabilitative, restorative, or ongoing services to those in need of assistance with activities of daily living. Long-term care facilities include extended acute-care facilities, rehabilitation centers, skilled-nursing facilities, permanent supportive housing, assisted-living facilities, and chronic-care hospitals. See 42 CFR § 8.2.
- **Medical director** is a physician licensed to practice medicine in the jurisdiction in which the OTP is located, who assumes responsibility for all medical and behavioral health services provided by the program, including their administration. A medical director may delegate specific responsibilities to authorized program physicians, appropriately licensed nonphysician practitioners with prescriptive authority functioning under the medical director's supervision, or appropriately licensed or credentialed nonphysician healthcare professionals providing services in the OTP in compliance with applicable federal and state laws. Such delegations will not eliminate the medical director's responsibility for all medical and behavioral health services provided by the OTP. See 42 CFR § 8.2.

- **Medication for opioid use disorder** (MOUD) means medications, including opioid agonist medications, approved by the Food and Drug Administration under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) for use in the treatment of OUD. As used in this part, "*continuous medication treatment*" is intended to be synonymous with the term "*maintenance*" *treatment* as used in 21 U.S.C. 823(h)(1), and the term "*withdrawal management*" is intended to be synonymous with the term "*detoxification*" as used in 21 U.S.C. 823(h)(1). See 42 CFR § 8.2.
- **Medication unit** means an entity that is established as part of, but geographically separate from, an OTP from which appropriately licensed OTP practitioners, contractors working on behalf of the OTP, or community pharmacists may dispense or administer MOUD; collect samples for drug testing or analysis; or provide other OTP services. Medication units can be a brick-and-mortar location, or a mobile unit. See 42 CFR § 8.2.
- **Nationally recognized evidence-based guidelines** are produced by a national or international medical professional association; public health agency, such as the World Health Organization; or governmental body with the aim of assuring the appropriate use of evidence to guide individual diagnostic and therapeutic clinical decisions for the management of OUD and other widely recognized health conditions in the United States. See 42 CFR § 8.2.
- **Opioid treatment program (OTP)** means a program engaged in treatment of individuals with OUD with MOUD registered under 21 U.S.C. 823(h)(1). See 42 CFR § 8.2.
- **Opioid use disorder (OUD)** is a cluster of cognitive, behavioral, and physiological symptoms associated with a problematic pattern of opioid use that continues despite clinically significant impairment or distress, within a 12-month period. [45] It is one of several types of substance use disorders (SUDs). See 42 CFR § 8.2.
- **Opioid use disorder treatment** means the dispensing of MOUD, along with the provision of a range of medical and behavioral health services, as clinically necessary and based on an individualized assessment and a mutually agreed-upon care plan, to an individual with OUD to alleviate the combination of adverse medical, psychological, or physical effects associated with an OUD. See 42 CFR § 8.2.
- **Patient-centered care** is a care model that encourages practitioners to deliver services that convey empathy, provide value to patients, support patient autonomy in making informed treatment decisions, and help patients achieve their individual recovery goals. (*Advisory:* Low Barrier Models of Care for Substance Use Disorders | SAMHSA)
- **Practitioner** means a healthcare professional who is appropriately licensed by a state to prescribe or dispense medications for OUD and, as a result, is authorized to practice within an OTP. See 42 CFR § 8.2.
- **Program sponsor** means the person named in the application for certification described in 42 CFR § 8.11(b) as responsible for the operation of the OTP and who assumes responsibility for all of its employees, including any practitioners, agents, or other persons providing medical, behavioral health, or social services at the program or any of its medication units. The program sponsor need not be a licensed physician but shall ensure that an actively licensed physician occupies the position of medical director within an OTP. See 42 CFR § 8.2.
- **Recovery** is a process of change through which people improve their health and wellness, live self-directed lives, and strive to reach their full potential (see 42 CFR § 8.2). There are four major dimensions that support recovery:
    1. Health—Overcoming or managing one's diseases or symptoms and making informed, healthy choices that support physical and emotional well-being.
    2. Home—Having a stable and safe place to live.

3. Purpose—Conducting meaningful daily activities and having the independence, income, and resources to participate in society.
4. Community—Having relationships and social networks that provide support, friendship, love, and hope. (Recovery and Recovery Support | SAMHSA)

- **Recovery capital** is the quantity and quality of resources available to patients to begin and maintain long-term recovery from SUDs, including OUD, and can include internal resources (e.g., physical health, values, hope) or external resources (e.g., community and cultural support, employment). (Treatment Improvement Protocol [TIP] 65, *Counseling Approaches To Promote Recovery From Problematic Substance Use and Related Issues* | SAMHSA)
- **Recovery support services** are the services that extend the continuum of care by strengthening and complementing SUD treatment interventions in different settings and stages. Recovery support services can include community-based recovery housing, peer recovery support services, social support, linkages to and coordination among allied service providers, and a full range of human services that facilitate recovery and wellness and contribute to an improved quality of life. See 42 CFR § 8.2.
- **Single State Agency** is the lead agency in each state or jurisdiction responsible for managing federal funds dedicated to addressing substance use prevention, treatment, and recovery. These agencies are governed by different statutes and regulations, vary in terms of their exact functions, size, and placement within state government. Yet these same agencies also share common characteristics as well. The development of effective federal policy requires an awareness and appreciation of the important role state alcohol and drug agencies play in managing our nation's prevention, treatment, and recovery system. (Role of State Alcohol and Drug Agencies | National Association of State Alcohol and Drug Abuse Directors)
- **Split dosing** means dispensing of a single dose of MOUD as separate portions to be taken within a 24-hour period. See 42 CFR § 8.2.
- **State Opioid Treatment Authority (SOTA)** is the agency designated by the governor of a state, or other appropriate official designated by the governor, to exercise the responsibility and authority within the state or territory for governing the treatment of OUD with MOUD in OTPs. See 42 CFR § 8.2.
- **Stigma** is discrimination against an identifiable group of people, a place, or a nation. Stigma about people with SUDs might include inaccurate or unfounded beliefs, such as they are dangerous, incapable of managing treatment, or at fault for their condition. (Words Matter: Preferred Language for Talking About Addiction | National Institute on Drug Abuse)
- **Substance use disorder (SUD)** is a medical illness, often chronic, associated with persistent, problematic use of a substance or substances and characterized by a cluster of cognitive, behavioral, and physical symptoms that can impair health, social functioning, and control over that use. SUDs are categorized by severity as mild, moderate, or severe, based on how many of the 11 diagnostic criteria a person meets at the time of assessment. These disorders have the potential for remission and recovery and may follow a pattern of stability alternating with recurrence. Even after long-term remission, there remains a risk of recurrence, although this risk diminishes over time. (*Diagnostic and Statistical Manual of Mental Disorders*, Fifth Edition, Text Revision)
- **Telehealth or telemedicine** is the delivery and facilitation of health and health-related services, including medical care; counseling, practitioner, provider, and patient education; health information services; and self-care via telecommunications and digital communication technologies. This includes Health Insurance Portability and Accountability Act–compliant video and audio-only communication platforms. See 42 CFR § 8.2.

- **Trauma** results from "an event, series of events, or set of circumstances that is experienced by an individual as physically or emotionally harmful or life threatening and that has lasting adverse effects on the individual's functioning and mental, physical, social, emotional, or spiritual well-being. Traumatic events may be experienced by an individual, a generation, or an entire community or culture." (*Practical Guide for Implementing a Trauma-Informed Approach* | SAMHSA)
- **Trauma-informed approach or trauma-informed care** refers to a program, organization, or system that realizes the widespread effect of trauma and understands potential paths for recovery; recognizes the signs and symptoms of trauma in clients, families, staff, and others involved with the system; and responds by fully integrating knowledge about trauma into treatment policies, procedures, and practices, and seeks to actively protect against re-traumatization. (*Practical Guide for Implementing a Trauma-Informed Approach* | SAMHSA)
- **Withdrawal management** means the dispensing of MOUD in decreasing doses to an individual to alleviate adverse physical effects incident to withdrawal from the continuous or sustained use of an opioid and as a method of bringing the individual to an opioid-free state within such period. Long-term withdrawal management refers to the process of medication tapering that exceeds 30 days. See 42 CFR § 8.2.

General Provisions and Practices

Organizational Structure and Key Staff

> **42 CFR § 8.12(b). Administrative and organizational structure.** (1) An OTP's organizational structure and facilities shall be adequate to ensure quality patient care and to meet the requirements of all pertinent Federal, State, and local laws and regulations. At a minimum, each OTP shall formally designate a program sponsor and medical director. The program sponsor shall agree on behalf of the OTP to adhere to all requirements set forth in this part. (2) The medical director shall assume responsibility for all medical and behavioral health services performed by the OTP. In addition, the medical director shall be responsible for ensuring that the OTP is in compliance with all applicable Federal, State, and local laws and regulations.

The organizational structure of an opioid treatment program (OTP) supports the safe and effective provision of medications and other services for opioid use disorder (OUD), the appropriate use of clinical judgment, and the importance of patient-centered care. This structure also facilitates compliance with federal law and regulations.

At a minimum, OTP leadership should include a program sponsor and a medical director. In some OTPs, these are not discrete roles, meaning that a program sponsor may also be a medical director. Some OTPs, particularly larger ones, may also have a program director that supports daily operations. These positions guide the mission, vision, values, and direction of the organization, with a focus on developing strong practitioner–patient relationships and empowering and supporting staff to work with patients to create individualized plans of care. The program sponsor and medical director also typically attend to the organization's fiscal viability and adherence to applicable federal, state, and local law; ensure quality care is provided to patients; and ensure adherence to the regulatory requirements governing care. Each role requires sufficient education, training, and experience to ensure the individual in the role can perform the assigned functions as needed in support of patient care. [46]

The general qualifications for the program sponsor, medical director, and program director roles are described in the following sections. Specific OTP leadership qualifications may differ based on state requirements.

Role of the Program Sponsor

Title 42 of the Code of Federal Regulations (42 CFR) § 8.2 defines the roles and responsibilities of the program sponsor as follows:

> *Program sponsor* is the person named in the application for certification described in 42 CFR § 8.11(b) as responsible for the operation of the OTP and who assumes responsibility for all its employees, including any practitioners, agents, or other persons providing medical, behavioral health, or social services at the program or any of its medication units. [47]

The program sponsor is responsible for the overall administrative and fiscal management and operations of the OTP. The program sponsor works closely with the medical director, and in some instances a program director, to ensure optimal care. The program sponsor also makes certain that the work conducted by OTP practitioners and other staff providing services is consistent with the allowable scope for their licensure, certification, or credential.

The Substance Abuse and Mental Health Services Administration (SAMHSA) recommends that the program sponsor have a strong understanding of substance use disorders (SUDs), specifically OUD, as well as proven management skills and knowledge of related state and federal regulations. Because program sponsors work closely with the medical director on clinical aspects of the program, a person in this role ideally would have a mix of clinical and management experience.

> The relationship between the program sponsor and the medical director is crucial to the effectiveness of an OTP and is the responsibility of both leaders. The medical director is responsible for all medical and behavioral health services provided by the program, including their administration. The program sponsor is responsible for all OTP employees, including the medical director. Therefore, the program sponsor needs to work closely with and understand the medical director's decisions, even if the program sponsor is not a licensed medical practitioner.

The activities of the program sponsor include:

- Promoting patient-centered and trauma-informed approaches to care.
- Overseeing the quality of care provided.
- Ensuring patients' rights are protected.
- Ensuring achievement of patient outcomes.
- Ensuring the OTP has a sufficient staffing pattern to allow patients to obtain and participate in the services they choose.
- Developing and reviewing policy and procedure with staff on a regular basis and enforcing it where applicable.
- Overseeing the OTP's strategic planning activities and engaging staff in strategic planning discussions.
- Soliciting, considering, and incorporating patient feedback in strategic plans, clinical policies and procedures, and changes to care.
- Ensuring the program complies with all accreditation standards as well as federal, state, and local laws and regulations.

The program sponsor is a key point of contact for operational activities as outlined in both SAMHSA and the Drug Enforcement Administration (DEA) regulations. Per 42 CFR § 8.11(e)(5), OTPs are required to notify SAMHSA in writing within 3 weeks of any replacement or other change in the status of the program sponsor.

Role of the Medical Director

42 CFR § 8.2 defines the roles and responsibilities of the medical director as follows:

> *Medical director* means a physician, licensed to practice medicine in the jurisdiction in which the OTP is located, who assumes responsibility for all medical and behavioral health services provided by the program, including their administration. A medical director may delegate specific responsibilities to authorized program physicians, appropriately licensed non-physician practitioners with prescriptive authority functioning under the medical director's supervision, or appropriately licensed and/or credentialed non-physician healthcare professionals providing services in the OTP, in compliance with applicable Federal and State laws. Such delegations will not eliminate the medical director's responsibility for all medical and behavioral health services provided by the OTP.

The role of the medical director is grounded in these rules and in core professional obligations. Medical directors are highly knowledgeable about the treatment of SUDs, particularly OUD, and related health conditions and social determinants of health affecting people seeking services in the OTP setting.

Medical directors also are well-versed in federal and state regulations, as well as other statutes, guidelines, policies, and standards that govern OUD care and OTP operations. As an actively licensed physician, the medical director should have completed an accredited residency training program and have at least 1 year of experience in addiction medicine or addiction psychiatry. Board certification in addiction psychiatry or addiction medicine is suggested. In some cases, one individual may serve as both medical director and program sponsor of an OTP; however, only a physician may serve as the medical director (42 CFR § 8.2).

The medical director plays many roles in the organization, such as: [48]

- Science expert, with knowledge of scientific advancements, medications, and treatments to support patients.
- Direct patient care provider.
- Patient advocate, who ensures care is culturally appropriate and responsive to patient needs and fosters a treatment environment that promotes and sustains patient engagement.
- Quality assurance expert, with knowledge of and accountability to local, state, and federal regulations, as well as accreditation standards.
- Leader, inspiring staff and leading the organization in modeling the use of clinical judgment, individualized care, and shared decision-making.
- External face of the organization, representing the OTP's values and standards to the community.

> The medical director often oversees other OTP practitioners who are healthcare professionals appropriately licensed by the state to prescribe and dispense medications for the treatment of OUD (MOUD) and, therefore, are authorized to practice within an OTP. The revised rule now allows additional types of licensed practitioners, such as nurse practitioners and physician assistants, to order and manage methadone and buprenorphine in an OTP.

The activities of the medical director include:

- Ensuring patient participation in the development and implementation of patient care plans, developing strategies to optimize care for co-occurring medical and mental health issues, and monitoring patients' overall health.
- Developing and implementing policies, procedures, and evidence-based practices to reduce the risk of overdose deaths during treatment and at the time treatment is discontinued. This includes implementing evidence-based practices to identify individuals at increased risk of overdose and providing appropriate strategies to mitigate or manage the risk.
- Promoting an understanding and importance of clinical judgment (the Services Delivered by the OTP chapter includes more information about clinical judgment).
- Monitoring and supervising all medical and nursing services provided by the OTP.
- Ensuring all medical, psychiatric, nursing, medication dispensing, toxicology, and other services offered at the OTP are conducted in compliance with federal, state, tribal, and local regulations.
- Overseeing the hiring, evaluation, and management of medical staff, including participating in hiring, overseeing, and evaluating behavioral health service providers and other OTP staff.

- Developing and implementing medical policies and procedures, contributing to other clinical policies and procedures, and delivering a high quality of addiction medicine and other medical care.
- Engaging with the multidisciplinary team providing care in the OTP to model and promote the use of individualized care that meets patients where they are and supports a focus on their goals.
- Overseeing quality improvement activities.
- Promoting a culture of patient-centered care.
- Promoting a cohesive and safe work environment.

Per 42 CFR § 8.11(e)(5), OTPs are required to notify SAMHSA in writing within 3 weeks of any replacement or other change in the status of the medical director.

Role of the Program Director or Program Manager

Some OTPs employ a *program director* or *program manager* who reports to the program sponsor or medical director. The revised rule does not offer any definition of a program director or manager, allowing OTPs to determine the roles and responsibility for this position. The program director or manager role often includes overseeing operational aspects of the program, such as health and safety, human resources, facilities management, and disaster management, in addition to working with the medical director on overseeing the provision of all direct services provided in the OTP.

Strong coordination, shared decision-making, and accountability among the program sponsor, medical director, and program director or manager are needed to ensure not only the effective operation of an OTP, but also attention to patients' goals and needs. Therefore, deep knowledge of care for people with OUD is important for all three roles.

Integrating Trauma-Informed Principles and Practices

Supportive, patient-centered services recognize that experiences of trauma contribute to and are associated with OUD and other SUDs. Integrating practices that are trauma-informed can enhance engagement and retention in treatment. Examples of organizational and clinical practices that reflect trauma-informed approaches include: [49]

- Empowering patients in decisions about their treatment and recovery.
- Encouraging collaboration among staff and patients in care planning.
- Creating a safe physical and emotional environment for patients and staff.
- Ensuring trustworthiness through open dialog among staff and patients.

> SAMHSA defines *trauma* as "result[ing] from an event, series of events, or a set of circumstances an individual experiences as physically or emotionally harmful or threatening, which may have lasting adverse effects on the individual's functioning and mental, physical, social, emotional, or spiritual well-being."
>
> SAMHSA's *Practical Guide for Implementing a Trauma-Informed Approach* contains a more thorough discussion of the impact of trauma on patients.

An organization that is trauma-informed:

- Understands the significant effects of trauma and potential paths for recovery.
- Recognizes the signs and symptoms of trauma in patients.
- Responds by fully integrating knowledge about trauma into policies, procedures, and practices.

- Seeks to actively protect against re-traumatization during treatment.

Examples of trauma-informed practices in an OTP may include: [50]

- Facilitating transparent interactions with patients to foster trust, dignity, and respect throughout the continuum of care.
- Using a strengths-based approach that encourages active involvement of patients in their treatment decisions and promotes shared decision-making.
- Including patients who have experienced trauma in reviews of and updates to policies and procedures.
- Training staff in culturally responsive trauma-informed screening, assessment, and treatment approaches, including the need to consider context for how patients perceive and process trauma.
- Screening for trauma and attending to trauma-related symptoms, especially in the context of co-occurring SUDs.
- Engaging referral sources and partnering organizations to ensure patients receive holistic, individualized care and recovery support.

SAMHSA recommends that all OTP staff receive training in trauma-informed care principles, practices, and policies. Additionally, leadership can cultivate awareness and provide support for staff who may also experience trauma, either from personal life events or from working with patients who have experienced trauma (i.e., secondary trauma). This is a key aspect of creating a trauma-informed organization.

SAMHSA's *Practical Guide for Implementing a Trauma-Informed Approach* offers more information about becoming a trauma-informed organization. Additional details about providing trauma-informed care are discussed in the Counseling Treatment and Recovery Support Services section of these Guidelines.

Human Resources Policies and Practices

SAMHSA recommends that OTP staffing patterns align with the size of the OTP, the scope of practice, the extent of services provided, and the number of patients served. Staff at all levels should be expected to promote patient-centered and trauma-informed care grounded in the use of non-stigmatizing principles and language.

Job Descriptions

It is recommended that each staff position in an OTP has a detailed position description that outlines the duties assigned to the position, the qualifications and competencies required to hold the position, and the training and performance standards required to remain in the position.

The position descriptions and assigned duties for both licensed clinical and medical professionals should align with the scope of practice assigned to each profession by its respective licensing authority. Developing clear job descriptions for nurses is particularly important, as registered nurses and licensed practical or vocational nurses have distinctly different scopes of practice. All licensed individuals employed in OTPs should comply with applicable licensing and credentialing requirements.

Non-licensed staff, such as peer specialists, community health workers, or technicians, may qualify for their positions through training, education, and experience. In states that permit non-licensed addiction staff, programs can develop the position description in accordance with standards established by a

formal body, such as those published by the National Certification Commission for Addiction Professionals. [51] OTPs may find SAMHSA's National Model Standards for Peer Support Certification helpful when hiring peer specialists.

Staff Documentation and Training Requirements

It is standard that OTPs maintain individualized personnel files as a record of employment. The files should contain, at a minimum:

- Documentation of qualifications, previous experience, contact information, and other appropriate employment and credentialing information, such as confirmation of current licenses, credentials, and certifications. Signed agreements to protect patients' rights and confidentiality.
- Detailed job descriptions for credentialed and non-credentialed staff that clearly define the qualifications and competencies needed to provide specific services.
- Documentation of initial and annual training and other trainings required for accreditation and certification relevant to the person's scope of practice and job description, including attendance records, the organizations that sponsored or provided the training, and indication that the training was specific to MOUD, related SUDs, and co-occurring conditions.
- Dates of employment, performance evaluations, and any updates to licensing and credentialing information, certification information, job descriptions, and other employment information deemed appropriate.
- Background check results (if required, per state regulations).
- Copies of current licenses and/or certifications.

Continuous Quality Improvement

> **42 CFR § 8.12(c). Continuous quality improvement.** (1) An OTP must maintain current quality assurance and quality control plans that include, among other things, annual reviews of program policies and procedures and ongoing assessment of patient outcomes.

The Centers for Medicare & Medicaid Services (CMS) defines *quality improvement* as a "framework used to systematically improve care." Quality improvement "seeks to standardize processes and structure to reduce variation, achieve predictable results, and improve outcomes for patients, healthcare systems, and organizations." [52]

Continuous monitoring of policies, procedures, practices, and patient outcomes helps OTPs enhance patient care and improve treatment outcomes. A robust continuous quality improvement (CQI) plan encompasses the following: [53]

- **Patient-centered care:** A description of the OTP's approach to delivering individualized, patient-centered care, explaining specific strategies and processes.
- **Performance measurement:** The use of relevant data to track patient outcomes, clinical performance, and operational efficiency.
- **Data-driven improvement:** Implementation of the Plan-Do-Study-Act cycle or a similar quality improvement methodology.
- **Staff development:** Provisions for ongoing staff education, individualized training plans, and regular performance evaluations.

- **Policy and procedure oversight:** An annual review and revision of program policies and procedures, including the diversion control plan (DCP).
- **Patient engagement:** Incorporation of patient input into quality improvement activities.
- **Patient satisfaction:** Regular assessment of patient satisfaction and patient responses to implementation of planned improvements based on feedback.
- **Infection prevention:** Adherence to universal or standard infection control precautions as promoted by the Center for Disease Control and Prevention's Guide to Infection Prevention for Outpatient Settings: Minimum Expectations for Safe Care.

Having objective measures of performance and a clear process for implementing CQI can help OTPs identify opportunities to improve organizational processes, treatment, and other services, along with patient and staff safety. Some states may require programs to have quality improvement plans in place for licensing purposes. Reimbursement for treatment is increasingly tied to quality improvement and patient outcomes. [54]

Staff are a key part of quality improvement. It is recommended that all staff receive training on quality improvement and how to review results from various performance measures. In addition to informing program improvements, the results from quality improvement activities can be used to demonstrate program effectiveness. More information about process improvement and how to use results of quality improvement activities to demonstrate program effectiveness is available from the University of Wisconsin's NIATx website and the Agency for Healthcare Research and Quality.

Patient Engagement and Satisfaction

OTPs may engage patients in shaping program activities and by incorporating their input into policy development and CQI activities. By empowering patients in this way, OTPs can enhance care delivery, boost patient satisfaction, and create a vibrant environment of care.

Key strategies include: [55]

- **Patient advisory committees:** Establishing patient advisory committees that assist in dissemination of information to patients, provide a vehicle for patient review of proposed policies and program planning, and ensure a body that advocates for patients' rights and needs**.**
- **Collaborative decision-making:** Incorporating patient input into policy development, procedure refinement, and operational improvements through surveys, focus groups, and advisory committees.
- **Data-driven insights:** Using aggregate clinical data and outcomes to inform care delivery, identify areas for improvement, and measure the impact of interventions.
- **Patient-centered care:** Prioritizing patient satisfaction through regular, anonymous, online surveys and feedback mechanisms and implementing strategies to address patient concerns.
- **Staff development and engagement:** Providing ongoing training, fostering a supportive work environment, and creating opportunities for staff input and professional growth.
- **CQI:** Implementing a robust quality improvement framework to monitor outcomes, identify areas for enhancement, and sustain a culture of excellence.

Patient Treatment Outcomes

Patient treatment outcomes can be a measure of OTP performance. Regularly monitoring specific indicators of progress can identify areas for improvement. For example, OTPs may examine metrics

related to treatment engagement, such as following through with appointments, distribution of take-home medication regimens, or participation in counseling and care management.

The degree of engagement among patients new to treatment is especially important. If engagement rates fall below the baseline the OTP typically expects, the OTP may consider assessing clinical and community-based issues, the care environment, and other factors that can affect engagement. Other treatment outcomes may include patients':

- Reduction of use of substances.
- Retention in treatment.
- Reductions in emergency department or hospital admissions for opioid and other substance-related issues.
- Improvement in quality-of-life measures, such as physical health, living arrangements, and employment status.
- Engagement in recovery support services, including peer support services.

Patient-Reported Outcomes

Patient-reported outcomes also can help OTPs assess the quality of services and inform relationships with OTP practitioners. These outcomes show the effect of treatment relative to patients' goals, values, and priorities. Examples of patient-reported outcomes may include: [56]

- Improved sense of well-being and interpersonal/social relationships.
- Affirmations of treatment as helpful in meeting specific goals.
- Reduced withdrawal and cravings.
- Reduced opioid use.
- Decreased worry and stress related to opioid use.
- Improved physical health.

Assessing a patient's recovery capital can be used to measure a patient's progress toward recovery. [57] *Recovery capital*, which is the quantity and quality of resources available to patients to begin and maintain long-term recovery from SUDs, including OUD, can include internal resources (e.g., physical health, values, hope) or external resources (e.g., community and cultural support, employment). [58] Greater recovery capital is associated with positive outcomes, such as attendance at follow-up appointments and reaching recovery plan goals. [59] Measures of recovery capital can help inform programs about the effectiveness of their services in meeting patient needs. SAMHSA's Treatment Improvement Protocol (TIP) 65, *Counseling Approaches To Promote Recovery From Problematic Substance Use and Related Issues* contains more information about recovery capital and tools for assessment.

Using Data To Improve Services and Outcomes

In addition to patient treatment and patient-reported outcomes, OTPs have a wealth of data available to them that can be harnessed to improve their services. For example, data on patient retention in treatment, admissions, and continuity of MOUD may be aggregated from information in patients' electronic health records. This may help practitioners evaluate retention variables and engage in clinical decision support for CQI. [60]

Opioid Treatment Program Certification

42 CFR § 8.11. Opioid Treatment Program Certification. (a) *General.*

(1) An OTP must be the subject of a current, valid certification from the Secretary to be considered qualified by the Secretary under section 303(g)(1)* of the Controlled Substances Act (21 U.S.C. 823(h)(1)) to dispense MOUD in the treatment of OUD. An OTP must be determined to be qualified under section 303(g)(1) of the Controlled Substances Act and must be determined to be qualified by the Attorney General under section 303(g)(1), to be registered by the Attorney General to dispense MOUD to individuals for treatment of OUD.

(2) To obtain certification from the Secretary, an OTP must meet the Federal Opioid Use Disorder treatment standards 42 CFR § 8.12, must be the subject of a current, valid accreditation by an Accreditation Body or other entity designated by the Secretary and must comply with any other conditions for certification established by the Secretary.

(3) OTPs are expected to maintain certification with the Secretary and to comply with any other conditions for certification established by the Secretary. Certification shall be granted for a term not to exceed 3 years, except that certification may be renewed during the final certification year if the OTP applies for certification renewal in accordance with the steps outlined in paragraph (a)(4) of this section.

(4) OTPs which satisfy the criteria for certification under this section may apply for renewal of their certification. OTPs are expected to apply for certification renewal during the final year of the OTP's certification period. OTPs should take steps to ensure that administrative tasks associated with renewal are completed before the OTP's certification expires. OTPs may apply for certification renewal in accordance with the procedures as outlined in paragraph (b) of this section. If an OTP anticipates any delays in routine certification renewal, an extension may be requested by submitting to the Secretary a statement justifying the extension in accordance with paragraph e of this section.

(5) OTPs that are certified and are seeking certification renewal, and who have been granted accreditation for 1 year by an Accreditation Body as provided under 42 CFR § 8.4(b)(1)(iii), may receive a conditional certification for one year unless the Secretary determines that such conditional certification would adversely affect patient health. An OTP must obtain a standard 3-year certification, as described in paragraph (a)(3) of this section, within the 1-year conditional certification period. If standard accreditation is not obtained by the OTP within the 1-year conditional certification period, the OTP's conditional certification will lapse, and the Attorney General will be notified that the OTP's registration should be revoked.

(6) OTPs whose certification has expired, and who seek re-certification, will be considered "new" programs and will be required to apply for provisional certification in accordance with paragraph (d) of this section.

(d) *Provisional certification.* New OTPs that have not received the Secretary's certification previously, except as provided in paragraph (a)(6) of this section, who are applying for certification from the Secretary, and who have applied for accreditation with an Accreditation Body, are eligible to receive provisional certification for up to 1 year. To receive provisional certification, an OTP shall submit the information required by paragraph (b) of this section to the Secretary along with a statement identifying the Accreditation Body to which the OTP has applied for accreditation, the date on which the OTP applied for accreditation, the dates of any accreditation surveys that have taken place or are expected to take place, and the expected schedule for completing the accreditation process. Provisional certification for up to 1 year will be granted, following receipt of the information described in this paragraph (d), unless the Secretary determines that patient health would be adversely affected by the granting of provisional certification.

(e) *Requirements for certification.*

(1) OTPs shall comply with all pertinent Federal and State laws and regulations. Nothing in this part is intended to limit the authority of State and, as appropriate, local governmental entities to regulate the use of MOUD in the treatment of OUD. The provisions of this section requiring compliance with requirements imposed by State law, or the submission of applications or reports required by the State authority, do not apply to OTPs operated

directly by the Department of Veterans Affairs, the Indian Health Service, or any other department or agency of the United States.

(2) OTPs shall allow, in accordance with Federal controlled substances laws and Federal confidentiality laws, inspections and surveys by duly authorized employees of the Department of Health and Human Services (HHS) or Substance Abuse and Mental Health Services Administration (SAMHSA), by Accreditation Bodies, by the Drug Enforcement Administration (DEA), and by authorized employees of any other Federal governmental entity with legal authority to conduct inspections or surveys on an OTP's premises.

(3) Disclosure of patient records maintained by an OTP is governed by the provisions of 42 CFR part 2 and 45 CFR parts 160 and 164, and every program must comply with these regulations, as applicable. Records on the receipt, storage, and distribution of MOUD are also subject to inspection under Federal controlled substances laws and under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 *et seq.*). Federally sponsored treatment programs are subject to applicable Federal confidentiality statutes.

(4) An OTP or medication unit or any part thereof, including any facility or any individual, shall permit a duly authorized employee of the Department of Health and Human Services or SAMHSA to have access to and to copy all records on the use of MOUD in accordance with the provisions of 42 CFR part 2 and 45 CFR parts 160 and 164.

(5) OTPs shall notify the Secretary in writing within 3 weeks of any replacement or other change in the status of the program sponsor or medical director.

(6) OTPs shall comply with all regulations enforced by the DEA under 21 CFR chapter II and must be registered by the DEA before administering or dispensing MOUD.

(7) OTPs must operate in accordance with Federal Opioid Use Disorder treatment standards and approved accreditation elements.

**OTPs are now authorized under section 303(h) of the Controlled Substances Act, or 21 U.S.C. § 823(h). In all instances in which the revised rule refers to Controlled Substances Act "section 303(g)(1)," it should refer to "section 303(h)" or "21 U.S.C. 823(h)."*

To provide services for OUD patients, OTPs need to successfully complete a certification and accreditation process. Certification is the process by which SAMHSA determines that an OTP is qualified to provide OUD treatment under the regulations. An accredited OTP is one that is the subject of a current, valid accreditation from an accreditation body approved by SAMHSA. An OTP-accrediting body is an organization that has been approved by SAMHSA to accredit OTPs dispensing MOUD. [61] By completing these processes, OTPs demonstrate that they have the resources, infrastructure, and staff expertise necessary to satisfy OTP regulatory standards.

Certification

Certification of an OTP through SAMHSA demonstrates that the program is equipped to provide patients with safe, quality care and services. The certification process protects both patients and the organization by ensuring that OTPs maintain standards of care.

There are different types of certifications:

- **Provisional certification.** New OTPs can apply for provisional (initial) certification as they are working toward becoming accredited by a SAMHSA-approved, OTP-accrediting body. The provisional certification is a temporary certification granted to a new OTP for up to 1 year, during which time it must become accredited. After a provisionally certified program becomes accredited, it must apply to SAMHSA for full certification via the renewal application process. [62]

- **Conditional certification.** This is a type of temporary certification that is granted to an OTP that has requested renewal of its certification and has received a 1-year (rather than a 3-year), temporary accreditation by an approved accreditation body. Within the 1-year accreditation period, OTPs can address areas of significant nonconformance with accreditation standards that do not involve immediate high-risk health or safety concerns. The expectation is that a conditional certification only lasts up to a maximum of 1 year, and that all significant nonconformance is remedied within that time.
- **Renewal certification.** Once certified, OTPs must renew their certification at least every 3 years, depending on the accreditation timeframe awarded.

To obtain certification after the provisional year, OTPs should: [63]

- Meet the standards in 42 CFR § 8.12.
- Be the subject of a current, valid accreditation by an accreditation body or other entity designated by SAMHSA.
- Comply with any other conditions for certification established by SAMHSA.

State licensing requirements for OTPs may vary. Appendix B provides more information about applying for certification and recertification.

Accreditation

Accreditation is a peer-review process that evaluates an OTP against 42 CFR part 8 requirements, and as reflected in the standards of SAMHSA-approved accrediting bodies. An accreditation review can assess whether programs and services meet quality standards in health and human services [64] and adhere to evidence-based practices. Through accreditation, OTPs demonstrate their commitment to patient-centered care by aligning services and funding sources with patient-focused standards that emphasize individualized care. Accreditation also provides evidence to federal, state, and local governments about the quality of programs and showcases strong management techniques focused on outcomes and patient satisfaction. [65]

The accreditation process includes site visits by specialists with experience in the provision of MOUD and related treatment activities. The purpose of site visits is to ensure that OTPs meet specific, nationally accepted standards for OTPs. OTP accreditation: [66]

- Enhances community confidence.
- Improves medical staff recruitment.
- Fulfills most state licensure requirements.
- Meets certain Medicare certification requirements.
- Influences liability insurance premiums.

Appendix C provides more information about revocation of accreditation.

Medication Units

Expanding access to OTP services in underserved communities is a key goal of the revised 42 CFR part 8 rule and may include the use of brick-and-mortar medication units and mobile units authorized to dispense MOUD.

Brick-and-Mortar Medication Units

Brick-and-mortar medication units are entities, with a separate DEA registration, established as part of, but geographically separate from, the primary OTP. These medication units may be located in a variety of different settings, including Certified Behavioral Health Centers, community mental health centers, Federally Qualified Health Centers and other primary care practices, community pharmacies, and correctional facilities. In the brick-and-mortar medication unit setting, appropriately licensed OTP practitioners, contractors working on behalf of the OTP, or pharmacists may dispense or administer MOUD, collect samples for drug testing or analysis, and provide any other OTP services as physical space and privacy considerations allow. [67]

Mobile Units

Another expansion option OTPs may consider is adding a mobile component or mobile unit to their existing registration. Mobile units can dispense MOUD and offer related services, expanding access to services in underserved areas and areas where people with OUD may be present, such as homeless shelters or correctional facilities. Because mobile units offer services in places that are convenient for such groups, they may increase treatment engagement and encourage people to receive services they would not otherwise access.

Under 42 CFR § 8.11(h), OTPs can add a mobile component to their program with less administrative burden. It should be noted, however, that applications for a brick-and-mortar OTP and a mobile unit cannot be submitted at the same time. Mobile units are considered an expansion of a brick-and-mortar location. [68]

DEA Rules for Mobile Units

On June 28, 2021, the DEA published the final rule Registration Requirements for Narcotic Treatment Programs With Mobile Components (86 FR 33861). [69] This change was designed to improve access to MOUD in places with limited treatment options, such as rural communities. [70]

Under § 8.11(h), OTPs that are authorized to dispense methadone for OUD can also be authorized to add a "mobile component" to their existing registration, eliminating the separate registration requirement for these mobile OTPs. [71]

The DEA's final rule regarding Registration Requirements for Narcotic Treatment Programs With Mobile Components is available from the *Federal Register,* which is updated continually. The mobile NTP may only operate in the same state in which the existing NTP is registered. Mobile NTP regulations can be found at 21 CFR 1301.13(e)(4) and 1301.72(e)(1)13.

Risk Management

SAMHSA recommends that OTPs take steps to prepare for accidents, program emergencies, and critical events that require immediate response and investigation, and to protect the safety of patients, staff, visitors, and the organization during those events. Appropriate steps may include developing policies and procedures to guide the OTP's overall response to specific types of events, ensuring that staff understand their roles should such an event occur, minimizing the effects of the event on patient care, and reporting the event to appropriate entities.

Events That Warrant Immediate Response and Investigation

Critical Incidents

Critical incidents are defined as occurrences posing an immediate risk to patient safety, staff well-being, or the surrounding community. Examples of critical incidents include:

- **Patient safety incidents:** Injuries, overdoses, or fatalities involving patients.
- **Staff safety incidents:** Injuries or fatalities involving OTP staff.
- **On-site incidents:** Accidents, property damage, or threats to public safety occurring within the OTP facility.
- **Security breaches:** Unauthorized access, theft, or diversion of medications.

These events necessitate prompt investigation and response to mitigate harm, prevent recurrence, and ensure the ongoing safety and well-being of all individuals involved.

Critical incidents should be reported to the appropriate federal and state agencies and the accreditation bodies and others, as applicable, and should be addressed in accordance with the OTP's procedures and any applicable regulatory and accrediting organization requirements. Advance preparation, reporting, investigation, or corrective action will vary by program and circumstance.

It is recommended that OTPs prepare for incidences with lifesaving protections that may be essential during critical incidents. These include ensuring that staff are adequately trained in cardiopulmonary resuscitation, control and prevention of infectious disease transmission, and other lifesaving protections, such as the use of personal protective equipment in the case of high levels of circulating respiratory infections or the use of naloxone and other opioid overdose reversal medications to rapidly reverse an opioid overdose. All OTPs should have naloxone or other opioid overdose reversal medications available for patients who may experience an overdose (42 CFR § 2.51 contains additional information on emergency medical response). More information about naloxone and other opioid overdose reversal medications is available in the Harm Reduction Services section.

To support staff and patients after a critical incident occurs, OTP staff can hold a critical incident stress debriefing. A debriefing provides both patients and staff the opportunity to openly discuss the incident and how it was handled, identify any necessary changes to policies and procedures as a result of the incident, and identify whether patients or staff experienced any lingering stress or anxiety following the event.

Adverse Events

Adverse events are events resulting in an undesirable experience associated with the patient's use of a medical product or an adverse outcome related to the healthcare a patient receives. Medication errors and negative medication interactions are examples of adverse events. It is recommended that OTPs develop policies and procedures outlining how to prevent and respond to adverse events. Specific investigation, reporting, and corrective action steps will vary by program.

OTP Closure Due to Weather or Other Emergency

Weather emergencies and other events (e.g., a power outage or nearby emergency services response) may limit patient access to the OTP (see the Disaster Management section for more information). It is recommended that OTPs develop policies and procedures to guide the OTP's overall response to such an event. These policies and procedures include:

- Informing patients as soon as possible about the need for, and expected duration of, the closure.

- Communicating with patients about medication continuation before (when possible) and during the OTP's closure. When applicable, patients can receive take-home medication doses to cover their ordered medication regimens during the expected length of the emergency closure. This minimizes the risk of patients experiencing withdrawal and recurrence of substance use if they do not have access to their medications.
- Coordinating care with nearby OTPs or hospital emergency departments, depending on the significance and duration of the emergency.
- Providing patients with information about the communication methods that will be available during the emergency.
- Addressing the needs of patients who may be homebound or who require specialized transportation.
- Ensuring that sufficient staff are available to maintain those channels of communication.

Patient Emergencies

Patient emergencies are situations that pose a risk to patient or staff safety and well-being. These incidents may include instances where a patient is experiencing acute distress, exhibiting disruptive behavior, or presenting with immediate physical or mental health concerns that are of sufficient severity to warrant emergency intervention.

OTPs can prepare for this type of emergency by ensuring patients and staff know when to find help and who to contact. OTP policies and procedures can outline how to respond to patient emergencies, including when to contact 911 for emergency medical services and when to contact 988 or local crisis numbers for mental health or substance use-related crises that the OTP cannot manage internally. The policies and procedures should specify the information to provide during these calls, and how to proceed once help arrives. Programs may remind patients of local emergency resources and crisis lines such as 988 by displaying the information in waiting areas. Finally, OTP policies and procedures can delineate how to respond to a potential overdose, provide education and training on overdose reversal to staff and patients, and ensure that naloxone or another opioid overdose reversal medication is readily accessible.

For patients who experience medical or psychiatric emergencies occurring outside of program hours of operation, it is important for OTPs to maintain an after-hours, emergency contact system through which another healthcare provider—such as an emergency department—can obtain information about the patient's care plan on a 24/7 basis, including type of MOUD, dose, and last doses received from the OTP. (OTPs should follow all applicable confidentiality regulations when sharing information, understanding that 42 CFR part 2 permits sharing of covered information in emergency situations.) Specifically, OTPs can also provide each patient with an identification card that shows which MOUD the patient receives through the OTP, along with emergency contact information for the OTP.

Policies and procedures can also address safety and security issues for patients and staff. Procedures can include a mechanism for reporting incidents to program staff or outside agencies, including accrediting bodies and the State Opioid Treatment Authority (SOTA), as appropriate. Staff can receive training to:

- Recognize and respond preemptively to de-escalate patients who demonstrate escalating behaviors, threats, or violence, or who may be experiencing a mental health crisis.
- Access crisis services on behalf of patients.
- Respond to an overdose, including how to administer basic life support.
- Secure their own safety and the safety of their patients if a violent or threatening situation cannot be de-escalated.

- Notify security guards or police when needed, recognizing that their presence may be retraumatizing to some patients and staff.

The SOTA is responsible for the oversight of OTPs in each state. SOTAs ensure that safe and quality care is accessible to patients. Other responsibilities include monitoring adherence with federal and state regulations, partnering with SAMHSA and the DEA to provide recommendations on relevant regulations, acting as a liaison for disaster and emergency planning, and advocating and intervening with OTPs and other entities on behalf of patients.

- State Opioid Treatment Authority (SOTA) Role Explained is a resource brief from the National Association of State Alcohol and Drug Abuse Directors that describes the key roles of the SOTA.
- SAMHSA maintains a continually updated list of SOTAs by state on its State Opioid Treatment Authorities webpage.

Incident Reporting

Documentation should include follow through on incident reporting requirements mandated by accrediting bodies and state regulations.

An effective reporting system may include the following attributes: [72]

- A supportive environment for event reporting that protects the privacy of the patients and of staff who report occurrences.
- Reports that can be received from a broad range of personnel.
- Summaries of reported events that are disseminated in a timely fashion.
- A structured mechanism in place for reviewing reports and developing action plans.

42 CFR § 8.12 describes the responsibilities of an OTP to ensure appropriate recordkeeping and patient confidentiality. In accordance with 42 CFR part 2, released in February 2024, programs should have clear guidelines for the access, transfer, and disposal of records, which may be particularly critical during an emergency. OTPs also should have record-retention policies and safeguards for the destruction of old containers, labels, printouts, and program records under normal operating conditions, as well as in the event of a disaster or program closure. The Recordkeeping and Documentation section includes more information about recordkeeping procedures.

Engaging Community Support

Although OTPs provide important services that help people recover from OUD, their patients may encounter stigma in their communities. Programs are encouraged to address this by proactively cultivating relationships with community organizations and agencies, as well as by being a good neighbor. These actions can help reduce stigma for patients who are seeking care and facilitate the community's acceptance of and willingness to support the OTP.

OTPs can benefit from a strong network of partnerships, including partnering with other OTPs in their areas, local law enforcement, courts, local hospitals, other healthcare providers, harm reduction organizations, and other community organizations. Benefits to OTPs include a community that is supportive in the event of an emergency, the ability to leverage partnerships when specific services are needed, and the ability to further support patients, among others. To build these connections, OTPs can work with hospitals, healthcare systems and practices, courts, and law enforcement officials to educate their respective staff about OUD treatment and recovery and to identify partnership opportunities that support access to treatment. OTPs can also take active steps to educate and engage the local

community about how their services save lives. Opportunities to work with the community may include partnering on community events or attending local community meetings.

Community engagement evolves over time and requires continuous effort. SAMHSA's evidence-based resource guides *Community Engagement: An Essential Component of an Effective and Equitable Substance Use Prevention System* and *Engaging Community Coalitions to Decrease Opioid Overdose Deaths* contains more information about the need for and role of community engagement in SUD treatment and prevention, including overdose prevention and response.

Additionally, CARF International's Community Relations Tips for Opioid Treatment Programs provides additional information about how OTPs can engage with the community. More information about community engagement, collaboration, and partnerships is in the Strategies for Ensuring Continuity of Care chapter.

Diversion Control

> **42 CFR § 8.12(c)(2). Diversion Control Plan.** An OTP must maintain a current "Diversion Control Plan" or "DCP" as part of its quality assurance program that contains specific measures to reduce the possibility of diversion of dispensed MOUD, and that assigns specific responsibility to the OTP providers and administrative staff for carrying out the diversion control measures and functions described in the DCP.

A DCP is a set of documented procedures that reduce the possibility of controlled medications being shared with others for whom the medication was not ordered or dispensed. OTPs previously used callbacks for bottle checks and toxicology testing; however, random checks have been reported by patients as disruptive to their lives. [73, 74] Further, research shows that people who use nonprescribed buprenorphine may do so to manage opioid withdrawal symptoms. [75]

Therefore, there can be many reasons patients do not respond to random callbacks. It is recommended that callbacks, if done, be considered only when clinically indicated and as part of a broader assessment to clarify concerns about clinical stability. If OTPs do callbacks, they may consider virtual callbacks. Before making any changes to the treatment regimen in response to callbacks, OTP practitioners should discuss any concerns with the patient and adjust take-home medication regimens, if necessary, only after considering the full clinical picture. Practitioners should be aware that any callback result represents only one clinical data point.

When creating a DCP, OTPs can balance the potential for diversion with a patient's need for medication. As such, flexibility is critical when supporting patient safety with take-home medication doses. Fears of diversion should not hinder patient access to the care and medication doses they need. The goals of a DCP are to ensure patient safety and to reduce the scope and significance of diversion and its impact on communities.

A DCP is meant to protect the patient, community, and staff. The DCP can help identify procedures related to potential staff and patient diversion. The medical and administrative staff of the OTP are responsible for carrying out the diversion control measures and functions described in the DCP. OTPs are encouraged to provide patient education on the safe transport and storage of take-home doses. The revised 42 CFR part 8 does not require OTPs to implement or to provide locked boxes for patients, but it does prioritize patient safety. Clear plastic bags or labeled lockboxes carried out in the open may signal that a patient is carrying controlled medications or valuables. OTP practitioners and clinical staff should refer to the DEA Narcotic Treatment Program Manual and work with individual patients to plan for safe transport and secure storage of medication. Education efforts, including where not to store medication

(e.g., in a refrigerator, out on a table or counter, or on a dresser) is documented in the patient's clinical record.

DCP Requirements

DCPs may address three general areas of concern:

- Program environment.
- Dosing and take-home medication doses.
- Prevention of multiple program enrollment.

Program Environment

Patient and staff diversion in the program environment can and should be deterred and addressed when detected. Regular surveillance and monitoring of areas in and around the program may help discourage diversion. Although some OTPs use video surveillance, few rely solely on this method. Employing security personnel or other staff who walk the interior and exterior of the clinic on a regular basis to observe activities can provide an opportunity to assess and intervene when suspicious behavior is seen.

OTPs will also want to consider the potential for staff diversion of medication. Although staff diversion rarely occurs, it compromises the OTP and risks treatment availability for patients. Clearly communicated policies and procedures around staff handling of medication can help address the potential for staff diversion. OTPs are required to report staff diversion to the appropriate state, federal, and accreditation oversight bodies.

Patient involvement in assuring a therapeutic and safe treatment environment is an essential part of a DCP. Patient advocacy groups or patient involvement in OTP advisory committees can provide recommendations on program policies and procedures and how they are implemented. Patients can make important contributions to problem solving and help balance diversion control strategies with individualized care needs.

Providing Take-Home Medication Doses

The revised rule states that patients are eligible for take-home doses of methadone on entry into treatment, based on the clinical judgment of the treating practitioner. This change recognizes the importance of the practitioner–patient relationship, and it allows for greater flexibility in creating care plans that promote recovery activities such as employment or education, while acknowledging the principle of using the least restrictive environment that will be safe and effective. This change also eliminates the barrier of needing to make frequent OTP visits when they are not clinically indicated.

The rule also provides revised guidance for factors that practitioners should consider in decision-making for take-home doses of methadone, highlighting practitioner discretion and the use of clinical judgment in determining the number of take-home doses given to each patient. More information about take-home doses is in the Medication Administration, Dispensing, and Use chapter.

Take-home medication doses are provided with careful attention to a risk–benefit analysis, as well as therapeutic benefit and safety. OTPs can do this by:

- Documenting practitioner decisions about take-home medication doses thoroughly and carefully.
- Informing patients about keeping take-home doses in a child-proof medication container and storing them in a secure location.
- Using technology, as individually indicated, that enhances medication security outside the OTP, such as automated locking boxes.

- Ensuring that each individual take-home dose is packaged in a manner designed to reduce the risk of accidental ingestion, including the use of child-proof containers. The Poison Prevention Packaging Act [76] contains more information about packaging standards.
- Involving supportive loved ones who, with the patient's consent, can help ensure the patient's safe and timely use of take-home medications. This could include involving loved ones in monitoring the time or day of medication ingestion and any side effects that could go unnoticed by the patient.
- Maintaining current and adequate procedures to identify and respond to the theft or diversion of take-home doses.

The provision of education on the safe and secure transport and storage of medication must be documented in the patient's clinical record. All staff members play a role in ensuring the safety and therapeutic benefits of take-home medication doses. Should any staff member obtain information or observe something relevant to the use of take-home medication while interacting with patients, that staff member should document the information and convey it to an OTP practitioner or medical director for their consideration when making future medication management decisions.

Addressing Diversion of Take-Home Medication

OTP practitioners are encouraged to apply clinical judgment and work with their SOTA to implement effective DCPs. Effective engagement with patients about their use of take-home doses calls for practitioners to have a solid understanding of the physiological processes related to the absorption, metabolism, and elimination of opioids, as well as medication interactions. This knowledge is crucial when interpreting and discussing a toxicology test result with a patient. For instance, if the test shows a negative result for methadone and its metabolites, results could indicate adherence or diversion issues, laboratory or sample processing error, or sample alteration.

Prevention of Multiple Program Enrollment

Patients who are simultaneously enrolled in multiple OTPs may obtain more medication than is clinically indicated. This situation should be addressed in an OTP's DCP. Documenting good-faith efforts to prevent multiple program enrollment is part of implementing diversion control procedures during admission and over the duration of treatment. In states that do not have central registries of patients enrolled in OTPs, an OTP, after obtaining patient consent, may contact other OTPs within a reasonable geographic distance (42 CFR § 2.34) to verify that a patient is not enrolled in another OTP.

For information regarding statutory authority for confidentiality of patient records, refer to 42 CFR § 2.1. Additional information about patient confidentiality is in the Patient Admission Criteria section.

Use of Central Registries and Prescription Drug Monitoring Programs in Diversion Control Planning

In states that have central registries, these registries are used to prevent enrollment in multiple treatment programs, maintain continuity of care, assist with disaster planning, and inform diversion control planning. Similarly, prescription drug monitoring programs (PDMPs) can be used as another clinical tool to help practitioners stay up to date on other prescriptions patients may be receiving, coordinate care, and address any medication interactions. OTPs are recommended to use both resources because methadone is not always included in PDMPs. Central registries may provide more information about other types of treatment a patient is receiving.

Although state programs may vary, before initiating dosing, all OTP practitioners and other healthcare practitioners should check their respective state's central registry, if one exists, and PDMP to determine

if a newly admitted patient is enrolled in treatment elsewhere or is being prescribed controlled medications that, in combination with methadone, may increase risk of sedation. Patients' receipt of other controlled medications is not a reason to avoid or delay initiating methadone or buprenorphine for the treatment of OUD. The information may be helpful in determining starting doses and titration schedules, frequency of clinic visits, and care coordination efforts. PDMP queries should also be done routinely when providing take-home medication doses and as part of ongoing care plan reviews. In some cases, the OTP may have reason to request specific enrollment or prescription information from a central registry or other OTPs. In such cases, OTPs can refer to 42 CFR § 2.34—Uses and Disclosures To Prevent Multiple Enrollments.

Up-to-date state PDMP profiles and contacts are available from the PDMP Training and Technical Assistance Center (TTAC). [77] The responsibility to implement and monitor each aspect of the DCP may be assigned to specific clinical, administrative, or medical staff members, as appropriate. These staff members can meet regularly to update one another on issues and concerns. This may be accomplished during regular meetings of a specific diversion control committee. In smaller programs, the DCP may be a regular topic during meetings of all staff. It is recommended that OTPs have specific procedures for monitoring and addressing diversion.

Resource Alert: PDMP TTAC

PDMPs are an important resource for OTPs to improve their understanding of whether patients have been prescribed controlled medications to treat OUD or other health conditions. The PDMP TTAC provides training, support, and resources on PDMPs. Training and technical assistance are provided in virtual and in-person training events, workshops and meeting presentations, and online information and resources.

The PDMP TTAC Training and Technical Assistance webpage provides more information and access to training resources.

Use of the PDMP To Coordinate Care

In some cases, query results will show the patient has no history of receiving prescriptions for controlled medications. In others, it will confirm the patient's self-reported history of receiving prescriptions for controlled medications unrelated to OUD treatment.

If a patient is being treated with controlled medications by another practitioner, OTP practitioners should explain to patients the potential risks of combining medications, including strategies to minimize adverse events from drug interactions. Ideally, OTPs will receive information from, and coordinate care with, the external providers. In the event a patient does not consent to this type of coordinated care, OTPs should continue providing services to the patient but work with them to better understand their concerns. Refusal may have implications for the assessment of the patient's stability in treatment and the safety of take-home doses. OTPs are encouraged to develop detailed policies and procedures to govern the use of and response to PDMP information for the safety of patients and the clinic.

Disaster Management

All emergencies, whether human-made, natural, or programmatic, have the potential to limit patients' access to care and interfere with program operations. It is recommended that OTPs prepare for a range of emergencies and have policies and procedures that protect patients and staff and ensure continuity of care.

Disaster planning is a continuous activity that begins with planning and includes training, testing, evaluating, revising, and additional planning, as needed. [78] Creating a disaster planning team is a key part of this process. This team:

- Develops, maintains, and disseminates a disaster plan to staff and patients.
- Revises the plan as needed.
- Monitors the plan to ensure it remains coherent and relevant.
- Coordinates testing and training based on the plan.
- Conducts post-disaster analysis of the effectiveness of the plan.
- Defines available options the program will utilize in an emergency to support continuity of medication services to patients, including emergency take-homes, guest dosing arrangements, medication delivery.
- Develops memorandums of agreements with other OTPs to assist with emergency dosing, arrangements with emergency departments, and/or use of mobile vans.
- Participates in local, regional, and state emergency management associations.

This up-to-date disaster plan can:

- Address fire events, including maintenance of fire extinguishers, fire drills, and emergency evacuation procedures.
- Ensure the availability of necessary supplies in an emergency requiring staff and patients to shelter in place.
- Include links to community agencies.
- Define how the OTP will provide information to patients about continuity of operations and OTP responses in an emergency.

Additionally, communication protocols are recommended to be part of all emergency planning. [79] During an emergency event, an OTP may need to implement guest dosing, which is when a patient's medication order and dispensing schedule are temporarily transferred to a different OTP to ensure medication continuity. Programs should maintain appropriate records for patients who are receiving guest dosing. Keeping an open line of communication with other local organizations along with other local, state (e.g., the SOTA), and federal partners can improve coordination and strengthen the OTP's emergency response, benefiting both the staff and the continuity of care for patients. When OTPs have strong partnerships with other OTPs, implementing agreements for emergency medication dosing and care at other locations, if needed, may be easier for staff and patients. However, it is recommended that all OTPs establish guest dosing policies and procedures that create the fewest barriers for patients who need medication continuity.

SAMHSA recommends that OTPs maintain an up-to-date emergency contact list of people to coordinate with during an emergency event. This list could include key state and federal contacts, including SOTA staff, SAMHSA/Center for Substance Abuse Treatment/Division of Pharmacologic Therapies, DEA personnel, local emergency responders, county emergency operation centers, and local emergency departments. Use of a state's central registry may help OTPs communicate with other OTPs and OTPs in other states, as applicable. To assist with managing an emergency event, OTPs may develop a patient contact list that is updated frequently and includes both phone numbers and email addresses.

SAMHSA's Technical Assistance Publication 34, *Disaster Planning Handbook for Behavioral Health Service Programs* provides more information about how programs, including OTPs, can engage in disaster planning and prepare for emergencies. It discusses continuity planning, management of

prescription medications during an emergency, and planning issues for pandemic disease, among other topics.

Voluntary and Involuntary Program Closures

OTPs have an important responsibility to ensure continuity of medication for patients during any closure, whether voluntary or involuntary. A closure puts patients at risk of experiencing withdrawal and recurrence of their OUD if they do not have access to their medications. Thus, OTPs, through state authorities and other relevant governmental entities, can establish procedures that ensure continuity of care for patients during a voluntary or involuntary program closure. The plan may include steps for the notification and orderly transfer of patients, records, and assets to other programs or practitioners. The plan may also include the procedure for securing and maintaining patient records for a specified period, in accordance with state and federal regulations.

A role of the SOTA is not only to ensure OTPs comply with federal and state regulations, but also to advocate for the continuity of care for patients. [80] When overseeing the closing of a facility, SOTAs are responsible for creating a plan for the transfer of records, minimizing the burden and effect on patients, and ensuring patients have continued access to care.

In an emergency or natural disaster, SOTAs may act as a liaison by connecting OTPs to the state emergency preparedness organization and communicating the needs of the OTP. A good source for details on the role of the SOTA is the National Association of State Alcohol and Drug Abuse Directors publication *Role of the State Opioid Treatment Authority*. [81]

Ultimately, OTPs can ensure continuity of care for patients by creating plans that will support them in the event of a voluntary or involuntary closure.

Recordkeeping and Documentation

> **42 CFR § 8.12(g). Recordkeeping and patient confidentiality.** (1) OTPs shall establish and maintain a recordkeeping system that is adequate to document and monitor patient care. This system is required to comply with all Federal and State reporting requirements relevant to MOUD approved for use in treatment of OUD. All records are required to be kept confidential in accordance with all applicable Federal and State requirements. (2) OTPs shall include, as an essential part of the recordkeeping system, documentation in each patient's record that the OTP made a good faith effort to determine whether the patient is enrolled in any other OTP. A patient enrolled in an OTP shall not be permitted to obtain treatment in any other OTP except in circumstances involving an inability to access care at the patient's OTP of record. Such circumstances include, but are not limited to, travel for work or family events, temporary relocation, or an OTP's temporary closure. If the medical director or program practitioner of the OTP in which the patient is enrolled determines that such circumstances exist, the patient may seek treatment at another OTP, provided the justification for the particular circumstances are noted in the patient's record both at the OTP in which the patient is enrolled and at the OTP that will provide the MOUD.

Accurate recordkeeping and attention to patient privacy help protect OTPs and patients. Careful documentation helps practitioners monitor patient progress and adjust care as needed. The same documentation can help ensure that patients receive uninterrupted care should they temporarily need to obtain services from another program or healthcare setting.

Patient Records

Patient records should be kept confidential and up to date. Electronic health records should conform with Health Insurance Portability and Accountability Act of 1996 (HIPAA) regulations and state-of-the-art cybersecurity procedures. Paper records should be secured in locked rooms.

Any patient's identity, diagnosis, prognosis, or treatment records related to substance use education, prevention, training, treatment, or research conducted, regulated, or assisted by any department or agency must be kept confidential, except as provided in 42 CFR part 2. Information in these records can be disclosed only for the purposes or circumstances expressly authorized in 42 CFR part 2. Proper patient consent is needed by the OTP before releasing or seeking medical records from other healthcare practitioners, except in the certain circumstances (e.g., medical emergencies) delineated in 42 CFR part 2.

As required by HIPAA, patients have the right to access their medical records and other health information. Programs should adhere to all applicable requirements of federal confidentiality regulations (42 CFR part 2) and HIPAA privacy, security, and breach notification regulations (45 CFR part 160 and 45 CFR part 164). All information in the patient record should be consistent with all applicable federal confidentiality regulations (42 CFR part 2) and HIPAA privacy, security, and breach notification regulations (45 CFR part 160 and 45 CFR part 164).

Programs may use standard intake forms as a way of gathering and organizing clinical information for each patient. At the same time, the OTP may gather sufficient data for outcome, cross-site, or other evaluations or studies or to support managed care data requirements. All entries should document individual patient treatment outcomes.

An individual patient record should contain:

- The initial screening examination conducted at the time of medication treatment initiation or, if completed by a non-OTP practitioner, within 7 days of admission.
- A full psychosocial assessment, including a risk assessment for imminent harm to self or others, completed within 14 days of admission or as required by state regulation.
- Medical reports from the full history and physical examination, including results of serology and other laboratory testing, must be completed within 14 calendar days following admission.
- Reports of any opioid overdoses, mental health crises, hospitalizations, or emergency department visits.
- Other medical reports, including nursing notes, laboratory reports (e.g., results of initial and regular toxicology screens), a list of medications updated as clinically indicated, and progress notes. Information in the medical record is entered by program practitioners and authorized healthcare professionals, as appropriate.
- Documentation that the approved central registry system (if applicable), PDMP, or alternative mechanism used to prevent dual or simultaneous OTP enrollments was checked.
- Documentation that the PDMP has been checked at admission and at regular intervals throughout care.
- Chronologically dated case entries of all significant contacts with patients, including a record of each counseling session.
- Dates and results of patient care planning, treatment team meetings, or other internal consultative processes.

- The care plan and any amendments to it; periodic reviews; updates of the assessment and care plan for the first year of continuous treatment and periodic assessments in subsequent years; care plan updates; and counselor summaries, which include an evaluation of the existing care plan and the patient's response to treatment.
- Documentation that all services listed in the care plan are available and were offered or provided as agreed upon with the patient, or the patient was referred to such services.
- Clinical documentation of the process used to make patient treatment decisions, such as take-home medication schedules, changes in counseling sessions, frequency of drug tests, or any other significant treatment changes.
- A record of correspondence with the patient, their family members, and other approved individuals.
- A record of each referral for service and the results.
- Documentation that the patient received a copy of the program's policies and a statement of patient rights and responsibilities and that these items were discussed with the patient.
- Consent forms; releases of information; and documentation of pertinent prescriptions, travel, employment, and take-home medication.
- Medication dosing history.
- Medication order history.
- A closing summary, including reasons for discharge and any referrals. In the case of death, the cause of death is documented.

All records should be retained for the duration of patient enrollment and in accordance with state and federal archival standards. Patient records typically include identifying information, demographic data, and other sensitive information, which may be recorded with a unique identification code. All information should be accessible and understandable to appropriate authorities and be consistent with 42 CFR part 2 and HIPAA privacy regulations.

SAMHSA's Center of Excellence for Protected Health Information develops and disseminates training, technical assistance, guidance, and educational resources on various protected health information and privacy laws and regulations as they relate to substance use and mental disorders. See also the CMS Documentation Matters Toolkit.

Records for Storing, Dispensing, and Administering MOUD

OTP policies and procedures should be consistent with Drug Enforcement Administration statutes and regulations pertaining to the recording of and accounting for the use of controlled medications. Other medications should be stored separately from methadone and buprenorphine. Medication orders and dosage changes should be written on an acceptable order sheet and signed by the ordering practitioner or processed through a comparable electronic system. OTPs operating in states with a Central Registry must ensure client dosage amounts are accurately reflected in the registry to support guest dosing services.

To maintain an accurate, ongoing inventory of all medications, including controlled medications, each dose administered or dispensed is immediately recorded electronically or on an administration sheet. This information is then documented in the patient's individual medication dose history. The healthcare professional administering or dispensing the medication either signs or initials each notation. If initials are used, the full signature of the healthcare professional administering or dispensing the medication appears at the bottom of each page of the medication sheet. The number of dispensed medication doses is totaled in milligrams daily. Programs should calibrate their medication-dispensing instruments

according to the manufacturer's recommendations to ensure accurate patient dosing and medication tracking.

This topic is discussed in detail in the Medication Administration, Dispensing, and Use chapter.

Facility Management

OTPs are responsible for providing a safe and supportive environment for patients to receive care. Attention to facility management communicates dignity and respect for patients and staff and supports a culture of trust, engagement, and individualized care.

Programs are expected to provide sufficient space, equipment, and maintenance of the facility to foster an appropriate therapeutic environment and to comply with local, state, and federal standards for health and safety. By being attentive to creating a sense of safety, the OTPs can be sensitive to the needs of people who have experienced trauma. For example, OTPs can ensure that the environment is:

- Clean and well-maintained, comfortable, and visually appealing in a manner consistent with healthcare facilities that provide a sense of respect and dignity for the patients and promoting a sense of community.
- Adequate in terms of space and with suitable equipment to provide all required services, including diagnosis, evaluation, and treatment of other substance use, medical, and psychiatric disorders, as applicable.
- In compliance with all safety and environmental codes, with supporting documentation of continuous compliance.
- In compliance with Americans with Disabilities Act Title III Regulations.[82] Facilities providing medical services are required to make reasonable modifications to ensure they meet the needs of patients with disabilities, so that all patients can participate fully in treatment.[83] OTPs should implement measures to prevent and address potential breaches of privacy. Privacy can be unintentionally violated in various ways, such as through windowed or open workspaces; cashier check-outs in public areas; untrained security guards; communal medication dispensing areas; and hallway conversations about care plans, positive urinalysis results, or psychiatric medications. Attention should also be given to the privacy of electronic patient information by ensuring computer screens are out of view, assigning individual login credentials to staff, and requiring regular password changes. For more information about health information privacy, see the HHS Summary of the HIPAA Security Rule webpage. For insights on a specific facility's accessibility, OTPs may want to consult directly with patients with disabilities who receive treatment there.
- Safe and supportive for patients' parents and children.
- Compliant with Occupational Safety and Health Administration (OSHA) workplace health and safety standards. OSHA provides more information about safety laws, regulations, and compliance on its Laws and Regulations webpage.

Medical and Clinical Provisions and Practices

Creating a Supportive, Healing Environment for Patients

Because opioid treatment programs (OTPs) provide access to and regular touchpoints for people with opioid use disorder (OUD), the *Federal Guidelines for Opioid Treatment Programs* (the Guidelines) emphasize the importance of culture change within OTPs and the need to foster a healing environment based on trust and collaboration. Often, people with OUD have had negative experiences with the healthcare system and are burdened by adverse childhood experiences and trauma. It is not uncommon for people with OUD to have received inaccurate information about medications for the treatment of OUD (MOUD) or have internalized stigma about their own condition and treatment with medications such as methadone. Given this, OTPs should prioritize flexible policies that include harm reduction strategies and *low-barrier care*—a model that prioritizes the availability and accessibility of treatment, [84] emphasizing positive engagement, and individualized, shared decision-making that reduces demands on patients. It is important that patients seeking treatment at an OTP experience a welcoming response, including expedited admissions, prompt initiation of medication, and access to additional treatment and supports that are decided upon with the patient, rather than for the patient.

Embracing low-barrier care, patient-centered care, shared decision-making, and harm reduction principles helps OTPs promote a nonjudgmental and accepting environment that encourages people to seek and receive the help they need without fear of stigma or discrimination. [85] Title 42 of the Code of Federal Regulations (42 CFR) part 8 incorporates low-barrier care principles by:

- Enabling people to enter treatment based on an OUD diagnosis, rather than adhering to generalized time- or age-related requirements (more information is in the Patient Admission Criteria section).
- Expediting admissions by allowing external practitioners to complete screening examinations.
- Expanding the use of telehealth and allowing audio–visual consent.
- Allowing consideration of take-home doses of medication from treatment entry.
- Allowing nurse practitioners and physician assistants to order MOUD for dispensing at the OTP if consistent with state law.
- Emphasizing the development of individualized care plans that remove cookie-cutter treatment requirements.

These revisions add flexibility and offer patients more choices for accessing and receiving treatment. Through these revisions, OTPs can reduce stigma while improving the environment of care.

Low-Barrier Models of Care for Substance Use Disorders

The Substance Abuse and Mental Health Services Administration's (SAMHSA) *Advisory:* Low Barrier Models of Care for Substance Use Disorders outlines the principles and components of low-barrier care and how low-barrier care can reduce gaps in access by engaging individuals in treatment. It also provides case examples of programs implementing low-barrier care.

The *Advisory* stresses that low-barrier care should:

- Be person centered.
- Use harm reduction approaches and meet patients where they are.
- Adopt a flexible approach to offering service and supports.
- Offer comprehensive services.
- Integrate culturally responsive care and inclusiveness.
- Recognize the effect of trauma on patients.

Another important component of low-barrier care is incorporation of harm reduction approaches and services. Although OTPs may implement low-barrier approaches, patients may still decide during the admission process that an OTP is not right for them or that they are not yet ready or able to commit to a care plan. Harm reduction acknowledges the complexity of substance use and does not support coercive abstinence. [86] It is recommended that OTPs implement flexible admission policies that show compassion for each prospective patient—in this case, allowing OTPs to support individuals who decline care with linkages to other care, recovery support organizations, prevention education, and medication that can reverse opioid-related overdose.

SAMHSA'S Harm Reduction Framework

Harm reduction approaches and services are important elements of OTP care even outside of the low-barrier care model. SAMHSA's Harm Reduction Framework defines *harm reduction* as a practical and transformative approach that incorporates community-driven public health strategies—including prevention, risk reduction, and health promotion—to empower people who use drugs and their families with the choice to live healthier, self-directed, and purpose-filled lives. The principles outlined in the Harm Reduction Framework that speak to cultivating relationships, focusing on engagement and listening, treating people with dignity and respect, and meeting people where they are, have applicability regardless of the extent of harm reduction services the OTP may provide.

For more information about harm reduction, see the Evidence-Based Practices section.

Patient Admission Criteria

42 CPR § 8.12(e)(1). Patient admission criteria. An OTP shall maintain current procedures designed to ensure that patients are admitted to treatment by qualified personnel who have determined, using accepted medical criteria, that: The person meets diagnostic criteria for a moderate to severe OUD; the individual has an active moderate to severe OUD, or OUD in remission, or is at high risk for recurrence or overdose. Such decisions must be appropriately documented in the patient's clinical record. In addition, a health care practitioner shall ensure that each patient voluntarily chooses treatment with MOUD and that all relevant facts concerning the use of MOUD are clearly and adequately explained to the patient, and that each patient provides informed consent to treatment.

New, streamlined admission criteria outlined in the revised 42 CFR part 8 rule include two significant changes from the previous regulations:

- Patients are no longer required to have OUD for at least 1 year before admission for MOUD.
- Patients under age 18 no longer need to have two documented unsuccessful attempts at withdrawal management or non-MOUD treatment within 1 year to be eligible for MOUD.

These changes—which align with long-standing federal priorities to expand access to MOUD and reduce opioid-related morbidity and mortality—expedite access to care; redirect attention to the patient's actual needs at the time of presentation, rather than to the preconditions to treatment; and reduce the potential for prospective patients to overdose while waiting to meet those preconditions. This flexibility is especially important for people who have been in recovery from OUD but whose opioid use has recurred, or for people with OUD who are being discharged from incarceration where MOUD has not been available, as they may be at higher risk of an overdose. [87] Eliminating preconditions to treatment also reinforces a commitment to low-barrier care and positions OTPs to meet patients where they are.

Criteria for admission now requires that a patient:

- Meets diagnostic criteria for moderate to severe OUD; or
- Has active, moderate to severe OUD or OUD in remission; or
- Is at high risk for recurrence of use or overdose.

These criteria may exist independently or in combination. For example, individuals who have mild OUD can be admitted to an OTP if they are at high risk of overdose. In the era of high-potency synthetic opioids, such as fentanyl, it is imperative that OTPs assess risk by conducting a thorough patient history and examination. Individuals with mild OUD or those who may not have developed physical dependence to opioids may need additional education about the pharmacology of methadone and buprenorphine before initiating these medications to ensure full informed consent and understanding of the difference between physical dependence and OUD.

The diagnosis of OUD includes signs and symptoms associated with compulsive, persistent use of opioids despite harmful consequences. *Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition, Text Revision* (DSM-5-TR) delineates the most commonly used diagnostic criteria describing these signs and symptoms. [88] The severity classification (i.e., mild, moderate, severe) of a patient's OUD is determined by how many of the 11 diagnostic criteria outlined in the DSM-5-TR the patient meets at a given time. Two to three criteria constitute mild OUD, the presence of four to five criteria define moderate OUD, and the presence of six or more symptoms indicates severe OUD. DSM-5-TR makes an important exception to the inclusion of tolerance and withdrawal as diagnostic criteria for OUD for "those individuals taking opioids solely under appropriate medical supervision" (p. 609). In this way, patients taking methadone or buprenorphine may achieve remission and recovery or a lower severity categorization based on the other nine diagnostic criteria. Reductions in the frequency or amount of use may also reflect changes in severity over time.

Providing patient-centered care and using a shared decision-making approach to treatment means the patient and practitioner are partners in the process of treatment and recovery. At the admission screening examination, this means the practitioner informs the patient about available medications and the benefits and side effects of each one, and the patient shares information about their needs, values, preferences, history of treatment, and treatment goals. The patient and practitioner then together confirm that admission to treatment is appropriate and, if it is, determine the medication and initial treatment services to be started. The patient-centered and shared decision-making approaches continue with the full examination and psychosocial assessments, during which additional history is gathered,

treatment goals and recommended services are refined, and agreed-upon referrals to other healthcare and social services are made. All of this information is documented in the individual's record, along with the patient's consent. Except where not required by state law, parental consent to treatment remains a requirement for patients younger than age 18. Written documentation should reflect the method of informed consent, which can include email.

Admission may not be appropriate for all individuals, and some people may decide the program does not meet their needs. In these instances, it is recommended that OTPs keep records of all discussions, including the reasons for non-admission and any referrals to alternate services, as well as provision of harm reduction supplies. OTPs are encouraged to provide referrals for office-based buprenorphine or extended-release naltrexone treatment when appropriate.

For more information on this topic, see SAMHSA's Treatment Improvement Protocol (TIP) 63, *Medications for Opioid Use Disorder*.

Use of Non-OTP Practitioner Assessments

An important aspect of the revised rule is the ability to use a non-OTP practitioners' examination to expedite the admissions process, as long as the exam is performed no more than 7 days before the individual's admission to the OTP. With proper consent, a non-OTP practitioner's finding can be transmitted to the OTP, where an OTP practitioner reviews, verifies, and integrates the findings into the patient's care plan. For example, the screening or full examination could be done by a primary care provider, an emergency department practitioner, or a hospital addiction medicine consultant. The report can be faxed, securely emailed, or transmitted through a health information exchange that is compliant with the Health Insurance Portability and Accountability Act of 1996 (HIPAA) for review and verification by the OTP practitioner.

Although this flexibility makes accessing OTP services faster and easier for everyone, it is particularly important for people who are being released from a hospital or correctional facility where they may have already been receiving MOUD. As more hospitals and correctional settings offer MOUD, there is greater need to ensure medication continuity for patients moving into the OTP setting. The revised rule enables OTPs to work with practitioners at local hospitals and correctional facilities, lowering barriers to ongoing care.

Readmission to Treatment

Patients may leave treatment for a variety of reasons, planned or unplanned, and for varying lengths of time. Patients who have a short break in care may not need to repeat the full admission process to be re-enrolled in OTP services. Instead, a brief assessment may be adequate to determine the circumstances around the interruption in care; the symptoms experienced since the last medication dose, including potential recurrence of use; and how the patient has managed those symptoms.

The revised rule does not specify an amount of time that constitutes a short break and a long break. OTPs are encouraged to evaluate substance use patterns during any period of disengagement and to use clinical judgment to determine the extent of assessment necessary to safely and effectively resume MOUD and other treatment services; identify any changes that may be called for in the care plan, including the intensity of treatment services; and clarify contributors to disengagement. A return to care presents an opportunity to identify and address social determinants of health or mental health issues that may have impacted the patient's ability to access or engage in care. OTPs may also consider licensing and accreditation standards to distinguish between the temporary disengagement of an active

patient and a new enrollment of an inactive patient. For returning patients, OTPs are encouraged to expedite enrollment to avoid delays in restarting MOUD. This process should be viewed by patients as easy and rewarding, rather than burdensome and punishing (e.g., delays in restarting MOUD can extend withdrawal symptoms).

To determine the dose of medication a patient should be given following an interruption in medication continuity, OTP practitioners should consider:

- The half-life of the MOUD the patient had been taking and may be resuming.
- The severity of withdrawal or sedation the patient may be exhibiting on re-presentation.
- The prior dose of MOUD.
- The use and last use of any other opioids.
- The presence of any other substance use disorders or risk factors for overdose.

Recalling that steady state for any medication requires approximately 5 to 7 half-lives may be helpful when deciding how to resume MOUD when a patient's break in medication continuity is less than 5 to 7 days. OTP practitioners also may want to consider how resuming MOUD at doses much lower than the patient's most recent dose may affect retention.

Additionally, OTPs should prepare to support patients who may be experiencing withdrawal symptoms since their last dose of MOUD or the return of cravings that have resulted in recurrent opioid misuse. Patients taking methadone or buprenorphine can experience withdrawal 72 to 96 hours after the last dose, with symptoms including tachycardia, elevated blood pressure, poor appetite, nausea, abdominal cramps, muscle and joint aches, insomnia, and restlessness. [89] After patients have restarted MOUD, OTPs are encouraged to resume prior take-home medication schedules when clinical judgment deems it appropriate. When readmitting a patient, OTPs may want to document patient reports about challenges experienced during prior treatment.

For patients who have been involuntarily discharged from an OTP for committing acts of violence toward patients or staff or for destruction of property, OTPs can connect the individual to resources to help them locate an alternate program or site. OTPs should also consider assisting with referrals for management of co-occurring mental health and physical health conditions, as appropriate. More information on involuntary or administrative discharge is provided in the Withdrawal Management section.

Telehealth

Telehealth is the delivery and facilitation of health and health-related services—including medical care; counseling, practitioner, provider and patient education, and health information services; and self-care—via telecommunications and digital communication technologies that use HIPAA-compliant platforms. [90]

Use of Telehealth for Ordering and Dispensing MOUD in OTPs

During the COVID-19 pandemic, SAMHSA exempted OTPs from the requirement to perform an in-person physical evaluation for any patient treated with buprenorphine if a program physician, primary care physician, or an authorized healthcare professional under the supervision of a program physician determined that an adequate evaluation of the patient could be accomplished via telehealth. This exemption was specifically tied to the period of the national public health emergency that ended in May 2023. The revised rule has now made this flexibility permanent, as noted in 42 CFR § 8.12(f).

Telehealth expands access to care and provides patients with flexibility to seek treatment with minimal disruption of recovery-oriented activities such as employment and education. The revised rule permits the use of telehealth for the initial screening examination, full examination, and the initiation of buprenorphine if a practitioner or primary care provider determines that an adequate evaluation of the patient can be, or was, accomplished via audio-only or audio–visual telehealth technology. [91] The additional expansion of telehealth in OTPs made possible by the revised rule is intended to facilitate wider use of individualized care while prioritizing access to services.

Telehealth for Patient Admission

For new patients who will be treated by the OTP with methadone, the revised rule allows for the use of audio–visual telehealth if a program practitioner or primary care provider determines that an adequate evaluation of the patient can be accomplished via an audio–visual telehealth platform. However, when audio–visual technologies are unavailable or the patient is unable to access or use them, it is acceptable to use audio-only devices to conduct the evaluation only when the patient is in the presence of a licensed practitioner who is registered to prescribe and dispense controlled medications. [92]

This might mean that the patient attends their primary care practitioner's office to have the physical examination portion take place in conjunction with the OTP practitioner who can meet and gather the necessary medical and substance use history from the patient by phone. The OTP practitioner would then coordinate with the primary care provider to transmit the results of the physical examination. The reason for this additional visual examination of a patient starting methadone is related to the different safety profile for methadone, a Schedule II controlled medication, compared to buprenorphine, a Schedule III controlled medication. The risk of drowsiness or medication interactions is higher with methadone than buprenorphine in the initial phases of treatment, making visual assessment of a patient before initiating the medication an important element. In this way, telehealth may be used to support decision-making when a practitioner who can conduct physical examinations and make diagnoses is physically located with the patient. [93]

Ultimately, the optimal method of assessment for initiating MOUD treatment rests with the clinical judgment of the treating practitioner. Whichever approach the practitioner selects should be undertaken in a manner that promotes patient autonomy, safety, and confidentiality. The OTP practitioner's decision-making to admit via telehealth should be documented in the individual's medical record. Additional information is in the Recordkeeping and Documentation section.

The regulations do not authorize the prescription of methadone based on a telehealth visit. The telehealth options provided in the rule apply only to the ordering of methadone by appropriately licensed OTP practitioners. Under existing OTP procedures, patients will still need to present to the OTP to receive any ordered medication doses. [94]

Resource Alert: Telehealth for the Treatment of SUDs

Leveraging telehealth services for people with substance use and mental health disorders can increase access to treatment by providing a flexible option that reduces barriers related to geography, transportation, socioeconomic status, and more.

The following resources can help OTP staff learn more about incorporating telehealth into treatment:

- SAMHSA: *Telehealth for the Treatment of Serious Mental Illness and Substance Use Disorders*
- U.S. Department of Health and Human Services (HHS): How can I use telehealth for substance use disorder?
- Centers for Medicare & Medicaid Services: Telehealth
- SAMHSA: *In Brief:* Rural Behavioral Health: Telehealth Challenges and Opportunities

Telehealth Compliance

The Centers for Medicare & Medicaid Services provide the following guidance applicable to OTPs regarding telehealth: [95]

- Medicaid guidelines require all providers to practice within the scope of their state practice. Some states have enacted legislation that requires providers using telemedicine technology across state lines to have a valid state license in the state where the patient is located. Any such requirements or restrictions placed by the state are binding under current Medicaid rules.
- Telemedicine services should be conducted via an interactive audio and video telecommunications system that permits real-time communication between the healthcare provider at the distant site and the patient at the originating site. An originating site is the location of the patient at the time the service being furnished via a telecommunications system occurs.

Many states now require that those practicing telemedicine adhere to the same standards as face-to-face services, have formalized policies in place, or obtain certification as a telehealth provider. [96] Some accrediting bodies have established a certification process for telemedicine providers, including providers of mental health and substance use disorder treatment services.

Services Delivered by the OTP

> **42 CFR § 8.12(f)(1). Required services.** (1) *General.* OTPs shall provide adequate medical, counseling, vocational, educational, and other screening, assessment, and treatment services to meet patient needs, with the combination and frequency of services tailored to each individual patient based on an individualized assessment and the patient's care plan that was created after shared decision-making between the patient and the clinical team. These services must be available at the primary facility, except where the program sponsor has entered into a documented agreement with a private or public agency, organization, practitioner, or institution to provide these services to patients enrolled in the OTP. The program sponsor, in any event, must be able to document that these services are fully and reasonably available to patients.

Opioid treatment programs (OTPs) are expected to offer the required services outlined in OTP regulations. These services remain consistent with, and build on, the requirements set forth in previous versions of the regulations. How these services can be provided has been modified in some respects (e.g., the expanded use of telehealth services), but OTPs still need to be able to provide screening, assessment, and comprehensive treatment services that meet the needs of each patient, including medical, counseling, vocational, and educational services. When OTPs cannot provide specialized services on-site, programs may enter into agreements with private or public agencies, organizations, practitioners, or institutions that can provide the services. In these situations, program sponsors should document that these services are reasonably available to all patients, ensure that patients are informed about how to access them, and facilitate access to and provision of those services through care coordination. For the purpose of this document, care coordination reflects the processes of coordinating with other providers and supports outside of the OTP.

The revised rule also embraces a more patient-centered approach to providing services. Examples include the focus on harm reduction approaches and effective counseling; an increased emphasis on ensuring that the combination and frequency of services is decided in collaboration with the patient; and services that are tailored to each individual patient's assessment findings, stage of change, and goals. The objective is to create comprehensive, welcoming OTP environments that support patients in the context of their full life and recovery goals.

The following sections address key components of required services, including:

- Informed consent, patient's rights, and patient-centered care planning.
- Initial medical screening.
- Effective and inclusive provision of services for specific populations, whether related to race/ethnicity, sexual orientation, gender identity, housing status, involvement with the criminal justice system, veteran status, pregnancy, or other identities.
- Initial and periodic physical and behavioral health assessments.
- Services to support recovery, including counseling, the use of evidence-based practices, connecting patients to peer support or other recovery support services, offering vocational services, and effective care coordination and case management.
- Drug testing and other types of laboratory testing.

Informed Consent

Informed consent is fundamental to protecting patients' rights and to establishing a trusting relationship during the initial engagement and admission process and throughout treatment. Informed consent

requires OTP staff to fully explain all aspects of treatment in a way the patient can understand. This includes details about medications for the treatment of opioid use disorder (MOUD), related services, risks and benefits, alternative treatments, the patient's role in treatment, and the right to refuse treatment. Informed consent supports treatment by ensuring patients have a clear understanding of medication side effects and risks, patient responsibilities, and OTP policies. Informed consent policies may include practices such as:

- Providing patients with education related to treatment procedures, service options, medication protocols, and other relevant polices (e.g., how to address grievances and concerns).
- Reviewing with patients the voluntary, written, program-specific informed consent to treatment and information about the specific pharmacotherapy that has been chosen by the patient.
- Reviewing with patients their rights and protections under the law.
- Requiring program staff to regularly review informed consent policies.

Patients' Rights

It is recommended that OTPs implement a policy and system of rights that establish a sense of safety among patients and ensure that they are treated with dignity and respect. These protections should cover physical, sexual, verbal, and financial abuse and uphold the rights to privacy, confidentiality, and the ability to file grievances and complaints without fear of retaliation. All individuals in opioid use disorder (OUD) treatment and recovery—including those receiving MOUD—are protected from discriminatory practices by various intersecting public laws, including the Americans with Disabilities Act, the Rehabilitation Act of 1973, the Fair Housing Act, and the Workforce Innovation and Opportunity Act. [97, 98]

OTP program sponsors and medical directors should ensure that all staff are familiar with clinic policies and relevant laws and can clearly explain patients' rights. This helps patients understand how they are protected from discrimination in areas such as employment, housing, and access to social and healthcare services, including treatment by the OTP itself. [99] Some programs have established patient advocate committees to help share this information with patients and to review patient complaints to ensure these rights are not violated.

Resource Alert: Know Your Rights: Patients Receiving MOUD

The Substance Abuse and Mental Health Services Administration's (SAMHSA) Medications for Substance Use Disorders webpage includes information about medications and patient's rights. To access this information, view the Medications and Patient Rights section.

SAMHSA's Treatment Improvement Protocol (TIP) 63, *Medications for Opioid Use Disorder* (see Part 4) discusses how practitioners can help patients advocate for themselves and contains a sample Standard Consent to Opioid Maintenance Treatment Form for OTPs.

For additional useful information on this topic, refer to the *MedlinePlus Medical Encyclopedia* entry, Consumer Rights and Protections.

Initial Medical Examination Services

42 CFR § 8.12(f)(2). Initial medical examination. (i) OTPs shall require each patient to undergo an initial medical examination. The initial medical examination is comprised of two parts: (A) A screening examination to ensure that the patient meets criteria for admission and that there are no contraindications to treatment with MOUD; and (B) A full history and examination, to determine the patient's broader health status, with lab testing as determined to be required by an appropriately licensed practitioner. A patient's refusal to undergo lab testing for co-occurring physical health conditions should not preclude them from access to treatment, provided such refusal does not have potential to negatively impact treatment with medications.

(ii) Assuming no contraindications, a patient may commence treatment with MOUD after the screening examination has been completed. Both the screening examination and full examination must be completed by an appropriately licensed practitioner. If the licensed practitioner is not an OTP practitioner, the screening examination must be completed no more than seven days prior to OTP admission. Where the examination is performed outside of the OTP, the written results and narrative of the examination, as well as available lab testing results, must be transmitted, consistent with applicable privacy laws, to the OTP, and verified by an OTP practitioner.

(iii) A full in-person physical examination, including the results of serology and other tests that are considered to be clinically appropriate, must be completed within 14 calendar days following a patient's admission to the OTP. The full exam can be completed by a non-OTP practitioner, if the exam is verified by a licensed OTP practitioner as being true and accurate and transmitted in accordance with applicable privacy laws.

(iv) Serology testing and other testing as deemed medically appropriate by the licensed OTP practitioner based on the screening or full history and examination, drawn not more than 30 days prior to admission to the OTP, may form part of the full history and examination.

(v) The screening and full examination may be completed via telehealth for those patients being admitted for treatment at the OTP with either buprenorphine or methadone, if a practitioner or primary care provider, determines that an adequate evaluation of the patient can be accomplished via telehealth. When using telehealth, the following caveats apply: (A) In evaluating patients for treatment with schedule II medications (such as Methadone), audio–visual telehealth platforms must be used, except when not available to the patient. When not available, it is acceptable to use audio-only devices, but only when the patient is in the presence of a licensed practitioner who is registered to prescribe (including dispense) controlled medications. The OTP practitioner shall review the examination results and order treatment medications as indicated. (B) In evaluating patients for treatment with schedule III medications (such as Buprenorphine) or medications not classified as a controlled medication (such as Naltrexone), audio–visual or audio only platforms may be used. The OTP practitioner shall review the examination results and order treatment medications as indicated.

The revised rule outlines a medical admission process that includes a screening examination followed by a full history and examination. Together, these protocols confirm admission criteria and identify co-occurring medical and psychiatric conditions that may need to be addressed to improve the individual's health and well-being. The revised rule makes changes to the admission process to expedite access to and initiation of MOUD, including expanding the use of telehealth, as described in the Patient Admission Criteria section. The changes also describe the practitioners who can conduct the examinations.

Medical Admission Process

Patients seeking treatment at an OTP must undergo a two-part initial medical admission process. This process includes a:

- **Screening examination,** which determines whether a patient meets the criteria for admission and, if so, whether there are contraindications to MOUD. If patients meet admission criteria and no

contraindications are found, patients may receive MOUD immediately following the screening examination. If the licensed practitioner is not an OTP practitioner, the screening examination must be completed within 7 days prior to OTP admission.

- **Full history and examination,** which informs practitioners of the patient's broader health status. The history and full exam should be completed within 14 calendar days of a patient's admission to the OTP. If patients have had laboratory and other testing completed within 30 calendar days prior to admission, those results can be used to inform the full history and examination, as deemed medically appropriate.

Both the screening examination and the full history and examination must be completed by a licensed practitioner. To increase the accessibility of MOUD and ensure that patients receive prompt care—especially in areas with limited treatment services and qualified staff—the revised rule expands the definition of *licensed practitioner*. The expanded definition includes appropriately licensed practitioners, such as nurse practitioners, physician assistants, whose scope of practice and licensure includes diagnostic abilities and prescribing and ordering of controlled medications, including medications dispensed at an OTP. The definition also includes appropriately licensed practitioners outside of OTPs who have the same diagnostic and controlled medication capabilities as OTP practitioners. Statutory and licensure regulations regarding the scope of practice and controlled medication capabilities of non-physician practitioners vary across states. OTP practitioners, medical directors, and sponsors should understand the specifics of these rules in the states where they provide OTP services.

Although non-OTP practitioners may now conduct screening and full history examinations, OTP practitioners are required to review and verify those results. Screening examinations should be completed, and the results transmitted to an OTP in accordance with applicable privacy laws, no more than 7 days before OTP admission if they will be incorporated into the medical admission process. Narrative results of the examination and available laboratory testing results should be transmitted to the OTP, verified by an OTP practitioner, and documented in the patient's record.

The full history and physical examination, including all clinically appropriate tests, should be completed within 14 calendar days of admission to the OTP. At this time, and as applicable throughout the course of treatment, OTPs may ask for patient consent to seek medical records from other healthcare practitioners and may seek the release of information from other treating physicians or prescribers identified through the state prescription drug monitoring program or other state health information exchanges.

Initial toxicology tests are a part of the initial medical admission process. At a minimum, samples are tested for opiates, commonly used opioids (e.g., fentanyl), amphetamines, cocaine, and benzodiazepines. Methadone and buprenorphine can be added if the patient has a history of taking these medications. If a patient has a history of prescription opioid analgesic misuse, practitioners should order an expanded toxicology panel that includes corresponding opioids. Additional testing may be performed according to individual patient need and local patterns and trends in substance use. However, test results, whether from toxicology or other clinically appropriate tests, do not need to be reviewed before medication is started to mitigate the overdose risk of a patient not returning for care.

Initial medical screening should consider cardiac risks for those who have been or who may be treated with methadone, understanding that limited evidence exists for the routine use of echocardiograms for prevention of cardiac risks in people treated with methadone. [100] OTP practitioners may wish to gather history of any arrhythmias or prior prolonged QTc interval as told to the patient, or family history of arrhythmias as steps to identify patients at higher risk for cardiac arrhythmias. Care coordination with external primary care and cardiology clinicians may be considered for those patients at higher risk for

cardiac arrhythmia. However, unless specific contraindications to initiating methadone exist (e.g., a prior episode of Torsade de Pointes while taking methadone), risks associated with delays in starting methadone must also be considered. [101] For more information about cardiac risk management, SAMHSA's TIP 63, *Medications for Opioid Use Disorder* discusses how to assess patient cardiac risks, particularly regarding the use of methadone. [102]

The results of the initial screening examination are used to develop the initial patient assessment and care plan. This plan can summarize:

- Substance use and severity levels of each diagnosed substance use disorder (SUD), including OUD.
- The selected MOUD, the rationale for its use, starting doses and expected plan for titration to a therapeutic level, and the anticipated response.
- Any early identification of co-occurring conditions and patient concerns that may need further evaluation and potential care coordination.
- Results from toxicology testing results that require further evaluation and how the evaluation will be accomplished.
- Gaps in health maintenance and how preventive services can be introduced.
- The patient education provided about health conditions and the potential interactions or complications that could occur because of the planned pharmacotherapy.
- The overdose prevention education and naloxone or other opioid overdose reversal medications provided.

With the addition of findings from the full examination, the medical admission process can identify the risk of patients having other undiagnosed, co-occurring conditions, such as viral hepatitis, HIV, sexually transmitted infections, diseases of the heart and lungs (i.e., cardiopulmonary diseases), or sleep apnea. This assessment informs the need for further diagnostic testing (e.g., laboratory studies, cardiograms).

OTPs can use the initial medical admission as an opportunity to address preventive health care, including reinforcing overdose prevention knowledge, and to educate patients about the need for routine screenings (e.g., women's health screening, colonoscopy, skin checks) and vaccinations to prevent viral hepatitis, tetanus, pneumococcal disease, and influenza. Positive screening results or the identification of disease risks necessitate the development of a care management plan that goes beyond the initial assessment and care plan, regardless of whether the plan can be achieved using services provided at the OTP or whether referral and care coordination with other practitioners are needed. Further, the OTP practitioner can use the initial medical admission process to engage the patient in a discussion about the benefits of having a consistent primary care provider.

As discussed in the Telehealth section, some elements of the full assessment and physical examination can be completed through telehealth, but other parts of the physical examination require an in-person visit with a practitioner. This in-person physical examination allows for exam steps such as examination of the nose and mouth, auscultation of the chest and lungs, palpation of the abdomen, examination of skin integrity, and laboratory specimen collection.

Because the patient will visit the OTP to receive their medication, the in-person components of the full examination can occur within the first 14 days of treatment. Appointments with assigned staff will allow for the completion of the medical and psychosocial assessment, as well as the development of a comprehensive care plan that goes beyond the initial assessment and care plan. While all efforts should be made to engage patients in completing the full examination, if a patient declines parts of it, including

bloodwork, the OTP practitioner should document this in the patient's record and continue to connect with and offer these components of the medical assessment beyond the 14-day timeline for completion.

At-Risk Populations

Although OTPs should tailor services to the needs and goals of all patients, SAMHSA recommends that programs understand the unique circumstances of some groups they are likely to serve on a regular basis. These include pregnant people, people younger than age 18, and people involved in the criminal justice system. This section discusses how OTPs can best address the needs of these groups.

Supporting Patients With OUD Who Are Pregnant or Postpartum

> **42 CFR § 8.12(f)(3). Special services for pregnant patients.** OTPs must maintain current policies and procedures that reflect the special needs and priority for treatment admission of patients with OUD who are pregnant. Pregnancy should be confirmed. Evidence-based treatment protocols for the pregnant patient, such as split dosing regimens, may be instituted after assessment by an OTP practitioner and documentation that confirms the clinical appropriateness of such an evidence-based treatment protocol. Prenatal care and other sex-specific services, including reproductive health services, for pregnant and postpartum patients must be provided and documented either by the OTP or by referral to appropriate healthcare practitioners. Specific services, including reproductive health services, for pregnant and postpartum patients must be provided and documented either by the OTP or by referral to appropriate healthcare practitioners.

Pregnant people seeking treatment for OUD are considered a priority for enrollment in OTPs. Methadone and buprenorphine are part of the evidence-based strategy for supporting the health of both parent and fetus. [103, 104, 105, 106] In addition to eliminating cravings and withdrawals for pregnant patients, methadone and buprenorphine also reduce a variety of conditions related to ongoing opioid use. When combined with additional supports, MOUD is an important aspect of a healthy pregnancy among those with OUD. More information about treating pregnant patients with OUD is available in SAMHSA's *Clinical Guidance for Treating Pregnant and Parenting Women With Opioid Use Disorder and Their Infants*.

Policies and Procedures To Support Pregnant Patients With OUD

Statutes and policies within states and care systems may present challenges for pregnant people who want to receive OUD treatment. OTPs and pregnant patients should be aware of requirements related to reporting prenatal substance use and carefully evaluate how those requirements may affect a pregnant patient's care plan. [107] Federal confidentiality requirements outlined in Title 42 of the Code of Federal Regulations (42 CFR) part 2 and the Health Insurance Portability and Accountability Act of 1996 (HIPAA) should always be considered when sharing patient information. As state laws pertaining to reproductive and pregnancy outcomes continue to change, OTPs should have a strong understanding of state rules, as well as stringent informed consent procedures, to ensure that pregnant people are aware of their legal rights and obligations. [108]

Providing compassionate, coordinated prenatal care and recognizing the pregnant patient as the expert on their own experience will help OTPs engage pregnant patients in shared decision-making and the tailoring of healthcare supports. It is recommended that OTPs observe the following policies and procedures when working with pregnant patients:

- OTPs should provide pregnant patients with education about OUD, as well as the risks, benefits, and pharmacotherapy options for the pregnant person and the effects of both untreated OUD and MOUD on the developing fetus.
- Fully informed decision-making is imperative, and the pregnant person should be made aware of state rules that may affect their right to privacy or invoke the involvement of Child Protective Services (CPS).
- In cases where appropriate prenatal care is unavailable, unaffordable, or declined by the patient, the OTP—at a minimum—should offer and document basic prenatal instruction on physical, behavioral, and dietary care as part of its counseling services. Advice on prenatal vitamins, particularly folate; screening for pregnancy-related issues (e.g., depression, safety, and gender-based violence); and care should be provided, in addition to routine screening for infectious diseases and sexually transmitted infections.
- If a pregnant patient refuses on-site or referred prenatal services, the treating physician or authorized healthcare professional, as appropriate, may ask the patient to acknowledge their decision in writing.

For pregnant patients receiving methadone, the OTP should have policies and procedures in place to ensure that patients receive care in line with the following best practices:

- The initial dose for a newly admitted pregnant patient and the subsequent titration and ongoing dosing strategy should follow the same effective dosing protocols used for all other patients.
- Increasing the dose or split dosing is often required, especially in the third trimester. A single daily dose of methadone may not control withdrawal symptoms over a 24-hour period for pregnant patients. In these cases, it may be appropriate to split doses. This decision will need to be made on a case-by-case basis as part of a patient-centered approach to care. [109]

Medically supervised withdrawal from pharmacotherapy is not recommended for pregnant or postpartum patients. Medically supervised withdrawal from pharmacotherapy is associated with a high risk of return to opioid use. Therefore, OTPs are encouraged to avoid discharging pregnant or postpartum patients. If a pregnant person receiving MOUD decides to undergo medically supervised withdrawal, OTPs are encouraged to provide education about the risks and benefits of treatment discontinuation. Given the medical complexity, medically supervised withdrawal in a controlled setting should be encouraged, [110] with a reminder that the patient may always return to outpatient treatment at the OTP if needed.

Resource Alert: Supporting Pregnant People With OUD

Resources are available for OTPs to learn how to take an active role in supporting the health of pregnant people who have OUD and their infants.

SAMHSA's *Advisory:* Evidence-Based, Whole-Person Care for Pregnant People Who Have Opioid Use Disorder provides information about universal prenatal SUD screening and assessment, pharmacological treatment, and person-centered care and services. It also provides information to healthcare practitioners about what they need to know about MOUD during pregnancy, including how to provide and manage pharmacotherapy over the course of pregnancy and how to offer whole-person care to pregnant people with OUD.

The *Advisory* also outlines how practitioners can offer compassionate care to pregnant people who have OUD by:

- Providing universal prenatal SUD screening and assessment.
- Offering person-centered care and services.
- Connecting pregnant people with lifesaving medications that can stop an opioid overdose and with other services related to harm reduction.

Ongoing Care After Pregnancy

The postpartum period is a critical time for all parents and infants. OTPs have a unique opportunity to support new parents and to encourage follow-up primary care for the parent and well-baby care for the infant.

Some infants born to people receiving MOUD may experience neonatal abstinence syndrome (NAS), and parents will need information about how to prepare for and manage the diagnosis, including ways to reduce symptoms, such as swaddling the baby and keeping noise levels and lights low. OTPs can make certain that newborns of OTP patients receive prompt medical evaluation if there is ongoing concern for NAS after discharge from the hospital.

New parents may struggle with anxiety and guilt as they cope with their newborn's withdrawal symptoms. They may blame themselves for their infant's discomfort, which may compound feelings of self-doubt. They also may fear the involvement of CPS and the potential removal of the newborn from their care. It is important for OTP practitioners to be present and responsive to the parent throughout the pregnancy and postpartum stages.

Because behavioral health conditions, including postpartum depression, can occur during any stage of pregnancy and after delivery, OTPs should monitor patients for depression and other aspects of well-being throughout pregnancy and after delivery. [111] Pregnant and postpartum people with OUD, and ideally their partners or other family members, should also receive overdose education and naloxone or other opioid overdose reversal medications for overdose prevention. [112]

As a result of toxicology testing of newborns, OTP staff may receive requests for information from CPS about a new parent receiving treatment for OUD. It is incumbent upon OTPs to understand these issues and their state's regulations regarding reporting requirements. Staff should be trained on the limits of mandatory CPS reporting requirements and the potential negative outcomes of reporting. [113]

Resource Alert: Child Welfare Resources

The National Center on Substance Abuse and Child Welfare offers resources that can help OTPs learn more about CPS and the court system:

- Working With Child Protective Services To Support Pregnant and Parenting People, Their Infants, and Families Affected by Substance Use Disorders: A Factsheet for Health Care Providers
- Resources for Professionals Working With Pregnant and Parenting People Affected by Substance Use Disorders and Involved With Child Welfare

Treating Pregnant People With Concurrent HIV Infection

Pregnant people with concurrent HIV infection should receive the same treatment opportunities and services, directly or by referral, as patients with HIV who are not pregnant. OTPs should ensure that all pregnant patients with concurrent HIV infection are:

- Informed that HIV medication treatment is currently recommended to reduce perinatal transmission.
- Provided with appropriate referrals and care management for this treatment.

Resource Alert: HIV and Pregnancy Resources

OTP practitioners can learn more about HIV and pregnancy from the following resources:

- The American College of Obstetricians and Gynecologists: HIV and Pregnancy
- Medline Plus: HIV and Pregnancy
- National Institutes of Health: HIV Medicines During Pregnancy and Childbirth
- Office on Women's Health: Pregnancy and HIV

Use of MOUD While Breastfeeding

Breastfeeding is considered safe for new parents who are receiving MOUD, and it should be encouraged unless the risks outweigh the benefits. [114, 115] Specifically, breastfeeding is not recommended if the person has HIV infection (unless the person has a sustained undetectable viral load [116]), human T-cell lymphotropic virus type I or type II infection, or untreated brucellosis. [117] OTPs should have policies and procedures in place to support patients who are receiving MOUD and desire to breastfeed. This may include connecting patients with lactation consultants and other supports who can help with decisions about breastfeeding.

Providing Services for People Under Age 18

42 CFR § 8.12(e)(2). Comprehensive treatment for persons under age 18. Except in States where State law grants persons under 18 years of age the ability to consent to OTP treatment without the consent of another, no person under 18 years of age may be admitted to OTP treatment unless a parent, legal guardian, or responsible adult designated by the relevant State authority consents in writing to such treatment.

The number of overdose deaths among people younger than age 18 continues to grow, making it essential to expand treatment access for this age group. The revised rule changed OTP admission requirements (discussed in the Patient Admission Criteria section), which makes it easier to initiate MOUD with these individuals.

When OTPs offer treatment for this age group, SAMHSA recommends considering the environment of care from the point of view of an adolescent. This includes integrating age-appropriate peer supports, adjusting dosing times and clinic attendance to accommodate education schedules, appropriately pairing patients with therapists' skill sets, and using communications and technology that are culturally relevant to the developmental stages of these patients.

Adolescence is a time of transition in which youth are faced with many physical, developmental, social, and emotional changes that prepare them for adulthood. Mental issues and substance misuse often first appear during this time due to changes in the adolescent's physical and social environments and exposure to adverse childhood experiences (ACEs). Risk factors for the development of mental health issues, including mental illness and substance use disorders, in youth include abuse and neglect, death of a loved one, and community violence. [118] OTPs can develop policies to ensure that adolescents receive age-appropriate care and support during treatment, such as evidence-based, trauma-informed psychosocial interventions and family involvement. Screenings and assessments tailored to adolescents ensure that MOUD is the most appropriate treatment for these patients.

The revised rule no longer requires that people under age 18 have two unsuccessful withdrawal management attempts before being admitted to OTP services. They may now receive treatment if they

have the written consent of a parent, legal guardian, or responsible adult designated by the relevant state authority. [119]

An exemption to this requirement can be requested from SAMHSA in states with laws granting people under age 18 the ability to consent without the involvement of a legal guardian. Emancipated minors may also receive treatment without the consent of a parent, legal guardian, or responsible adult. In such cases, the OTP should confirm the emancipated status of the individual and document review of applicable legal documents in the patient's record. Exemptions to these requirements can be granted to OTPs serving this population. Therefore, OTPs should consider developing appropriate policies and procedures, staff training, and informed consent procedures that specify protocols to ensure they can provide access to treatment for this population.

Supporting People Involved in the Criminal Justice System

Individuals involved with the criminal justice system are at significantly higher risk of OUD, and for those leaving the system, lack of access to MOUD may result in a higher risk of recurrence and overdose. [120]

OTPs may help address MOUD access issues by partnering with jails, state and federal prisons, and other parts of the justice system to provide care for this population. Incorporating jails and prisons into a system of care allows individuals to continue or initiate MOUD upon incarceration and to connect with MOUD services upon reentering the community. Further, OTPs can develop procedures to coordinate and communicate with the criminal justice system and advocate for continuous treatment of patients who are incarcerated, on probation, or on parole. Providing those individuals within the criminal justice system with opioid overdose reversal medications, such as naloxone or another opioid overdose reversal medication, upon release may also reduce risk of overdose. [121]

There are several options available for OTPs to partner with correctional facilities to provide treatment services to the criminal justice population. If the correctional facility does not have a certified OTP, an OTP can partner with the correctional facility through a memorandum of understanding or a contract to ensure patients have access to MOUD. Partnerships with correctional facilities can take several forms:

- Correctional facility staff bring patients to the OTP to get and take their medication at the OTP.
- The OTP delivers patient medication as take-home doses to the correctional facility, or correctional facility staff pick up take-home medication doses from the OTP through a chain-of-custody arrangement for secure storage and observed administration in the facility by appropriate correctional staff. The DEA's Narcotic Treatment Program Manual provides further information on this topic.
- The OTP establishes a medication unit in the correctional facility and dispenses medication directly to patients in the facility or transports the medication to the correctional facility with a mobile medication unit, which dispenses the medication.
- The prison or jail becomes a certified OTP.
- The OTP serves as a community reentry site for correctional facilities that are registered with the Drug Enforcement Administration as a hospital/clinic and that provide MOUD, including the provision of methadone to patients who have a primary physical or behavioral condition other than addiction.

SAMHSA's evidenced-based resource guide *Use of Medication-Assisted Treatment for Opioid Use Disorder in Criminal Justice Settings* offers practical information to consider when selecting and implementing programs; practices to address use of MOUD in criminal justice settings; and guidance and resources for implementing evidence-based programs and practices, monitoring outcomes, and improving quality. [122] This includes efforts by OTPs to reduce barriers to care, prioritize access, and

ensure seamless transitions for patients who take MOUD returning to the community from correctional settings to ensure medication continuity.

Other Populations Served Frequently by OTPs

OTPs serve a variety of populations with unique needs, including people who identify as lesbian, gay, bisexual, transgender, queer, intersex, asexual, Two Spirit, or other identity (LGBTQIA2S+); people experiencing homelessness; people who have disabilities; veterans; and people from different cultural backgrounds. Staff must receive training to ensure they provide quality care to these groups, including effective engagement, comprehensive assessments, useful care plans, and culturally responsive services and approaches. If the OTP does not have the resources to provide culturally responsive care, it should foster relationships with providers that can provide those services.

Resource Alert: Cultural Responsiveness

- SAMHSA's *Advisory:* The Substance Use Disorder Counseling Competency Framework: An Overview (based on Technical Assistance Publication 21) discusses the development of counseling competencies, evidence-based practices, cultural competency, and important changes in the SUD field.
- SAMHSA's TIP 59, *Improving Cultural Competence* helps professional care providers and administrators understand the role of culture in the delivery of mental health and substance use services. It describes cultural competence and discusses racial, ethnic, and cultural considerations.
- SAMHSA's Behavioral Health Equity Fact Sheet describes efforts to advance behavioral health equity by promoting mental health, preventing substance misuse, and providing treatments and support to foster recovery and improve the lives of underserved communities.

Actively partnering with organizations and practitioners that support specific populations helps OTPs establish referral relationships that benefit clients of both organizations. OTPs can refer patients to the partner organization for specialized support and services not offered by the OTP. Clients of the partner organization who are not currently receiving OUD treatment—but who may benefit from it—can be referred to the OTP. This partnership effectively expands the reach of OTP services while ensuring patients receive needed care. More information on this topic is provided in the Strategies for Ensuring Continuity of Care chapter.

OTPs should understand that many people with OUD have experienced trauma that may impact their health and recovery. For example:

- There is a strong association between youth with OUD and ACEs. Youth with more ACEs have higher odds of recent opioid misuse. [123]
- People who are experiencing homelessness or housing instability have higher rates of trauma, often related to ACEs, than their counterparts in the general population. [124, 125] In addition, the experiences of homelessness and housing instability are traumatic. [126]
- People who identify as LGBTQIA2S+ are also more vulnerable to certain traumatic events, such as hate crimes, intimate-partner violence, and sexual assault. [127] They may also experience internalized homophobia. [128]
- Veterans may have trauma related to experiences during service or deployment, including physical or sexual assault, or they may have sustained injuries during combat that have resulted in long-term trauma or pain. [129, 130]
- People who identify as sex workers may have experienced ACEs and are at high risk of experiencing physical or sexual violence during their work. [131]

People who have disabilities, especially intellectual and developmental disabilities, may have experienced ACEs, such as violence and bullying, discrimination, poverty, and abuse. [132, 133, 134]

Although some groups may be at higher risk, trauma, especially ACEs, can affect anyone and may manifest as a single event or as part of a long-term, chronic pattern. ACEs may include: [135]

- Physical, sexual, and emotional abuse.
- Living with a family member who has active mental illness or an SUD.
- Witnessing or experiencing intimate-partner violence.
- Chronic poverty.
- Racism, discrimination, or oppression.
- Violence in the community.

To ensure optimal care for patients who have experienced trauma, OTP practitioners and staff should be well-versed and trained in trauma-informed care. *Trauma-informed care* is a whole-person approach that acknowledges the effect of trauma on the individual. The key principles of trauma-informed care, outlined by the American Academy of Family Physicians, are: [136]

- Realizing the widespread effects of trauma.
- Recognizing the signs and symptoms of trauma not only in patients, but also in staff and the clinical care team.
- Responding to the effects of trauma by fully integrating knowledge about trauma into policies, procedures, and practices.
- Being mindful of potential re-traumatization during care delivery, including in urine drug screening and security protocols, by actively seeking to develop systems and individual practices that are sensitive to trauma and patient centered.

In addition to helping OTPs better address issues that may have contributed to a patient's OUD, a trauma-informed approach recognizes that the environment of care can affect the patients' sense of safety and is sensitive about preventing re-traumatization. For example, patients who have experienced sexual assault may require a focus on establishing a safe physical and emotional environment where safety measures are in place and practitioner responses are consistent, predictable, and respectful. [137] Most importantly, practitioners need to recognize that each person's experience is unique and requires an individualized approach to trauma-informed care. [138] For more information about trauma-informed care, see Integrating Trauma-Informed Principles and Practices section in the General Provisions and Practices chapter.

Exhibit 1 highlights key considerations and provides selected resources tailored to the needs of selected populations served by OTPs.

Exhibit 1. Key Considerations and Resources for OTPs by Population

Population	Key Considerations	How OTPs Can Help	Resources
Black and African Americans	Opioid overdose rates for Black and African Americans have grown in recent years. [139]	OTPs can better support Black and African Americans by understanding the complex trauma potentially experienced by these patients and by training staff in culturally responsive and trauma-informed care. [140]	*The Opioid Crisis and the Black/African American Population: An Urgent Issue* | SAMHSA
American Indians and Alaska Natives	Opioid overdose rates for American Indian and Alaskan Native populations have grown in recent years. [141, 142]	OTPs can better support American Indian and Alaska Native populations by understanding the complex traumas they may have experienced and by training staff in culturally responsive and trauma-informed care. [143]	TIP 61, *Behavioral Health Services for American Indians and Alaska Natives* |SAMHSA
People who identify as LGBTQIA2S+	People who identify as LGBTQIA2S+ may experience stigma and discrimination, trauma, [144] intimate-partner violence, [145] and internalized homophobia, [146] which are associated with higher rates of SUDs [147] and higher rates of suicide, [148] as well as lower engagement in treatment and other related services. [149]	OTPs have an opportunity to fully support this population by: [150] • Training staff in LGBTQIA2S+-affirming care and in culturally responsive and trauma-informed care. • Creating a safe environment for people who identify as LGBTQIA2S+ to explore their sexual and gender orientations and how their related experiences with trauma, stigma, and discrimination may affect their SUD treatment. • Screening for suicide risk and referring for care as indicated. • Recognizing and modifying staff's perceived attitudes and beliefs about working with people who identify as LGBTQIA2S+.	Lesbian, Gay, Bisexual, Transgender, Queer, and Intersex (LGBTQI+) is a SAMHSA webpage that hosts multiple resources on serving LGBTQI+ populations. It includes national survey reports, agency and federal initiatives, and related behavioral health resources.

Exhibit 1. Key Considerations and Resources for OTPs by Population

Population	Key Considerations	How OTPs Can Help	Resources
Veterans	Veterans have higher rates of trauma and co-occurring mental and physical health conditions, including chronic pain and increased risk of opioid misuse and OUD; [151] thus, they require additional services to support their needs. [152, 153, 154]	Interventions that have demonstrated effectiveness in veterans include opioid overdose reversal medication distribution, harm reduction, and increased provision of low-threshold services, including MOUD. [155]	OTPs should learn about local Department of Veterans Affairs (VA) healthcare resources, SUD treatment at the VA, and the VA Community Care program that can help connect veterans to services in the community that can support their comprehensive health needs.
People experiencing homelessness or housing instability	People experiencing homelessness or housing instability face multiple barriers and are more likely to have substance use and mental disorders or experience an overdose. [156] In addition to not having housing and having a higher risk of significant co-occurring mental disorders or medical conditions, this population faces stigma and discrimination and may experience challenges with seeking and remaining in treatment. [157]	Keeping MOUD safe while experiencing homelessness or transporting the medication are both significant challenges that OTPs should consider for this population. OTP staff should be aware of these challenges and provide individualized services to ensure that these patients can fully engage in services and receive and store medication safely. OTPs can help provide transportation services for this population and connect them with safe housing options to support their needs. OTPs can learn about local community organizations that can connect these patients to related services, such as housing, financial, and other supports.	Evidence-Based Resource Guide: *Expanding Access to and Use of Behavioral Health Services for People Experiencing Homelessness* | SAMHSA

Exhibit 1. Key Considerations and Resources for OTPs by Population			
Population	**Key Considerations**	**How OTPs Can Help**	**Resources**
People living in rural areas	People who live in rural areas may face more significant challenges in receiving treatment for OUD because of transportation issues, limited access to services, and fewer integrated services in their communities. [158]	OTPs can help bridge these gaps by providing more comprehensive services to those in treatment; reducing barriers to treatment, such as increasing access to mobile units, telehealth, and transportation, where possible; and connecting patients to other needed services in the community.	Rural Behavioral Health | SAMHSA
People with disabilities	People with a spectrum of disabilities are at risk for mental and substance use disorders, including OUD, and often face additional challenges accessing services. [159] For example, adults who are deaf or hard of hearing have significantly higher risk for OUD-related emergency department visits. [160] Individuals with traumatic brain injury may be uniquely susceptible to opioid misuse and the consequences of OUD. [161]	OTPs will need knowledge about and competency in treating patients with disabilities to ensure they offer appropriate treatment services to this population. Referring patients with disabilities to other community services for additional support is also encouraged.	The Americans with Disabilities Act protects people with OUD who are in treatment or recovery from discrimination, including in criminal justice settings. For example, people receiving MOUD cannot be denied access to their medication, including while in the prison system. For more information on how OTPs can better serve people with intellectual and developmental disabilities. *Advisory:* Mental and Substance Use Disorder Treatment for People With Physical and Cognitive Disabilities | SAMHSA

Exhibit 1. Key Considerations and Resources for OTPs by Population			
Population	**Key Considerations**	**How OTPs Can Help**	**Resources**
People who identify as sex workers	Sex workers may have significant trauma because of the increased risk of sexual assault and physical harm they may have faced in the past. These experiences may affect their willingness to engage in treatment at OTPs. For those who continue to engage in transactional sex work, developing safety plans, avoiding cues and triggers related to opioid and other substance use, and promoting health and reproductive autonomy may increase engagement and improve outcomes.	Individuals with a history of sex work may have experienced trauma, including assault and violence. These experiences can impact engagement in treatment settings. OTPs should prioritize trauma-informed care and create safe spaces for individuals with such histories. Developing strategies to enhance safety, reduce triggers, and promote overall well-being can improve treatment outcomes and engagement. In addition to embracing trauma-informed approaches in care, OTPs can help support this population by teaching harm-reduction strategies (especially those related to sex work and HIV prevention). [162]	Refer to the U.S. Department of Health and Human Services (HHS) Overdose Prevention Strategy webpage for more information on trauma-informed approaches to care and harm reduction.

Exhibit 1. Key Considerations and Resources for OTPs by Population			
Population	**Key Considerations**	**How OTPs Can Help**	**Resources**
People who have acute or chronic pain	Comprehensive pain assessments are essential for effectively managing acute and chronic pain, especially among individuals with OUD. To optimize treatment outcomes, providers should consider the multifaceted nature of pain, including its impact on physical, emotional, and functional status, without overburdening patients.	For this population, patients can and should receive MOUD and receive treatment for their pain simultaneously, preferably with non-opioid pharmacological medications and other pain interventions. [163] However, opioid analgesia should not be withheld from patients with OUD if needed for adequate pain management, as pain can itself be a trigger for OUD recurrence. Pain management, including with opioids if needed, can be managed by an outside practitioner, while care coordination can occur between the OTP and the external practitioner. Patients in recovery, including those taking MOUD, may want to avoid opioid analgesic medications, if possible. OTP practitioners may want to consider split dosing of methadone or buprenorphine for this population as an additional opioid-sparing strategy. Patient education is necessary for informed consent and shared decision-making. [164]	In 2022, in conjunction with the U.S. Department of Defense, the VA published Clinical Practice Guidelines that discuss the use of opioids in the management of chronic pain. The Centers for Disease Control and Prevention (CDC) published a revised guideline on the use of opioids in the management of pain in 2022. Clinical Practice Guideline for Prescribing Opioids for Pain—United States, 2022 | CDC *Advisory:* Opioid Therapy in Patients With Chronic Noncancer Pain Who Are in Recovery From Substance Use Disorders | SAMHSA
People who have experienced trauma	Global estimates indicate that more than 70 percent of people experience at least one traumatic event in their lifetime. In the United States, 90 percent of adults report exposure to at least one traumatic event. [165]	OTPs can help by implementing trauma-informed care to those who have experienced trauma.	Trauma and Violence | SAMHSA *Practical Guide for Implementing a Trauma-Informed Approach* | SAMHSA

Initial and Periodic Physical and Behavioral Health Assessment Services

42 CFR § 8.12(f)(4). Initial and periodic physical and behavioral health assessment services. (i) Each patient admitted to an OTP shall be given a physical and behavioral health assessment, which includes but is not limited to screening for imminent risk of harm to self or others, within 14 calendar days following admission, and periodically by appropriately licensed/credentialed personnel. These assessments must address the need for and/or response to treatment, adjust treatment interventions, including MOUD, as necessary, and provide a patient-centered plan of care. The full, initial psychosocial assessment must be completed within 14 calendar days of admission and include preparation of a care plan that includes the patient's goals and mutually agreed-upon actions for the patient to meet those goals, including harm reduction interventions; the patient's needs and goals in the areas of education, vocational training, and employment; and the medical and psychiatric, psychosocial, economic, legal, housing, and other recovery support services that a patient needs and wishes to pursue. The care plan also must identify the recommended frequency with which services are to be provided. The plan must be reviewed and updated to reflect responses to treatment and recovery support services, and adjustments made that reflect changes in the context of the person's life, their current needs for and interests in medical, psychiatric, social, and psychological services, and current needs for and interests in education, vocational training, and employment services.

(ii) The periodic physical examination should occur at least once per year and be conducted by an OTP practitioner. The periodic physical examination should include review of MOUD dosing, treatment response, other substance use disorder treatment needs, responses and patient-identified goals, and other relevant physical and psychiatric treatment needs and goals. The periodic physical examination should be documented in the patient's clinical record.

Full Physical and Behavioral Health Assessments

The full physical and behavioral health assessments occur after the initial screening examination and admission to the OTP and are used to refine the care plan and establish a baseline for measuring how the patient responds to treatment. Assessment is the process of identifying the precise nature and extent of a patient's SUD and other physical and mental health issues. The full physical and behavioral health assessments should be conducted within 14 calendar days following admission to an OTP, and then periodically by appropriately licensed/credentialed personnel. The assessments, which can be done by one or more OTP personnel, include completing a thorough personal substance use history, physical and mental health examination, laboratory testing, and determination of other SUD, physical health and mental illness diagnoses and severity. The SUD history of each patient includes the natural history of substance use, including opioid use, as altered by time and treatment, as well as the patient's experience with treatment and recovery.

Patients starting treatment should be screened for mental health issues and imminent risk of harm to self or others. The risk for suicide is higher among individuals who misuse substances; thus, appropriate screening, intervention, and referrals for care are vital to patient health and engagement in treatment activities.

The full initial psychosocial assessment should include preparation of a care plan that identifies the patient's goals and mutually agreed-upon actions for the patient to meet those goals. When possible, goals should be specific, measurable, attainable, and patient-centered. However, some patients may want to work toward goals that are not as specific or measurable, and OTPs are encouraged to support goal attainment. Patients may agree to pursue engagement with harm reduction and recovery support

services, education, vocational training, and employment. The care plan also may include additional medical and psychiatric, psychosocial, economic, legal, housing, and other recovery support services.

Careful examination of mental, physical, and oral health, along with disability, harm reduction, and recovery support needs can inform staff about barriers patients may experience that may make it difficult to engage in treatment. Additionally, assessment tools and processes should be culturally informed and address race, ethnicity, sexual orientation, religion, gender identity, housing, and transportation issues, among others. Awareness of the social drivers of health, or conditions that affect a range of quality-of-life outcomes, can help OTP practitioners and clinicians as they assess patient needs in these areas. The HHS Office of Disease Prevention and Health Promotion groups social drivers, sometimes called determinants, of health into five domains: healthcare access and quality, education access and quality, economic stability, neighborhood and built environment, and social and community context. [166] Attention to a patient's needs in these domains can help inform the care plan.

The care plan also should identify the recommended frequency with which services are to be provided. The plan will need to be reviewed and updated periodically to reflect patient responses to treatment and recovery support services, as well as changes in patient goals. Adjustments can be made that reflect changes in the context of the patient's life; their current needs for and interests in medical, psychiatric, and social services; and current needs for and interests in education, vocational training, and employment services. Documentation of the care plan can be included as part of the progress notes as allowable under state regulations. A care plan is not a static event but is considered to be a continuous, evolving clinical process of SUD and OTP treatment services.

Ongoing Assessment and Support

42 CFR § 8.12(f)(4) requires periodic physical examination as part of ongoing assessment and support for continuity of care. These periodic exams should occur at least one time each year and be conducted by an OTP practitioner, given the medication management responsibilities of the OTP. While information from primary care providers and other practitioners external to the OTP can be helpful to include as part of these periodic exams, non-OTP providers may gloss over or miss important aspects of OUD treatment with methadone or buprenorphine. Therefore, the examination can include review of medication dosing, treatment response, other SUD treatment needs, patient-identified goals, and other relevant physical and psychiatric treatment needs and goals. Information from the examination should be documented in the patient's clinical record. Patient assessment will need to occur repeatedly throughout the treatment experience, as the stage of treatment, as well as the unique variables of the individual patient, will change over time.

Periodic evaluation of progress and outcomes provides an opportunity to reassess the patient's progress in addressing the needs identified during the initial assessment and admission process and identify new issues to be addressed. Procedures may include close examination or appraisal of a patient's health, including the patient's physical and psychosocial status. Results enable OTP practitioners and clinical staff to determine the patient's current degree of substance use and the length of time the patient has achieved remission and recovery or is currently struggling with unstable OUD and other SUDs. Ideally, results may also confirm successful progression through the patient's own care plan.

As such, it is important for OTPs to re-assess the effectiveness of the patient-centered care plan at regular intervals, such as during each treatment visit, or quarterly, unless otherwise dictated by applicable regulations and state rules. This ongoing assessment may be used to revise the care plan for greater efficacy, ensuring that the plan still aligns with and supports the patient's goals. Because patients' lives may shift during treatment, patient progress toward identified goals may be assessed as

part of the periodic evaluation, along with the feasibility and appropriateness of goals, as well as the response to treatment.

Patients taking MOUD who continue to misuse opioids or continue to use benzodiazepines and alcohol have an increased risk for opioid overdose. Further, the adulteration of street substances such as stimulants and counterfeit pills may also present overdose potential. Practitioners may decide to work with the patient to determine what needs are not being met and if a dose increase should be considered to address craving and withdrawal symptoms. [167] Other strategies may include medication change, split dosing, referrals for care coordination, assessment for higher levels of care, managed withdrawal of other substances, and other supportive services.

Many patients benefit from a full range of more intensive supports, including psychosocial services and medical treatment. Often, intensity and duration may be greater at the beginning of the treatment or at times of OUD recurrence. Since determination of services and service frequency is a shared decision between both the OTP multidisciplinary team and the patient, staff will need to skillfully navigate the therapeutic alliance to address concerns of vulnerability with the patient. Unless therapeutic benefits no longer outweigh risks, there should be no limits on a patient's duration of treatment or dosage level of medication. Likewise, there should be no limitations on the psychosocial services offered to patients, even when they no longer receive medication.

Programs should make every effort to retain patients in treatment as long as it is clinically appropriate, medically necessary, and acceptable to the patient. Maintaining a patient on medication, even when psychosocial services or other clinic services may not be yielding optimum results, is beneficial to both the individual patient and public health. In addition, pharmacotherapy may still benefit patients who require only minimal non-pharmacological behavioral services.

Assessing and Treating Co-Occurring Disorders

Patients with OUD often have one or more co-occurring disorders, such as other mental and substance use disorders. [168] Co-occurring disorders are most effectively treated and managed at a single treatment site. OTPs are in a strong position to offer integrated SUD treatment and other mental health services in a single setting. However, if the appropriate level of expertise is not available within the program, staff members can arrange for the patient to receive appropriate care elsewhere, while considering barriers to treatment (e.g., financial, housing, and transportation burdens, travel time to and from care, availability of childcare). For more information, see SAMHSA's Co-Occurring Disorders webpage.

OTP practitioners should have knowledge of SUDs and co-occurring mental disorders and able to offer or link patients to related services if they are not available within the OTP itself. OTPs may find it easier to address patients' co-occurring SUDs than co-occurring mental disorders. Patients may also present with or develop physical health conditions, both related and unrelated to the OUD, that need attention. Substance use may exacerbate chronic conditions such as diabetes and hypertension, whereas other conditions, such as HIV and hepatitis C virus (HCV) infections, may represent complications of the SUD. In either case, it is important for OTP practitioners to address co-occurring substance use and mental disorders and physical health conditions for optimal outcomes for patients with OUD. Thus, it may also be essential for OTPs to develop a referral and consultative relationship with a network of agencies and practitioners capable of providing primary and specialty services for the range of patients' co-occurring mental health conditions, medical complications, and infectious diseases if these services are not offered on-site. Information exchange across this network should both facilitate treatment and protect patient privacy.

Specifically, OTP practitioners and clinical staff should be familiar with the assessment, diagnosis, and treatment of SUDs, including those involving:

- Tobacco.
- Alcohol.
- Benzodiazepines.
- Cocaine.
- Other stimulants.
- Cannabis.

There may be special considerations with each SUD. However, MOUD should not be withheld or suspended if the patient has a co-occurring SUD, unless risks of providing MOUD within a given clinical circumstance exceed therapeutic benefits. [169] For example, Food and Drug Administration (FDA) guidance cautions practitioners about withholding MOUD from patients taking benzodiazepines or other drugs that depress the central nervous system. [170] More information is available from the FDA Drug Safety Podcast: FDA urges caution about withholding opioid addiction medications from patients taking benzodiazepines or CNS depressants: careful medication management can reduce risks. OTP practitioners need to evaluate patients without delay to assess and implement timely resumption of MOUD following any instance in which MOUD has been withheld or suspended.

Several resources are available from SAMHSA to help OTPs support patients with co-occurring disorders, such as:

- Screening and Treatment for Co-Occurring Mental Health and Substance Use Disorders video
- TIP 42, *Substance Use Disorder Treatment for People With Co-Occurring Disorders*
- TIP 63, *Medications for Opioid Use Disorder*

Given that gambling problems often co-occur with SUDs, [171] OTP practitioners may want to offer a brief screening to assess these issues early. Additional support may need to be provided to those who meet the *Diagnostic and Statistical Manual of Mental Disorders*, Fifth Edition, Text Revision, criteria for gambling disorder.

OTP practitioners and clinical staff should be familiar with the side effects of each MOUD and the best practices for addressing acute and chronic pain, including the use of split methadone or buprenorphine dosing and the need for routine monitoring of medications (including all opioids). All healthcare professionals, including practitioners working in OTPs and those caring for patients with OUD in other clinical settings such as emergency departments, would benefit from remembering that patients taking methadone or buprenorphine for OUD obtain relatively little pain relief from a once daily dose of these medications and may need other analgesia to manage acute or chronic pain. Temporarily increasing and splitting methadone or buprenorphine doses may be one strategy to avoid adding other opioids. Non-opioid pharmacological options and non-pharmacological pain interventions may be preferred. More information is available in SAMHSA's *TIP 54, Managing Chronic Pain in Adults With or in Recovery From Substance Use Disorders*

Addressing Oral Health Needs

Oral health and OUD are directly linked. Chronic opioid use is associated with tooth loss, extraction, and decay. [172] People with oral health conditions and OUD have been historically undertreated. [173] A lack of dental insurance or coordinated oral and behavioral health supports can exacerbate these disparities. Also, people with OUD may avoid oral health intervention because of associated stigma, negative prior

experiences, or concerns over adequate pain management for dental procedures. [174] OTP practitioners have an opportunity to address pertinent MOUD side effects, such as dry mouth; reinforce appropriate dental hygiene; and provide and support appropriate linkages to oral health care.

Regarding pain management during dental or oral health appointments, CDC offers recommendations and implementation considerations regarding non-opioid pain management options.

Harm Reduction Services

The revised rule promotes the incorporation of harm reduction principles, approaches, and services within OTPs as both a guiding framework and a set of strategies that can help support patients with OUD. Harm reduction services are essential components of comprehensive care for individuals with OUD. OTPs should integrate harm reduction principles and strategies to mitigate health risks and improve patient outcomes. [175]

Resource Alert: Understanding Harm Reduction

SAMHSA defines *harm reduction* as "a practical and transformative approach that incorporates community-driven public health strategies—including prevention, risk reduction, and health promotion—to empower people who use drugs (PWUD) and their families with the choice to live healthy, self-directed, and purpose-filled lives. Harm reduction centers the lived and living experience of PWUD, especially those in underserved communities, in these strategies and the practices that flow from them." [176]

SAMHSA's Harm Reduction Framework outlines harm reduction pillars, principles, and core practice areas that underpin harm reduction initiatives, programs, and services. [177]

Other resources that can help OTP staff learn more about harm reduction include:

- National Institute on Drug Abuse: Harm Reduction
- *TIP 65, Counseling Approaches To Promote Recovery From Problematic Substance Use and Related Issues*

Examples of harm reduction services include:

- **Overdose prevention:** Providing overdose education, overdose response training, and distribution of naloxone and other opioid overdose reversal medications.
- **Infectious disease prevention:** Offering testing and treatment for communicable infections, including HCV and HIV, as well as access to syringe services, as allowable by state and local laws.
- **Substance use safety:** Distributing fentanyl and xylazine test strips, as permissible by state and local laws, to reduce the risk of overdose from adulterated substances.
- **Supportive services:** Addressing basic needs such as food, hygiene, and housing to enhance overall well-being. [178]

By incorporating these services, OTPs can create a supportive environment that promotes health and recovery while acknowledging the complex realities of substance use. [179]

The OTP's ability to distribute opioid overdose reversal medications and offer related overdose education programs is critical to reducing risks of overdose among patients. These services have successfully reduced opioid overdose deaths in recent years. [180] Naloxone and other opioid overdose reversal medications can rapidly reverse an opioid overdose and are essential harm reduction tools for people who take opioids or have an OUD. OTPs should have naloxone or another opioid overdose reversal medication available on-site for patients, should have staff trained to use it, and should ensure that patients and the people around them have naloxone or other opioid overdose reversal medications

readily available. Even patients who may not themselves be at the highest risk for overdose may be in a position to save someone else's life from overdose by carrying naloxone or another opioid overdose reversal medication. All OTP staff should have awareness and working knowledge of naloxone and other opioid overdose reversal medications. They should know how to recognize and respond to an overdose and know other harm reduction strategies that can help support positive change and the recovery goals of their patients.

Resource Alert: Naloxone and Other Opioid Overdose Reversal Medications

Some online naloxone-related resources include:

- SAMHSA's Overdose Prevention and Response Toolkit
- SAMHSA's Opioid Overdose Reversal Medications webpage
- CDC's Lifesaving Naloxone webpage
- The National Harm Reduction Coalition' Understanding Naloxone webpage

The revised rule also allows OTPs to distribute supplies that enable patients to test their personal drug supply for adulteration with substances, such as fentanyl, which, when present, increase the risk of overdose. This drug-checking approach is typically combined with overdose education and distribution of opioid overdose reversal medications for greatest impact.

On April 7, 2021, SAMHSA and CDC published a joint announcement stating that federal funding could be used to purchase rapid fentanyl test strips for drug-checking purposes. [181] In the summer of 2023, the FDA approved a moderate-complexity point-of-care (POC) urine test for detecting fentanyl in human urine samples. OTPs should be familiar with FDA-approved tests for distribution and use in the clinic. Other laboratory testing to detect fentanyl is available, but it requires sending samples to a laboratory. Test results are available to OTP practitioners and clinical staff within several days after specimen collection.

Incorporating fentanyl testing has become increasingly important for OTPs given the dramatic spike in overdose deaths, which has been largely driven by the use (both intentional and unintentional) of potent synthetic opioids, primarily illegally made fentanyl. Fentanyl test strips can be used as a harm reduction, drug-checking strategy to determine whether drugs contain fentanyl. Testing provides communities and people who use drugs, especially those who may also use cocaine and methamphetamine, with important information about fentanyl so they can take steps to reduce their risk of overdose.

Harm reduction strategies are described in more detail in the Evidence-Based Practices section.

Testing for Emerging Substances

The landscape of substance use and misuse is constantly changing and varies by community. Testing for emerging substances can provide additional information about the risk of exposure for patients and inform medication treatment. One example of an emerging substance that OTPs and practitioners may consider testing for is xylazine, a veterinary tranquilizer used to sedate large animals. Xylazine is not approved for human use. [182] In November 2022, the FDA issued an alert cautioning healthcare professionals about the dangers of xylazine, including sedation, increased overdose risk when combined with fentanyl, and development of necrotic wounds. Xylazine has been detected in fentanyl, heroin, and other illicit drug overdoses. Its effects may not be reversible with naloxone, but naloxone or other opioid overdose reversal medication should still be administered in any potential overdose situation because of the virtually universal presence of fentanyl along with xylazine. Because routine drug testing does not detect xylazine, FDA recommends identifying other strategies for screening patients at risk for xylazine exposure. These strategies can include understanding the epidemiology of the local drug supply. [183]

Care and Case Management

These revised OTP guidelines call for OTPs to develop comprehensive approaches for providing care to people with OUD. SAMHSA recommends incorporating a recovery-oriented approach to care planning and clinical care, which includes a strength-based partnership between patient and counselor. Recovery orientation is grounded in the assumption that recovery from problematic substance use occurs along different pathways, is shaped by the patient's goals, takes time, and may include abstinence or reduced use. This paradigm also acknowledges that patient goals typically change over time, and clinicians should be adequately prepared to use motivational interviewing techniques to clarify patient goal-related changes and as a tool of exploration and planning with the patient. [184]

Care management is an overarching, coordinated, individualized approach that links patients with services to address their needs and achieve their goals. For patients with OUD, care management can help them focus on and stay in care [185] and connect them to critical resources to support them should they leave treatment. An important role for care managers is building relationships in the community that can support patients at all stages of treatment and recovery.

Care management should not be confused with case management. Care management should include treatment and care planning and refers to an ongoing, comprehensive approach to assist patients with managing one or more chronic conditions. Within the context of the guidelines, care management refers to processes that occur within the OTP but may include care coordination with agencies and supports outside of the OTP. Case management, on the other hand, is usually time-limited and provided by one point of contact for specific needs, such as transportation and other recovery supports. [186]

For example, case managers can facilitate communication among and offer referrals to programs that provide or financially support the provision of physical, mental health, social, housing, employment, educational, or other follow-up services when the OTP does not offer these services onsite. [187]

Key principles of case management include: [188]

- Offering patients a single point of contact with a healthcare or social service system.
- Ensuring community-based, patient-centered services and care.
- Providing services that are culturally sensitive, non-stigmatizing, and pragmatic.

Resource Alert: Care Management and Case Management

The Center for Medicare & Medicaid Services' *Chronic Care Management Toolkit* provides resources and education about chronic care management for improving patient health and satisfaction.

SAMHSA's *Advisory:* Comprehensive Case Management for Substance Use Disorder Treatment provides information about principles and models of case management, discusses reasons SUD treatment providers might consider implementing or expanding the use of case management, and lists some case management-related resources and tools.

Care Planning

Care planning should be conducted by skilled OTP practitioners and clinical staff members who understand the importance of an empathic, positive approach and who engage in shared decision-making with the patient to understand and incorporate that person's individual preferences, needs, values, and their level of recovery capital into the care plan. [189, 190] The clinical staff involved in care planning collaborate with the patient to develop a care plan. This care plan also identifies others who are supportive of the patient's treatment and recovery goals. The Counseling Treatment and Recovery Support Services section discusses recovery supports in detail.

SAMHSA offers recovery support tools and resources on a number of topics, including shared decision-making, that can help OTP staff actively engage in person-centered interactions with patients. In addition, TIP 65, *Counseling Approaches To Promote Recovery From Problematic Substance Use and Related Issues* discusses the skills necessary to provide recovery-oriented services that incorporate a strengths-based, patient-centered approach.

Counseling and Recovery Support Services

42 CFR § 8.12(f)(5). Counseling and psychoeducational services. (i) OTPs must provide adequate substance use disorder counseling and psychoeducation to each patient as clinically necessary and mutually agreed-upon, including harm reduction education and recovery-oriented counseling. This counseling shall be provided by a program counselor, qualified by education, training, or experience to assess the psychological and sociological background of patients, and engage with patients, to contribute to the appropriate care plan for the patient and to monitor and update patient progress. Patient refusal of counseling shall not preclude them from receiving MOUD.

(ii) OTPs must provide counseling on preventing exposure to, and the transmission of, human immunodeficiency virus (HIV), viral hepatitis, and sexually transmitted infections (STIs) and either directly provide services and treatments or actively link to treatment each patient admitted or readmitted to treatment who has received positive test results for these conditions from initial and/or periodic medical examinations.

(iii) OTPs must provide directly, or through referral to adequate and reasonably accessible community resources, vocational training, education, and employment services for patients who request such services or for whom these needs have been identified and mutually agreed-upon as beneficial by the patient and program staff.

Counseling Services

OTPs should offer patients evidence-based, quality, and empathetic SUD counseling and psychoeducation services to aid in achieving their treatment and recovery goals as their needs evolve and change over time. Quality counseling requires structured, trauma-informed, and evidence-based

interventions to treat patients. Evidence-based interventions, such as motivational interviewing, cognitive–behavioral therapy, and contingency management have demonstrated effectiveness with people with SUDs. See the Evidence-Based Practices section for more information on various treatment modalities.

Types, Frequency and Intensity of Counseling

Patients may seek or benefit from different types, frequencies, and intensities of counseling. For some, counseling may include only periodic visits with an OTP practitioner or clinical staff member to assess response to treatment services and progress toward treatment goals, work through necessary care or case management needs, reinforce harm reduction education and access to related services, and identify additional needs or concerns that may have arisen. Other patients may benefit from a structured intervention, such as group counseling sessions, psychoeducational groups, or intensive outpatient treatment services with an increased frequency (i.e., "dose") of group and individual counseling sessions. Patients should continue to have access to MOUD while OTP practitioners and clinical staff work to engage them in recommended services.

In general, counselors can support patients by: [191]

- Identifying and building on the strengths of the patient.
- Letting the patient's preferred recovery goals and pathway shape their work together.
- Taking a supportive approach to counseling, which addresses the patient's needs, wishes, and values.

Connecting the client to recovery support and other services that can improve their well-being and quality of life.

It is recommended that OTP practitioners and clinical staff become familiar with Motivational Enhancement Therapy, [192] particularly the Transtheoretical Model (Stages of Change), [193] to recognize patient "change talk" and support any positive changes patients make in their substance use. This approach can help practitioners and clinical staff understand their patients' decisions about counseling and other service engagement. In addition, motivational interviewing can be a helpful counseling technique for helping patients who feel ambiguity about taking MOUD, especially if loved ones have expressed disagreement with treatment choices.

To determine which potential areas to address in counseling, counselors should evaluate each patient's pattern of opioid use, screen and assess for the presence of other SUDs, identify any risk of exposure to infectious diseases, and identify any potential co-occurring psychiatric or medical conditions and talk with the patient about their use. When patients continue to use other substances in ways that reduce the effectiveness of MOUD, counselors may consider other factors, SUDs, or mental health conditions that may be involved. All OTP staff are encouraged to maintain a nonjudgmental, compassionate demeanor as they work with patients. In cases where patients have co-occurring conditions or are at risk for infectious disease transmission, additional services may complement MOUD and harm reduction services. All efforts to provide the patient with information about counseling should be documented.

> OTPs should be aware that individual states may have their own counseling requirements. The same may be true of third-party payers. OTPs should adhere to the requirements of their states in a manner that is patient centered and offers benefit to the patient.

Patients also can seek counseling outside the OTP, or the OTP may assist with coordination of care. The OTP staff can provide or refer patients for specific counseling for HIV, viral hepatitis, sexually

transmitted infections, or other infectious diseases. OTPs can also provide patients and their partners with referrals for or linkages to treatment of these conditions, but the need for counseling in these areas must be addressed. OTP practitioners and clinical staff are optimally suited to provide these services given the challenge patients may experience by having to obtain services in multiple locations.

42 CFR § 8.12(f)(5)(iii) states that OTPs should offer adequate medical, counseling, vocational, and educational services along with other assessments and treatment services. Although OTPs are required to offer counseling, a patient's refusal to participate in a counseling session should not result in withholding a medication dose. As OTPs work to develop policies and procedures to address these changes, they may find SAMHSA's technical assistance resources helpful.

It is expected that counselors in OTPs will be skilled in the core or foundational counseling competencies as well as in more specific competencies to support their specific work. The Differentiated Competency Model offers a framework for understanding core and specific competencies. The four transdisciplinary foundational competencies are: [194]

- Understanding SUDs.
- Treatment knowledge.
- Application to practice.
- Professional readiness.

The eight SUD-specific practice dimensions representing expanded competencies are: [195]

- Clinical evaluation.
- Care planning.
- Referral.
- Service coordination.
- Counseling.
- Patient, family, and community education.
- Documentation.
- Professional and ethical responsibilities.

More information about these competencies is available in the SAMHSA *Advisory*, The Substance Use Disorder Counseling Competency Framework: An Overview.

Resource Alert: Levels of Care

The American Society of Addiction Medicine (ASAM) offers a framework that supports clinicians in assessing and determining the most appropriate level of care. The ASAM Criteria is the most widely used and comprehensive set of standards for placement, continued service, and transfer of patients with addiction and co-occurring conditions. For more information, or to find out if your state has adapted ASAM Criteria, see ASAM's State Implementation guidance.

Cultural Responsiveness

OTPs should be sensitive to the culture, identities, and values of patients (e.g., gender, sexual orientation, age, language, co-occurring disorders, developmental/other disabilities) and offer counseling and other treatment supports tailored to those needs. All program staff will need to be culturally responsive and be able to work effectively with their local community to solicit input from

community members and to accept the advice of individuals with knowledge of gender, cultural, and language issues.

In addition, written nondiscrimination policies can ensure equal access to treatment for all persons in need, regardless of race, ethnicity, gender, sexual orientation, disability, language, and age (with specific reference to policies for minors). All printed materials, electronic media, and course offerings can employ unbiased and nonprejudicial language. Policies and services should be available in a language the person served understands.

Evidence-Based Practices

Several evidence-based practices have been discussed across this document. These practices are strategies shown to be effective in reducing the negative effects of substance use and SUDs. In addition to MOUD, common evidence-based practices implemented in OUD treatment and recovery include: [196]

- Harm reduction.
- Motivational interviewing.
- Contingency management.
- Cognitive–behavioral therapy.
- Recovery support services.

Harm Reduction

Harm reduction is an evidence-based approach that can be effective in reducing the harms associated with substance use. Specific harm reduction principles, approaches, and practices are discussed in more detail in the Initial and Periodic Physical and Behavioral Health Assessment Services section.

Motivational Interviewing

Motivational interviewing is a person-centered counseling technique that is widely used in SUD treatment to explore uncertainty about changing behaviors that may be related to problematic substance use. This approach emphasizes compassion, patient autonomy, acceptance, and bringing forward a patient's thoughts and ideas about their goals. Motivational interviewing can help strengthen patients' motivation to participate in treatment and make decisions that support their recovery. [197]

SAMHSA's *Advisory:* Using Motivational Interviewing in Substance Use Disorder Treatment discusses how healthcare professionals can effectively use motivational interviewing in SUD treatment and provides tools that they can use. [198]

Contingency Management

Contingency management is an evidence-based treatment practice grounded in the principle of operant conditioning. In this approach, patients can increase desired behaviors while reducing negative behaviors. Incentives, prizes, or privileges provide immediate reinforcement for substance nonuse, which encourages positive behavior change. [199] In patients with OUD, contingency management can be an effective strategy for improving outcomes in patients, such as engagement in treatment activities. [200]

SAMHSA's *Treating Concurrent Substance Use Among Adults*, an evidence-based guide, offers more information about contingency management. [201]

Cognitive–Behavioral Therapy

Cognitive–behavioral therapy is a common evidence-based treatment intervention for people with SUD. This therapy is grounded in the assumption that people continually interpret and respond to information perceived from their internal and external environments. People then use this information to develop representations of their environments in the form of thoughts, attitudes, and beliefs. These representations affect how people feel and behave. Cognitive–behavioral therapy focuses on helping people change their thought patterns and risk behaviors in ways that support and sustain recovery. [202, 203]

Examples of cognitive–behavioral therapy strategies include: [204]

- Learning to recognize, reevaluate, and replace unhelpful thought patterns that contribute to behaviors related to substance use.
- Learning about the behavior and motivation of others.
- Using problem-solving skills to cope with challenging situations.
- Developing confidence in one's own abilities.

SAMHSA's TIP 65, *Counseling Approaches To Promote Recovery From Problematic Substance Use* contains more information about cognitive–behavioral therapy in practice.

Recovery Support Services

OTPs can include recovery support services in their patients' care plans. Recovery support services may involve connecting patients to recovery housing, mutual support groups, and recovery community organizations. Evidence suggests that recovery support services, particularly peer recovery supports, can help patients with SUD increase treatment engagement, motivation, and retention; adherence to SUD care plans; general self-efficacy; and satisfaction with the overall treatment experience, among other outcomes. [205]

Peer support specialists (also known as peer support workers, recovery coaches, peer specialists, or peer advocates) are nonclinical professionals who have lived experience with substance use or SUDs. They can play an important role in helping patients achieve their recovery goals. [206] Peer support specialists can serve as educators, facilitators, role models, mentors, resource navigators, and recovery advocates. Peer support specialists are experts with lived experience, working across the community as support advocates. These staff help build relationships within the community and with the patient to promote well-being, safety, and recovery as the patient defines it. They also collaborate with others as a part of the OTP care team and build connections with social service agencies, local businesses, and other organizations that can help provide support to a patient. [207] There are a variety of peer roles, titles, and credentials, which vary from state to state.

OTPs can offer recovery support services for problematic substance use and ensure that individuals in or seeking recovery are aware of and can access these services, including those provided by peer support specialists.

Training and certification requirements for peer support specialists differ by state. Although no single peer certification is accepted nationwide, some states recognize certifications from other states. [208]

Resource Alert: Peer Support Specialists

SAMHSA provides information and guidance on the role of the peer support specialist (PSS) in recovery. The following resources contain more information about peer support:

- The National Model Standards for Peer Support Certification offers guidance to promote quality and encourage alignment and reciprocity across state peer support certification entities. The Model Standards were created to broaden adoption and integration of the peer workforce and to strengthen the foundation set by the peer workforce. [209]
- TIP 64, *Incorporating Peer Support Into Substance Use Disorder Treatment Services* contains more information about PSS. The TIP discusses how to successfully integrate and sustain the services peer workers provide, how to manage and supervise peers to avoid role drift and confusion, required training and certification, family peer services, and the benefits and challenges peer workers often experience.

As the peer support specialist position may be relatively new in OTPs, guidance on developing job descriptions may be needed. Developing clear job descriptions for a peer specialist position can ensure that this position's role and responsibilities are clear to the person applying and other staff at the OTP. Additionally, the more care taken in developing clear job descriptions for peer positions, the better chance a program has of successfully incorporating recovery support services and peer support specialists into the program. Poorly defined peer job descriptions can lead to role confusion and organization-wide misunderstandings about the duties of peer specialists, making it hard for them to succeed and integrate into the workplace. Leadership or other staff involved in hiring peer support specialists may want to consult with other OTPs that provide recovery support services, reviewing their peer specialist job descriptions and discussing how the job descriptions helped or hurt the process of hiring and integrating peer specialists. The job description can also specify whether applicants need to hold state certification or be in the process of becoming certified. [210]

Recovery-Oriented Systems of Care

A recovery-oriented system of care (ROSC) includes a network of services that connects and coordinates multiple sectors that are often traversed by people with SUD and co-occurring mental health conditions. The network includes specialty SUD treatment providers, mental health and physical health services, acute care medical services, social services, recovery community organizations and other recovery support services, housing services, and first responders and law enforcement. [211] OTPs play a critical role within a community's ROSC and can advocate for and support patients across systems that may not have full understanding of patient needs, MOUD, or the services provided by the OTP. This support can help reduce the stigma encountered by patients taking methadone or buprenorphine.

Resource Alert: Recovery-Oriented Support

SAMHSA provides information and guidance for supporting people in recovery.

- TIP 65, *Counseling Approaches To Promote Recovery From Problematic Substance Use and Related Issues* provides guidance to counselors, administrators, and supervisors about recovery-oriented services, supports, and care, allowing them to better serve individuals in or seeking recovery from problematic substance use.
- Recovery from Substance Use and Mental Health Problems Among Adults in the United States presents self-reports of recovery among adults ages 18 and older in the United States. These findings provide a clearer characterization of the factors associated with recovery among adults and how future efforts can foster a whole-health approach to sustain recovery from mental health and substance use conditions.

Other resources discussing recovery-oriented care include:

- Recovery Oriented Methadone Maintenance is a seminal monograph that presents considerations for more effective methadone treatment.
- Recovery-Oriented Systems of Care: A Perspective on the Past, Present, and Future presents an overview of ROSC, its history, and considerations for the future conceptualization. [212]

Additionally, in playing a role in a ROSC, and adopting a recovery-oriented approach, OTPs can more quickly connect their patients with necessary services and supports. For instance, a patient with OUD may also have a psychiatric condition. With ROSC participation, an OTP may be poised to more quickly connect a patient receiving MOUD to a licensed mental health professional in the community to address psychiatric concerns. With patient consent, the mental health practitioner may communicate with the OTP practitioner to ensure continuity of care.

A ROSC approach is: [213]

- Individually tailored to each patient's needs.
- Person centered.
- Committed to continuity of care and integrated services.
- Trauma informed.
- Culturally responsive.
- Inclusive of family and significant supports.
- Evidence based.
- Outcomes driven.
- Inclusive of the lived experiences of patients.

When OTPs engage in the ROSC approach, they can support patients in meeting their recovery goals within their own environment. OTPs can accomplish this by developing relationships with other healthcare practitioners, including mental health service providers and community organizations.

A critical aspect of recovery is ensuring ongoing access to resources that aid patients in managing their care, improving their health, rebuilding their relationships, and leading meaningful lives. [214] A recovery-oriented approach emphasizes shared decision-making, meeting people where they are, and working with patients to determine the best support services during various points in the recovery process.

Drug Testing Services

42 CFR § 8.12(f)(6). Drug testing services. When conducting random drug testing, OTPs must use drug tests that have received the Food and Drug Administration's (FDA) marketing authorization for commonly used and misused substances that may impact patient safety, recovery, or otherwise complicate substance use disorder treatment, at a frequency that is in accordance with generally accepted clinical practice and as indicated by a patient's response to and stability in treatment, but no fewer than eight random drug tests per year patient, allowing for extenuating circumstances at the individual patient level. This requirement does not preclude distribution of legal harm reduction supplies that allow an individual to test their personal drug supply for adulteration with substances that increase the risk of overdose.

The purpose of drug testing is to support patients in meeting their treatment and recovery goals. In the past, drug testing focused on identifying ongoing substance use and was often used in a punitive manner. Current drug testing approaches are designed to affirm patient progress, uphold patient dignity, and support patient recovery within a therapeutic environment. OTPs are encouraged to engage patients with transparency in all aspects of drug testing treatment components, as drug test results provide OTPs, practitioners, and patients with information and considerations for the types of individualized treatment and supportive services that might be beneficial.

After a patient's initial drug test at admission, practitioners can determine the frequency of drug testing by evaluating the clinical appropriateness in relation to the patient's stage of treatment and by performing a risk assessment. Although 42 CFR part 8 specifies that patients should receive a minimum of eight drug tests per year, programs may be able to request exemptions under § 8.11(g) for patients who may not require this frequency of drug testing or who are not able to meet this requirement for medical or other documented reasons. Practitioners should discuss testing frequency with patients to ensure shared decision-making.

Drug test results can inform decision-making for take-home medication doses or signal necessary changes to treatment interventions or care plans, but no treatment decision should rely solely on these results. Clinical care decisions can be driven by drug test results along with patient outcomes such as retention in treatment, lack of withdrawal symptoms, reductions of illicit drug use, improvements in physical and mental health, increased sense of stability, reductions in criminal activity, and improvements in employment, housing, and interpersonal relationships. [215]

Drug Testing

Drug testing panels typically test for opiates and opioids, including fentanyl, methadone and its metabolites, and buprenorphine and its metabolites; benzodiazepines; cocaine; and amphetamines. Panels also may test for barbiturates, delta-9-tetrahydrocannabinol, and metabolites of alcohol. Practitioners can decide to test for specific substances based on patterns of drug use in the community, the patient's self-reported substance use, assessed risk of use of particular substances, the specific clinical situation, and other medical indications.

It is recommended that presumptive (also referred to asor screening) test panels include tests for benzodiazepines, barbiturates, and alcohol, often done by testing for ethyl glucuronide. Alcohol is the most widely used mood-altering substance in the United States, and benzodiazepines and barbiturates are often prescribed for withdrawal management and chronic seizure disorders. Opioid use leads to respiratory depression, and when coupled with other (respiratory) depressants, such as alcohol, barbiturates, or benzodiazepines, the combined effects can be detrimental. [216] Therefore, the detection

of benzodiazepines, barbiturates, or alcohol is an important part of ongoing assessment, care planning, medication management, and patient safety. If these substances are detected during drug testing, it is important to discuss the reasons for their use with the patient and to work with patients to include external prescribers, with appropriate patient consent, in discussions about medication management. Benzodiazepines, barbiturates, and alcohol should not be suddenly stopped, as the risk of seizure and adverse events increases. OTPs may also decide to prioritize the testing of substances based on trends and patterns specific to the geographic location of the clinic.

POC drug testing can be offered at OTPs. POC tests can be used to test urine and, less commonly, oral fluid samples for a small number of drugs and a relatively narrow range of drug classes (e.g., opioids, including methadone and buprenorphine, benzodiazepines, barbiturates, cocaine, amphetamines—the specific drugs vary depending on the test panel used). These tests may use sensitive automated immunoassay technologies and may require certificates from state laboratory authorities. Tests approved for use under the Clinical Laboratory Improvement Amendments (CLIA) may require a CLIA Certificate of Waiver. [217, 218] Although POC tests have a role in clinical decision-making, they are insufficient for forensic or employment-related purposes and may not provide the full complement of results (e.g., for methadone or buprenorphine metabolites) for clinical management of MOUD. Practitioners should use their best judgment and may want to consult national guidelines to determine the type of testing to use with each patient. [219]

In particular clinical situations, OTPs may want to pursue more sophisticated, confirmatory laboratory-based drug testing. This type of testing (i.e., gas chromatography–mass spectrometry, liquid chromatography–mass spectrometry, tandem mass spectrometry) provides definitive test results about the specific substances used, including metabolites. This testing should be included in the OTP's established procedures for addressing potentially false positive test results when a patient's history and test result do not align, and in situations in which there is clinical concern for a false negative result on immunoassay-based tests.

OTPs and practitioners are encouraged to select the type of drug test and collection method on a patient-by-patient basis and to make testing as minimally invasive as possible. Although urine samples traditionally have been used for testing, the revised rule does not specify urine as the only type of biological sample that can be tested. Methods of testing and reliability in oral fluid testing have improved significantly in the last two decades, [220] and it is SAMHSA's view that sufficient information is now available for medical directors to decide on the adequacy of oral fluid testing in the OTP setting.

Individual states may adopt specific language or requirements related to the type of biological specimen acceptable for testing. In addition to reviewing these Guidelines, OTPs should be aware of and carefully comply with any regulations or requirements imposed by the state that exceed federal standards related to drug testing.

Collection of toxicology samples should be managed in a therapeutic context that conveys trust and respect. Observed urine collection can be distressing or re-traumatizing for patients—but particularly for transgender people, who are statistically more likely to have experienced sexual violence and may feel especially uncomfortable with observation during specimen collection. [221, 222] (Exhibit 2 outlines processes OTPs can adopt to support the needs of transgender individuals who are asked to provide specimens for drug testing.) Reliance on direct observation is neither necessary nor appropriate for all patients.

Exhibit 2. Supporting People Who Are Transgender in Drug Testing Services

Transgender individuals have unique considerations when providing urine samples for drug testing. Drug testing procedures should aim to eliminate shame and promote a supportive environment by using the following strategies:

- **Inclusive language:** Use gender-affirming and gender-inclusive language when discussing drug testing procedures. Respect individuals' gender identities and use the names and pronouns they specify.
- **Privacy and dignity:** Prioritize privacy during drug testing to uphold the dignity of individuals. Provide a designated and private space, ensuring confidentiality and respect for personal boundaries.
- **Cultural responsiveness:** Ensure staff members are trained in cultural responsiveness related to transgender issues. Understand the potential effect of stigma and discrimination, and work to create an affirming and supportive environment.
- **Sensitivity training:** Provide training to staff members that specifically addresses the unique considerations and sensitivities involved when transgender individuals provide biologic samples for drug testing. Sensitize staff to the potential discomfort transgender individuals may feel during the process, and foster empathy and understanding among staff.
- **Flexibility in procedures:** Be flexible in sample collection procedures to accommodate the diverse needs of transgender individuals. Adapt protocols to respect individual preferences, ensuring the person providing the sample feels comfortable and affirmed.
- **Gender-affirming practices:** Implement gender-affirming practices among staff collecting biologic samples for drug testing. Emphasize respect for gender identity.

For more information on best practices for specimen collection from transgender people, review the National Drug and Alcohol Screening Association's Guidance for Transgender Collections Under Direct Supervision webpage.

Discussing Results

During discussions with patients about drug testing and test results, testing is best framed as a way for practitioners to monitor progress and adjust care plans—not as a way to identify misuse. The practitioners and clinical staff members who discuss the results of drug tests with patients should have a thorough understanding of testing procedures, differences among laboratories, and the factors that affect the absorption, metabolism, and elimination of opioids and other substances.

For drug testing to be an effective therapeutic tool, OTPs should promptly discuss the results with patients and document both the results of the tests and any follow-up interventions in the patient record. Practitioners can rapidly intervene to therapeutically address the disclosure of misuse of drugs, a positive drug test, or possible diversion of opioid medication, as may be evidenced by the absence of opioids or related metabolites in drug test results. Practitioners and clinical staff members who have conversations about test results that indicate a patient may not be taking medication as ordered should consider the different reasons for the unexpected test result, be nonpunitive, and seek to understand the patient's behavior and goals.

An unfavorable test result is not necessarily an imperative to take immediate action. The following best practices may be considered when discussing drug test results with the patient: [223]

- Share that drug testing is used as a tool to gather information—it is not intended to be used to "catch" patients in "wrongdoing."
- Affirm patient motivation and progress.
- Share that the purpose is to monitor patient safety on medication.

- Use a patient-centered approach and language.
- Discuss patient goals and a care plan in relation to the positive test findings.

More information on talking to patients about drug test results is available in SAMHSA's TIP 63, *Medications for Opioid Use Disorder*.

Discharging patients from OTP care based solely on drug test results contradicts the purpose of treatment and the principles and values undergirding the revised 42 CFR part 8 rule, including patient-centered care, harm reduction, and shared decision-making. Positive test results can be used as information to help the OTP practitioners and the patient determine whether changes to the care plan would be helpful. The information can help practitioners and patients re-evaluate goals and decide whether medication dose changes, changes in the type of MOUD, or other supportive services are needed. As substance use may continue for some time or re-occur during treatment, OTP practitioners and clinical staff must be prepared to address ongoing or intermittent substance use as part of treatment. It is also important to differentiate between the use of substances and the presence of a SUD, as they are not equivalent.

Random drug testing may be part of a patient's care plan but should not be disruptive to the patient. If the goals are positive change, recovery, engagement in treatment, and retention in care, random drug testing should be feasible for patients without causing major disruption to their work, education, and life. Also, patients can refuse drug testing or blood work at the OTP and may elect to be tested by their own doctor instead. Should a patient choose to have drug testing done elsewhere, releases of information should be completed to allow practitioners to obtain those results and communicate about the test results and the patient's care plan to maintain patient safety and continuity of care. OTPs are encouraged to develop policy and procedure pertaining to coordination of care for external drug testing circumstances.

Other Laboratory Testing

As discussed in the Initial Medical Examination Services section, people with SUDs, especially those who inject substances, have an increased risk of bloodborne infections. For example, injection drug use is a direct route of HIV and HCV transmission. People living with HIV are at high risk of having another sexually transmitted infection, with increased odds of having co-occurring HCV infection. [224] Thus, OTP practitioners may request additional laboratory testing to determine if a patient has a sexually transmitted infection, HIV, or HCV. [225]

If a patient tests positive for HIV, they may discuss options for care with their OTP practitioners, including antiretroviral treatment. Patients may elect to use an outside provider for laboratory testing of other infectious diseases. For those who choose to test within the OTP, test results may lead to a conversation about the risk of exposure, enabling the practitioner to provide education and discuss harm reduction strategies.

Serology testing for hepatitis can determine if a patient is positive, as well as the type of hepatitis (e.g., hepatitis B or C). With this information, practitioners can help reduce spread and support patients in determining the best option for treatment or vaccination. Given the highly effective, well-tolerated, and curative nature of the direct-acting antiretrovirals for HCV that are now available, OTPs are particularly well-suited to serve as sites for testing and treating patients with HCV.

Resource Alert: Addressing HCV in OTPs

The Addiction Technology Transfer Center's HCV Current Initiative provides the resources for OTP implementation of infections disease prevention, screening, and treatment services. The following Toolkits are currently available:

- Your Guide to Integrating Infectious Disease Testing and Treatment Services in Opioid Treatment Programs
- Your Guide to Integrating HCV Services into Opioid Treatment Programs
- Supplement to Your Guide to Integrating HCV Services into OTP

Medication Administration, Dispensing, and Use

42 CFR § 8.12(h). Medication administration, dispensing, and use. (1) OTPs must ensure that MOUD are administered or dispensed only by a practitioner licensed under the appropriate State law and registered under the appropriate State and Federal laws to administer or dispense MOUD, or by an agent of such a practitioner, supervised by and under the order of the licensed practitioner and if consistent with Federal and State law.

(2) OTPs shall use only those MOUD that are approved by the Food and Drug Administration under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) for use in the treatment of OUD. In addition, OTPs who are fully compliant with the protocol of an investigational use of a drug and other conditions set forth in the application may administer a drug that has been authorized by the Food and Drug Administration under an investigational new drug application under section 505(i) of the Federal Food, Drug, and Cosmetic Act for investigational use in the treatment of OUD. Currently the following MOUD will be considered to be approved by the Food and Drug Administration for use in the treatment of OUD:

(i) Methadone;

(ii) Buprenorphine and buprenorphine combination products that have been approved for use in the treatment of OUD; and

(iii) Naltrexone.

(3) OTPs shall maintain current procedures that are adequate to ensure that the following dosage form and initial dosing requirements are met:

(i) Methadone shall be administered or dispensed only in oral form and shall be formulated in such a way as to reduce its potential for parenteral misuse.

(ii) For each new patient enrolled in an OTP, the initial dose of methadone shall be individually determined and shall include consideration of the type(s) of opioid(s) involved in the patient's opioid use disorder, other medications or substances being taken, medical history, and severity of opioid withdrawal. The total dose for the first day should not exceed 50 milligrams unless the OTP practitioner, licensed under the appropriate State law and registered under the appropriate State and Federal laws to administer or dispense MOUD, finds sufficient medical rationale, including but not limited to if the patient is transferring from another OTP on a higher dose that has been verified, and documents in the patient's record that a higher dose was clinically indicated.

4) OTPs shall maintain current procedures adequate to ensure that each MOUD used by the program is administered and dispensed in accordance with its FDA approved product labeling. The program must ensure that any significant deviations from the approved labeling, including deviations with regard to dose, frequency, or the conditions of use described in the approved labeling, are specifically documented in the patient's record.

Expanded Workforce for Ordering and Managing MOUD in OTPs

Because the Controlled Substances Act classifies methadone as a Schedule II controlled medication, opioid treatment programs (OTPs) and OTP practitioners and other staff who order and administer medications for the treatment of opioid use disorder (MOUD) are closely overseen by federal entities. Since 2000, incremental changes—notably regarding buprenorphine flexibilities—have broadened access to MOUD and resulted in better patient outcomes. Unlike buprenorphine, a Schedule III controlled medication that can be prescribed by any practitioner with a current, valid Drug Enforcement Administration (DEA) registration, methadone for the treatment of opioid use disorder (OUD) can only be ordered for direct dispensing to a patient, as stipulated in 21 U.S.C. 823(h), and not prescribed for the patient to pick up at a pharmacy.

Historically, Title 42 of the Code of Federal Regulations (42 CFR) part 8 limited the ordering of methadone in an OTP to physicians only, with formal exemptions required for advanced practice nurses to order medication. The definition of *practitioner* under 42 CFR § 8.2 expands who can order MOUD in an OTP, and 42 CFR § 8.12(f)(2)(v) also adds the ability of OTPs to use telehealth to expedite admission to treatment, as discussed earlier. Other changes to the regulations involve updated dosing recommendations and patient-centered approaches to medication management. This section provides guidance on all of these areas.

The revised rule expands the types of licensed practitioners beyond physicians who can order MOUD in accordance with state laws. A *practitioner* is now defined, in 42 CFR part 8, as a "health care professional who is appropriately licensed by a State to prescribe and/or dispense medications for opioid use disorders and, as a result, is authorized to practice within an OTP." 42 CFR part 8 allows nurse practitioners and physician assistants who have prescriptive authority under state law to order MOUD for dispensation at the OTP, including in a mobile unit or brick-and-mortar medication unit. With more practitioners able to provide MOUD, OTPs will have greater flexibility in how they address staffing shortages, particularly in areas with fewer providers.

Of note, state laws have varying rules about which medical disciplines can prescribe or order controlled medications and the extent of physician supervision, if any. Some licensing boards provide more latitude for the prescribing and ordering of controlled medications for advanced practice providers (e.g., nurse practitioners and physician assistants) than others. State statutes may be more restrictive than federal statutes, so it is important for OTPs to understand how these state regulations may affect their adherence to the revised guidelines and adjust their staffing plans accordingly. OTPs are encouraged to connect with their State Opioid Treatment Authority (SOTA) and appropriate state licensing boards for questions related to scopes of practice for advanced practice nurses and physician assistants and their ability to prescribe/order different schedules of controlled medications.

Medication Options and Management

Practitioners are obligated to discuss the medication options available to the patient and the patient's needs and goals. Practitioners should match the patient with the medication best suited to them.

Methadone

Methadone has a half-life of 24 to 36 hours and accumulates in the body with repeated dosing. [226] The full effect of a single dose increase may not be noticeable for several days. Consequently, appropriate patient- and situation-specific dosing should be informed by knowledge and experience of methadone pharmacodynamics. Practitioners should carefully monitor patient responses to accumulating doses, particularly in the first few weeks of treatment, to prevent excessive agonist effects. [227] Once steady state has been reached, a patient taking a therapeutic dose of methadone will not exhibit any side effects such as sedation, sometimes called somnolence. For more information on how the pharmacologic properties of methadone guide clinical decision-making, refer to the Substance Abuse and Mental Health Services Administration's (SAMHSA) Treatment Improvement Protocol (TIP 63), *Medications for Opioid Use Disorder*.

The total dose of medication and the interval between doses may need to be adjusted for patients with co-occurring health conditions or atypical metabolic patterns or if the patient takes other prescribed medications that have detectably altered the rate at which the opioid medication is metabolized. How a

patient metabolizes medication can influence dosing schedules. The following medications can increase methadone metabolism: [228]

- Some antibiotics (e.g., rifampin).
- Antiretrovirals (e.g., efavirenz, nevirapine, ritonavir).
- Anticonvulsants (carbamazepine, phenobarbital, phenytoin).

Other medications can decrease methadone metabolism and may create a variety of effects on the methadone serum concentrations. The following medications could lead to withdrawal and cravings, or sedation and risk for overdose: [229]

- Some antibiotics (e.g., ciprofloxacin, erythromycin).
- Antacids (e.g., cimetidine).
- Antifungals (e.g., fluconazole).
- Antidepressants (e.g., fluvoxamine, paroxetine, sertraline).

OTPs may want to consider obtaining peak-and-trough blood serum ratios, along with other measures, to assess dosage efficacy. Assessment is especially important if patients experience somnolence 2 to 4 hours after the daily dose yet continue to struggle with cravings, withdrawal symptoms, or ongoing illicit opioid use. The peak represents the point of highest medication concentration in a patient's body, whereas the trough represents the point of lowest concentration. For methadone, the peak effect typically occurs 2 to 4 hours after dose administration. The trough concentration usually occurs at the end of the dosing period, just before the next dose is due. Understanding the pharmacodynamics of methadone is important to guide timing of peak-and-trough methadone concentration testing.

Methadone can cause sedation and, at its extreme, respiratory depression in the initial phases of methadone titration and with large dose increases. [230] Practitioners should plan to monitor patients during these periods to balance the goal of relieving withdrawal with the potential risk of sedation and respiratory depression.

Treatment with less than a patient's optimal dose that does not sufficiently suppress withdrawal may result in the continued use of opioids, increasing the risk of overdose. This may inadvertently create treatment barriers and lead the patient to discontinue care. Determining the optimal clinically appropriate dosage for patients and adjusting as necessary is critical. This is particularly important for pregnant patients, due to the changes in methadone metabolism and blood volume associated with pregnancy. Educating patients on the induction process before and during the titration phase can be helpful when preparing patients and their family members for what to expect and be aware of regarding the effects of methadone. A combination of discussions with patients and printed materials can be used to prepare them for the induction protocol. Educational materials can include:

- A simple summary of the titration protocol (e.g., estimated number of days, goals).
- Information on physiological experiences that can occur during the titration process (e.g., residual withdrawal symptoms, sedation, urges to use other opioids).
- Strategies to manage these physical and emotional experiences.
- An overview of the medical risks associated with returning to heroin or other illicit opioids during the titration process).
- Information on safe transport and storage of any take-home medication doses.

The continued use of opioids and other substances should not result in automatic reductions of a patient's methadone dose, as this would likely only lead to further destabilization of the OUD. For

example, an unexpected drug test result should not reflexively lead to a reduced dose. In fact, if the patient continues to use opioids, a methadone dose increase may be warranted. OTPs are encouraged to work with individuals to address other substance use disorders (SUDs) in the process of achieving a clinically effective dose of methadone. OTPs may offer increased counseling, contingency management, medication treatment, case management, or recovery support services for patients with co-occurring SUDs, as appropriate for the specific SUD. By offering increased supports, OTPs may engage patients in shared decision-making to manage and address other SUDs that may complicate or impact their ability to effectively stabilize their OUD. Finally, OTPs might consider telehealth counseling for patients who struggle with in-person counseling attendance.

Buprenorphine

Although methadone is still the predominant form of MOUD in OTPs, increasingly, OTPs are also offering patients buprenorphine-containing medications as a medication option. Buprenorphine, a Schedule III controlled medication, may carry benefits for some patients, as it can also be prescribed by any practitioner holding an active DEA registration and in accordance with state laws. With a lower risk of sedation and respiratory depression than methadone, buprenorphine's broader safety profile may make it an appealing option for patients with limited cardiopulmonary function, complicated cirrhosis, or other contraindications to methadone.

The goal of treatment during the first week of buprenorphine is to suppress opioid withdrawal symptoms while minimizing sedation. Buprenorphine induction can begin at the OTP or at home. Home-based induction may increase access to care by removing the barrier of transportation. Whether induction is office-based or home-based, practitioners are responsible for ensuring patients are educated and aware of the following:

- Risks and benefits of buprenorphine.
- Appropriate storage and use of the medication.
- Recommended time to start the medication based on the induction strategy.
- What to do in case of sedation within 1 to 2 hours after the first dose.
- Adjunctive medications to address withdrawal symptoms on induction day.
- Method of contacting the practitioner during the induction period.

The standard induction strategy for buprenorphine requires patients to experience opioid withdrawal before starting buprenorphine, which may present some challenges for initiating treatment. In addition, buprenorphine initiation for patients with chronic fentanyl use has been complicated in practice by the development of precipitated withdrawal—even when they receive standard doses of buprenorphine that do not prompt this response in patients who use heroin. One alternative induction strategy to reduce the risk of precipitated withdrawal involves low-dose induction. Low-dose induction is a strategy where the patient starts with a low dose of buprenorphine and increases dosages by 50 to 100 percent per day (individual doses will vary by patient). [231] This method has been used in emergency departments, rural clinical settings, and primary care. [232, 233]

Another alternative to starting buprenorphine and reducing the risk of precipitated withdrawal includes buprenorphine patch bridging. This strategy entails off-label use of the buprenorphine patch to bridge the patient to a sublingual formulation of buprenorphine. [234] When practitioners make dosing adjustments that differ from Food and Drug Administration (FDA) labels or ordering information, the clinical rationale, dose, risks, benefits, and plan should be thoroughly documented.

The FDA has approved two formulations of long-term injectable buprenorphine for the treatment of moderate to severe OUD. [235] The weekly formulation may be used with patients who initiated treatment with transmucosal buprenorphine and is available in doses of 8 mg, 16 mg, 24 mg, and 32 mg. The monthly injectable is initiated with a 300 mg dose and continued with a 100 mg dose monthly. Doses are stored refrigerated in prefilled syringes with safety needles and administered by subcutaneous injection in the abdomen. Peak buprenorphine concentrations occur about 24 hours after the injection. Stabilization is achieved after 4 to 6 months. For ongoing therapy, the 100 mg extended-release injection is administered monthly at a minimum of every 26 days. Practitioners may adjust this dose to 300 mg if patients can tolerate the 100 mg injection but continue to report illicit opioid use or test positive for illicit opioids. [236]

Initial Medication Dosing

The initial full-day dose of medication, either methadone or buprenorphine, is based on the practitioner's assessment of the patient's severity of opioid withdrawal at the time of the screening examination and the timing of any recent opioid taken, with or without additional sedating substances. The practitioner may consider medical and psychiatric conditions of the patient that would serve as a contraindication to starting MOUD; the patient's level of opioid tolerance, age, and gender; and any physical findings of drowsiness or sedation during the screening examination. The practitioner may consider local conditions, such as the prevalence of heroin as compared to fentanyl availability in the drug supply. Medication dosage should also consider possible over-the-counter medications and prescription medications, including those that are controlled.

To address individual patient needs, the revised rule allows for greater flexibility in initial methadone dosing than the prior 42 CFR part 8 rule. Opioid tolerance levels may be higher in areas where fentanyl predominates than in areas where heroin or other prescription opioids are still substantial parts of the drug supply. For patients with higher opioid tolerance, particularly when they are presenting with moderate to severe opioid withdrawal, initial methadone doses of up to 50 mg on the first day may be reasonable and are permissible under 42 CFR § 8.12(h)(3)(ii).

In some clinical situations, an initial dose that exceeds 50 mg may be warranted. For example, the revised rule highlights instances when patients on a methadone dose greater than 50 mg transfer to a different OTP, or when methadone has been initiated in other settings, such as during hospitalizations or incarceration. There may also be some circumstances in which a patient's withdrawal on presentation to the OTP is so severe that an initial dose higher than 50 mg may be clinically reasonable. OTP practitioners should make this determination based on clinical judgment, keeping in mind the unique pharmacokinetic properties of methadone. OTP practitioners should document all starting medication dose decisions and related clinical reasoning in the patient's medical record.

An initial dose that is lower than 50 mg may be warranted for patients with lower opioid tolerances, if following an opioid-free period, if presenting with signs of sedation or somnolence, or if other medications or medical or psychiatric conditions would increase sedation risks. A patient-centered, individualized approach is essential when determining the appropriate methadone dose for a given patient.

Observation in the clinic for a period following administration of the first dose may be appropriate for patients initiating buprenorphine formulations at the OTP to address any precipitated withdrawal that might occur. Alternatively, patients can receive buprenorphine-containing medication for home initiation. OTP practitioners should become familiar with different approaches to starting buprenorphine, both low-dose and high-dose initiation techniques, recognizing that research on the

effectiveness of these approaches is still emerging, and some clinical protocols use medications in off-label ways.

Medication Dosing to Therapeutic Range

Once a patient has received the initial dose of methadone or buprenorphine, dosing increases are made to achieve an individualized therapeutic dose for each patient. The goal is to achieve a stable dose of either methadone or buprenorphine that effectively suppresses opioid withdrawal and reduces cravings, while minimizing side effects. OTP practitioners should monitor patients closely and adjust medication doses as needed to reach that therapeutic goal and optimize treatment outcomes.

OTP practitioners should have a good understanding of and apply their knowledge of the pharmacology of methadone and buprenorphine in adjusting doses to balance the time needed to reach a therapeutic dose with the time needed to reach steady state. Factors such as the patient's metabolism, tolerance level, and response to treatment should guide dosing decisions. For patients with recent fentanyl exposure, more rapid dose escalation may be necessary to effectively manage withdrawal symptoms.

Split Dosing

Split dosing means dispensing a single dose of MOUD as separate portions to be taken within a 24-hour period. Split dosing is indicated among patients who:

- Possess a genetic variant that increases methadone metabolism.
- Concurrently use other medications or alcohol that also cause the liver to process the methadone more quickly, leading to more rapid metabolism of methadone.
- Are pregnant.
- Are sensitive to agonist effects of the medication at higher dosages.
- Take methadone or buprenorphine to treat concurrent pain, because the duration of the analgesic effects of these medications is far less than 24 hours.

Split dosing may involve dividing a dose of methadone or buprenorphine into 2 or more daily doses, typically taken 10 to 12 hours apart, or adding an evening dose to increase the overall daily dosage amount. For pregnant patients, increasing the overall daily dosage amount with split dosing can help reduce uncomfortable withdrawal symptoms associated with metabolic changes, particularly for patients in the third trimester of pregnancy. Split dosing can also make medications for OUD more tolerable for people experiencing nausea and may be needed for people taking other medications or with certain physiologic profiles that could lead to rapid metabolism of MOUD. [237]

If an individual is receiving split take-home doses of methadone, then the total daily dose comprising split portions should be considered 1 day of medication. For patients requiring a split-dosing schedule, OTP practitioners can still calculate dose regimens for take-home medication according to the number of days, rather than number of doses.

Resource Alert: Dosing

The following resources include information about dosing:

- SAMHSA's TIP 63, Medications for Opioid Use Disorder
- SAMHSA's *Advisory:* Evidence-Based, Whole-Person Care for Pregnant People Who Have Opioid Use Disorder
- American Society of Addiction Medicine's National Practice Guideline for the Treatment of Opioid Use Disorder

Continuous Medication Treatment

According to revised rule 42 CFR § 8.2, *continuous medication treatment* "is intended to be synonymous with the term 'maintenance' treatment as used in 21 U.S.C. 823(h)(1)." Both terms refer to the uninterrupted treatment for OUD involving the dispensing and administration of MOUD at stable dosage levels for a period in excess of 21 days.

OUD medication can be taken on a short- or long-term basis as part of medically supervised withdrawal or continuous treatment. Patients may come into care with misconceptions, misunderstanding, and stigmatized views of methadone or buprenorphine based on what they have heard from family or friends. OTP practitioners and clinical staff would do well to address these perceptions, explaining the difference between physical dependence caused by methadone or buprenorphine and the symptoms of OUD.

Reviewing the diagnostic criteria for OUD, along with definitions of remission and recovery that can occur with medication (or, for some people, without it), may be helpful. OTP practitioners and clinical staff may find that analogies to other chronic conditions such as diabetes or hypertension resonate with patients. Some patients may also appreciate hearing about research demonstrating high rates of return to illicit opioid use with short-term withdrawal management and knowing that entities such as SAMHSA do not consider withdrawal management as standard of care for OUD.

OTP practitioners also can educate patients, their family members, community members, and even other OTP staff about the neurobiology and chronic disease nature of addiction, and the benefits of MOUD in reducing risk of infectious disease transmission, overdose, or death [238] and increasing recovery capital. [239] With this knowledge comes an understanding that achieving remission and recovery often takes time and may not happen along a straight path. Many patients stop using illicit opioids while taking MOUD. However, others might continue to use illicit opioids in smaller quantities.

Based on DEA regulations, certification as an OTP is not required for the initiation, continuous medication treatment, or withdrawal management of a patient admitted to a facility that is registered with the DEA as a hospital/clinic for the treatment of medical conditions other than OUD, as long as such treatment is permitted under applicable federal law. Further to this, 21 CFR 1306.07(c) only refers to a "physician or authorized hospital staff" to administer or dispense narcotic drugs [….]". This regulatory provision also applies to correctional settings that are registered with the DEA as a hospital/clinic and in which the OUD is secondary to a primary health condition other than addiction. For more information, refer to DEA regulations under 21 CFR 1306.07(c).

Take-Home Doses of Medication

42 CFR § 8.12(i). Unsupervised or "take-home" medication doses. Unsupervised or "take-home" medication doses may be provided under the following circumstances:

(1) Any patient in comprehensive treatment may receive their individualized take-home doses as ordered for days that the clinic is closed for business, including one weekend day (e.g., Sunday) and State and Federal holidays, no matter their length of time in treatment.

(2) OTP decisions on dispensing MOUD to patients for unsupervised use beyond that set forth in paragraph (i)(1) of this section shall be determined by an appropriately licensed OTP medical practitioner or the medical director. In determining which patients may receive unsupervised medication doses, the medical director or program medical practitioner shall consider, among other pertinent factors that indicate that the therapeutic benefits of unsupervised doses outweigh the risks, the following criteria:

(i) Absence of active substance use disorders, other physical or behavioral health conditions that increase the risk of patient harm as it relates to the potential for overdose, or the ability to function safely;

(ii) Regularity of attendance for supervised medication administration;

(iii) Absence of serious behavioral problems that endanger the patient, the public or others;

(iv) Absence of known recent diversion activity;

(v) Whether take-home medication can be safely transported and stored; and

(vi) Any other criteria that the medical director or medical practitioner considers relevant to the patient's safety and the public's health.

(3) Such determinations and the basis for such determinations consistent with the criteria outlined in paragraph (i)(2) of this section shall be documented in the patient's medical record. If it is determined that a patient is safely able to manage unsupervised doses of MOUD, the dispensing restrictions set forth in paragraphs (i)(3)(i) through (iii) of this section apply. The dispensing restrictions set forth in paragraphs (i)(3)(i) through (iii) of this section do not apply to buprenorphine and buprenorphine products listed under paragraph (h)(2)(ii) of this section.

(i) During the first 14 days of treatment, the take-home supply (beyond that of paragraph (i)(1) of this section) is limited to 7 days. It remains within the OTP practitioner's discretion to determine the number of take-home doses up to 7 days, but decisions must be based on the criteria listed in paragraph (i)(2) of this section. The rationale underlying the decision to provide unsupervised doses of methadone must be documented in the patient's clinical record, consistent with paragraph (g)(2) of this section.

(ii) From 15 days of treatment, the take-home supply (beyond that of paragraph (i)(1) of this section) is limited to 14 days. It remains within the OTP practitioner's discretion to determine the number of take-home doses up to 14 days, but this determination must be based on the criteria listed in paragraph (i)(2) of this section. The rationale underlying the decision to provide unsupervised doses of methadone must be documented in the patient's clinical record, consistent with paragraph (g)(2) of this section.

(iii) From 31 days of treatment, the take-home supply (beyond that of paragraph (i)(1) of this section) provided to a patient is not to exceed 28 days. It remains within the OTP practitioner's discretion to determine the number of take-home doses up to 28 days, but this determination must be based on the criteria listed in paragraph (i)(2) of this section. The rationale underlying the decision to provide unsupervised doses of methadone must be documented in the patient's clinical record, consistent with paragraph (g)(2) of this section.

(4) OTPs must maintain current procedures adequate to identify the theft or diversion of take-home medications, including labeling containers with the OTP's name, address, and telephone number. Programs also must ensure that each individual take-home dose is packaged in a manner that is designed to reduce the risk of accidental ingestion, including child-proof containers (see Poison Prevention Packaging Act, Pub. L. 91–601 (15 U.S.C. 1471 *et seq.*)). Programs must provide education to each patient on: Safely transporting medication from the OTP to their place of residence; and the safe storage of take-home doses at the individual's place of

residence, including child and household safety precautions. The provision of this education should be documented in the patient's clinical record.

There are significant differences between the prescribing, administration, dispensing, and use of buprenorphine and methadone. As discussed in the beginning of this chapter, methadone is scheduled under the Controlled Substances Act as a Schedule II controlled medication and has a narrower safety profile than buprenorphine. As such, methadone historically has been regulated with greater intensity, and 42 CFR part 8 previously required that patients meet rigorous criteria to receive take-home medication doses. [240] Buprenorphine has been available for patients to take at home after filling a prescription at a pharmacy or in an OTP, where it has not been—and continues not to be—subject to the take-home dose considerations delineated for methadone. [241] This section applies to methadone take-home doses. OTP practitioners should still weigh risks and benefits when engaged in decision-making about take-home doses of buprenorphine-containing formulations and should document this in the patient's medical record.

During the COVID-19 public health emergency (PHE), SAMHSA issued exemptions for state regulatory authorities to request blanket exemptions to allow patients to take home more doses of methadone. With this flexibility, OTPs could dispense take-home doses of methadone to patients who OTP practitioners believed could safely handle this level of medication. The intention of the methadone take-home flexibility was to reduce the risk of COVID-19 virus transmission among patients and providers, but the benefits extended beyond that. This regulatory flexibility also promoted expanded access to take-home methadone doses in historic ways and offered an opportunity to study and learn from this experience. Both research produced during the COVID-19 PHE and experiences by patients and OTPs highlighted the positive impacts of this increased flexibility. [242, 243, 244] Patients no longer had to travel to the OTP each day for months, and sometimes years, to receive medication. By reducing the burden on patients to visit the OTP daily, the flexibility reduced stigma for those seeking treatment and provided more equitable access to care. It allowed those who reside far from an OTP or who lacked access to reliable transportation to receive treatment, while also being able to secure or maintain employment, care for loved ones, and engage in other activities of daily living. [245]

The revised 42 CFR part 8 rule makes these flexibilities permanent by updating the criteria OTP practitioners should consider when making clinical decisions about take-home methadone doses. The rule also allows for take-home doses to be available as soon as patients are admitted into treatment. [246] (Note that although federal regulations have expanded the availability of take-home doses, each state may have its own regulations guiding this process.)

Take-home doses are a valuable therapeutic tool and an important means of individualizing treatment. The availability of take-home doses often is a critical issue for patients who are deciding whether to enter or remain in treatment. The OTP medical director should ensure that any clinical policies related to take-home doses balance patient-centered approaches and reducing diversion risk. The medical director and program sponsor are encouraged to create a culture for the entire staff—including other practitioners, clinicians, peers, and other support staff—to participate in the development and application of flexible and patient-centered clinical policies, with the principles of harm reduction and individualized care as core tenets.

Clinical policies and individualized clinical decisions for take-home doses may consider common socioeconomic barriers, such as transportation, safe housing, employment circumstances, and chronic medical or mental health conditions, that may impact clinic attendance, participation in care planning, and medication adherence. Patient-centered clinical policies may also consider ways to standardize

offers of additional support, such as community-based outreach from case managers or peers. Patients receiving take-home doses can also be supported through individually tailored telehealth visits with practitioners, counselors, and other services as needed, in addition to in-person visits as indicated.

Clinical policies on take-home doses may also describe ways to involve supportive family and friends in the patient's take-home dosing plan to reinforce the efficacy of care planning while maintaining a take-home dose protocol that reduces the burden on patients. Finally, OTP practitioners should consider patient progress as part of decision-making for take-home doses, as most patients who stay actively engaged in treatment will show improvements (e.g., reductions in substance use) over time. [247]

42 CFR part 8 states that OTP practitioners should consider six criteria when making decisions about ordering methadone take-home doses for patients:

- Absence of active SUDs and other physical or behavioral health conditions that increase the risk of patient harm as it relates to the potential for overdose or the ability to function safely.
- Regularity of attendance for supervised medication administration.
- Absence of serious behavioral problems that endanger the patient, the public, or others.
- Absence of known recent diversion activity.
- Whether take-home medication can be safely transported and stored.
- Any other criteria that the medical director or OTP medical practitioner considers relevant to the patient's safety and the public's health.

The criteria are designed to foster a risk–benefit analysis for decision-making related to take-home doses of methadone and are not meant to represent a rigid checklist. OTP practitioners should not reserve take-home doses as a reward for perceived good behavior, nor should take-home doses be reduced or removed in a punitive manner. Rather, take-home doses are an integral part of a care plan that promotes engagement, retention, and recovery by allowing individuals the time to engage in employment, education, childcare, or other activities that build recovery capital in the least restrictive environment while weighing risks of medication misuse, sharing/selling, or theft or loss. Research and experience from the COVID-19 period found fewer patients with risks related to methadone take-home doses and a greater number of patients who benefited from increased take-home dose flexibility and less frequent clinic visits. [248, 249, 250]

The maximum number of take-home doses patients can receive increases with the length of time they have been in treatment. 42 CFR part 8 states that take-home doses may be offered according to the following schedule:

Days in Treatment	Maximum Number of Take-Home Doses
1–14	7
15–30	14
31 or more	28

There are some instances in which take-homes may be offered regardless of the regulations delineated factors for consideration. These include days the clinic is closed for business, such as state and federal holidays or regularly scheduled closure days (e.g., weekend-day closure). [251] For patients who benefit from frequent dosing or for whom the risks of take-home doses outweigh the benefits, treatment plans should include alternative arrangements for methadone dosing. These may be guest dosing at another OTP or arranging for a trusted *designated other* (described in the Provision of Medication to Patients With Mobility Barriers section) to pick up and hold responsibility for the safe storage and administration of the take-home dose.

OTPs should note any state statutes pertaining to take-home medication. More information about dosing and state statues is available at SAMHSA's Methadone Take-Home Flexibilities Extension Guidance webpage.

The Importance of the Use of Clinical Judgment in Decisions About Take-Home Medications

The revised rule recognizes the critical role of clinical decision-making and practitioner discretion when considering provision of take-home doses. Rather than imposing rigid, one-size-fits-all dosing schedules, the rule gives practitioners the ability to determine the appropriate number of take-home doses based on each patient's individual needs, goals, progress, and stability. This discretion enables practitioners to respond to changes in a patient's circumstances and adjust treatment strategies accordingly, which promotes a more dynamic, patient-centered approach to care and aims to improve outcomes and promote long-term recovery.

Additionally, SAMHSA recommends that OTPs directly involve patients in making decisions about their care plan. Through such a shared decision-making process, practitioners can foster a sense of collaboration, trust, and empowerment that is essential for treatment engagement and adherence.

The new rule significantly enhances practitioner discretion within OTPs by shifting from rigid, rule-based decision-making to a more flexible, patient-centered care approach. This shift emphasizes the importance of individualized care plans informed by the practitioner's professional judgment and deep understanding of each patient's unique needs and circumstances.

Practitioner discretion refers to the freedom and responsibility of healthcare providers to make clinical decisions based on their expertise, training, and comprehensive knowledge of their patients. This discretion is crucial for delivering high-quality, personalized care, particularly in the context of treating OUD.

Developing and implementing individualized care plans are the cornerstone of this person-centered care model. Practitioners collaborate closely with patients and the multidisciplinary clinical team to create iterative, individualized care plans that encompass SUD, medical, mental health, and recovery support services tailored to the patient's specific needs and goals. These plans are continuously updated based on ongoing assessments and the patient's progress, reflecting the dynamic nature of treatment and recovery.

Measuring and Monitoring Practitioner Discretion

Measuring and monitoring practitioner discretion within OTPs reinforces the need for practitioners to use their professional judgment to deliver high-quality, individualized care. This process uses multiple strategies to show how practitioners exercise their discretion and the effect it has on patient outcomes. These strategies include:

- **Review of clinical decision-making records.** These records should include the rationale behind treatment choices, any changes made to care plans, and specific adjustments tailored to individual patients. Regular audits of these records help ensure that practitioners tailor treatment decisions to individual patient needs, leveraging clinical expertise alongside established best practices and guidelines.
- **Development and continuous updating of patient care plans.** Care plans should reflect a personalized approach to treatment and incorporate tailored SUD, medical, mental health, and

recovery support services. By regularly reviewing and updating these plans, it becomes evident how practitioners adapt their strategies to suit each patient's evolving circumstances. This ongoing documentation demonstrates the practitioner's capacity to customize care based on their comprehensive knowledge of the patient.

- **Patient outcomes.** Reduced recurrence rates, higher patient satisfaction, and better overall health metrics indicate that practitioners are delivering effective, personalized care. Collecting and analyzing data on these outcomes offers valuable insights into the effectiveness of shared decision-making.
- **Direct feedback from the practitioners.** Surveys, interviews, and focus groups with healthcare providers can reveal their experiences and perceptions of discretion in their roles. This feedback helps identify areas where practitioners feel empowered to make clinical decisions and highlights constraints they may face. Insights from these discussions can inform policy adjustments and support mechanisms to enhance practitioner discretion.
- **Peer reviews and case conferences.** These forums allow practitioners to discuss and review each other's clinical decisions, promoting the sharing of best practices and offering insights into how clinical discretion is exercised in various scenarios. Constructive feedback from peers ensures that clinical decisions remain patient centered and evidence based, fostering a culture of continuous improvement.
- **Training and continuing education.** This ensures practitioners possess the latest knowledge and skills required for effective clinical decision-making. Regular evaluations of training programs help determine whether practitioners feel confident and capable in their roles, reinforcing the importance of ongoing professional development.
- **Compliance with regulations.** While promoting discretion, it is vital to verify that practitioners adhere to relevant legal and ethical guidelines. Regular compliance checks help maintain a balance between the freedom to tailor care to individual patients and the obligation to uphold high standards of practice.
- **Direct feedback from patients.** Patient satisfaction surveys and interviews can reveal whether patients perceive their care plans as individualized and whether their practitioners are attentive and responsive. This feedback helps assess the effect of practitioner discretion on the patient experience.

Provision of Medication to Patients With Mobility Barriers

There are many reasons patients may be unable to physically present to the OTP in person to receive their medication dose(s) or see an OTP practitioner or clinician. Such circumstances include illness, pregnancy, incarceration, participation in residential treatment, and lack of transportation to the clinic. When these situations occur, OTPs face two issues: (1) continuing the patient's treatment safely and (2) ensuring appropriate handling and delivery of medication to the patient.

Medication Delivery

OTPs may consider allowing staff to deliver medication to patients who are unable to come to the clinic and who do not have a person they can designate (often called a *designated other*) to pick up the medication on their behalf. In these instances, the medication is dispensed at the OTP as take-home doses that are delivered to the patient by an OTP staff member. Such deliveries will need documentation showing the quantity and dosage and confirming patient receipt. A best practice for such documentation is the use of a chain-of-custody record, which is a document containing the signatures of each person who handles the medication. This documentation should be placed in the patient record once all signatures are recorded. The patient or the person ultimately giving the

medication to the patient can contact the program immediately if the medication seems altered in any way.

Guest Dosing

For patients for whom the risks of providing take-home medication doses outweigh the therapeutic benefits, guest dosing is a strategy to minimize disruptions in medication continuity for patients temporarily unable to access their home OTP. OTPs should facilitate guest dosing arrangements in these circumstances, whether those are related to work travel, vacation, displacement, or other unforeseen circumstances. Such facilitation includes assisting patients in locating and coordinating timely care with an alternative OTP.

To streamline the process, the home OTP should provide the guest OTP with essential patient information, such as the medication dosage, treatment plan details, and recent clinical status. Advance notice is recommended whenever possible to ensure a smooth transition, but patients should not be automatically turned away from an OTP if they present for guest dosing. It is incumbent upon the guest OTP to contact the patient's home OTP to clarify the situation and obtain guest dosing orders.

It is expected that OTPs will make every attempt to provide guest dosing, including providing guest dosing for out-of-state travelers and for patients who are displaced from their home OTPs. Further, the guest or alternative OTPs are expected to maintain dosing levels established by the home OTP or collaborate with the patient's home OTP medical team to discuss any changes to the medication regimen. Patients also need to be involved in these discussions, preferably in advance of any changes to dosing, when possible, such as during a planned change in residence.

Guest dosing is an essential service of OTPs and a critical tool in ensuring medication continuity for patients during periods of disruptions or temporary changes in residence. OTPs should consider the goal of sustaining a seamless continuity of care when providing the guest dosing services and to limit the use of prohibitive policies that can disrupt continuity or increase the risk of disengagement from care.

Designated Other

OTPs may consider providing medication to a person who is designated by the patient as being able to pick up, transport, and deliver the medication to the patient if the patient is unable to travel to the clinic or when the risks of providing the take-home doses directly to the patient outweigh the therapeutic benefits. To have a designated other serve in this role, the patient will submit information about the individual for the OTP's review. The OTP will consider the person's stability, ability to comprehend instructions, and reliability in safely picking up, securing, and delivering the medication to the patient.

To obtain an exemption under 42 CFR § 8.11(g) from SAMHSA for a family member or significant other with whom the OTP has met or communicated, screened, and approved to pick up the medication, the OTP should complete the **Exception Request and Record of Justification Under 42 CFR § 8.11(g)** form (Form SMA-168) and submit it online at https://otp-extranet.samhsa.gov. SAMHSA has historically used the term "exceptions" to reference take-home medication exemptions as a way to track these types of exemption requests separately from other types of exemptions.

Safe Transport and Storage of Take-Home Medications

OTPs should establish policies and practices that balance the need to keep medication safe during transport and meet applicable state requirements with individual patients' resources. OTP practitioners and clinical staff should educate patients how to safely transport medication from the OTP to their

residence, how to safely store take-home doses, and how to take safety precautions that protect children, pets, and other members of the household. Patients may be asked to sign an attestation that they understand the program's policies and have received safety and security-related education, and this documentation can be added to the patient's clinical record.

There is no requirement in the revised rule mandating that patients bring lockboxes to the OTP in order to receive or physically pick up medication take-home doses. Procedures adequate to identify the theft or diversion of take-home doses include labeling containers with the OTP's name, address, and telephone number. Programs should ensure that each individual take-home dose is packaged in a manner to reduce the risk of accidental ingestion.

OTPs also should provide patients with training and education about how to reach Poison Control (online at https://www.poison.org or by phone at 1-800-222-1222), if needed, and what patients should do if they lose their medication or if it is stolen. All patients should have access to naloxone or other opioid overdose reversal medications.

Unsupervised Take-Home Medication Exemption Requests

Despite the expanded take-home dose flexibilities included in the revised rule, on occasion, OTP practitioners may determine that a patient needs an amount of take-home medication that exceeds the number of take-home doses allowed by the regulations within a particular time period. This may happen in the initial weeks of treatment if patients have transportation hardships, employment or vacation requests, or medical disabilities. There may also be circumstances, such as international travel or prolonged work assignments, in which the OTP practitioner determines it is therapeutically beneficial to order an amount of take-home medication exceeding 28 days. In these instances, the practitioner should submit an exemption request, pursuant to 42 CFR § 8.11(g), to the SOTA and SAMHSA via the OTP Extranet (https://otp-extranet.samhsa.gov). Clinical variances from the rule, such as starting methadone for an emancipated minor-aged patient, may also be submitted to SAMHSA via the OTP Extranet (https://otp-extranet.samhsa.gov). SAMHSA has historically used the term "exceptions" to reference take-home medication exemptions as a way to track these types of exemption requests separately from other types of exemptions.

Take-home medication exemption requests do not need to be submitted to SAMHSA for the provision of care as outlined in 42 CFR part 8. Because 42 CFR part 8 places no federal limit on the maximum dose of methadone allowed for a patient in treatment, an exemption request is not required by SAMHSA for methadone dose determinations.

In emergency situations such as natural disasters or weather events, every effort should be made to ensure continuity of medication for patients. OTPs should include plans for ensuring continuity of medication access in emergencies (including individual patient emergencies) in their disaster plans. When large-scale emergency events occur, sponsors and medical directors should seek guidance and assistance from their SOTAs regarding broad-scale take-home medication requests. In such circumstances, requests for take-home medication exemptions, as necessary, can be submitted to SAMHSA retroactively.

Callbacks

The field refers to the practice of calling patients to return to the clinic with empty and full take-home medication bottles as "callbacks." Some OTPs and practitioners have historically relied on callbacks to

determine if patients are taking medications as directed or if diversion has occurred; other OTPs incorporate the practice into their procedures for medication management or diversion prevention, implementing it only when they are concerned about patient safety. When conducted routinely, this practice has been perceived as punitive by many patients. [252, 253]

Currently, there is no rigorous evidence to support the effectiveness of random callbacks of take-home medication doses in reducing medication diversion. Although the use of callbacks should align with state regulations, SAMHSA strongly encourages OTPs to consider the disruptive nature of random callbacks for patients, as callbacks may require patients to secure unplanned transportation and childcare and can affect employment, causing patients to not respond as expected. SAMHSA therefore recommends that callbacks, if done, be considered only when clinically indicated and as part of a broader assessment to clarify concerns around clinical stability. SAMHSA also recommends implementing any callbacks in a manner that supports patient safety, reduces interference in the patient's life, and does not discourage engagement with treatment or willingness to continue medication. If OTPs do callbacks, they may consider virtual callbacks.

OTPs and practitioners considering callbacks may identify clinical rationale for when callbacks are appropriate. For example:

- A patient is not responsive to telephone check-ins or sessions.
- A patient returns early for medication or appears confused about medication dosing instructions.
- A patient resumes take-home dosing after a previously reported loss or theft of take-home doses.
- There are overt signs of diversion.
- A patient requests callbacks as part of their treatment plan.

There also may be alternatives to callbacks that are less disruptive and reduce interference and the burden on patients in their daily lives. Other methods to ensure safety may include:

- Providing education to family members.
- Connecting patients with peer support at the OTP or through a recovery community organization.
- Using secure storage options and medication administration visualization tools, including smart technology.

Before making any changes to the treatment regimen in response to callbacks, OTP practitioners should discuss any concerns with the patient and adjust take-home medication regimens, if necessary, only after considering the full clinical picture. Practitioners should be aware that any one callback result represents only one point in time during a person's treatment.

Withdrawal Management

> **42 CFR § 8.12(e)(3). Withdrawal management.** An OTP shall maintain current procedures that are designed to ensure that those patients who choose to taper from MOUD are provided the opportunity to do so with informed consent and at a mutually agreed-upon rate that minimizes taper-related risks. Such consent must be documented in the clinical record by the treating practitioner.

In the revised rule, *withdrawal management* is intended to be synonymous with the term "detoxification" as used in 21 U.S.C. 823(h)(1). The revised rule removed this latter term and uses withdrawal management to more accurately reflect both the patient experience and the practitioners' interventions and to reduce stigma. This term is also known as *medically supervised withdrawal*, and it describes the administration of either methadone or buprenorphine in progressively smaller doses to

alleviate the symptoms of opioid withdrawal, typically from illicit opioids, until a patient reaches an opioid-free state. Given that physical dependence, manifested as withdrawal, occurs with methadone and buprenorphine, *Long-term withdrawal management* refers to a process of medication tapering that exceeds 30 days. Patients may undergo long-term, medically supervised withdrawal as part of a care plan that involves eventually stopping MOUD.

To support shared decision-making between practitioner and patient, OTP practitioners can provide education to ensure patients fully understand the risks of stopping or tapering MOUD too quickly, including the elevated risk of OUD recurrence and overdose. These discussions also may cover reasons for the patient's interest in stopping or tapering MOUD, including side effects, pressure from family or friends, concerns about the long-term use of methadone or buprenorphine, upcoming relocation where access to MOUD is uncertain. Discussion on this topic also may occur in the context of long-term recovery.

With information from such discussions, some situations may call for restabilizing at a lower dose only while in other circumstances, the patient may, with informed consent, choose to taper off MOUD altogether. In these cases, patient autonomy should be respected, and a care plan developed to support the patient's goals. Dose reduction should occur at a mutually agreed-upon rate that minimizes risk to the patient. The rate of dose reduction should be tailored based on shared decision-making that includes patient preferences and OTP practitioners' recommendations based on their knowledge of methadone and buprenorphine pharmacodynamics and patient assessment. A goal of any tapering schedule includes minimizing the risk of adverse outcomes such as withdrawal, cravings, and return to use.

Frequent reassessments and readjustment of tapering schedules may be necessary to meet these goals. Patients should not be discharged from the OTP without tapering the medication first. It is important to note that care also does not end when a patient tapers off medication. OTP practitioners and clinical staff should work with patients to understand their ongoing needs and develop an appropriate aftercare plan that maintains patient safety and provides supports to meet their recovery goals.

There are some instances in which the OTP practitioner may recommend MOUD dose reduction or tapering due to the development of adverse side effects or medical contraindications. In such circumstances, OTP practitioners, in ordering dose reductions or tapering schedules, will also need to account for the clinical factors underlying the reason for changes in MOUD dosing. These changes should be discussed with patients. In addition, OTP practitioners should work with patients, OTP clinical staff, and any outside providers on alternative OUD treatment options.

Voluntary Medically Supervised Withdrawal

Voluntary medically supervised withdrawal from MOUD is initiated by practitioners in collaboration with, and at the request of, the patient. The practitioner reduces medication dosages at a rate that is well-tolerated by the patient and in accordance with the practitioner's sound clinical judgment and close observation of the patient. SAMHSA's TIP 63, *Medications for Opioid Use Disorder* provides further guidance.

Careful review of the risks and benefits of tapering from medication therapy should be provided, and thorough informed consent should be obtained from patients. Exhibit 3 offers additional considerations related to medically supervised withdrawal using buprenorphine and methadone.

Exhibit 3. Medically Supervised Withdrawal Using Buprenorphine or Methadone

Medically supervised withdrawal using buprenorphine or methadone is appropriate when patients: [254]

- Prefer it to continuous treatment with medications after they have been fully informed of the risks and benefits of this approach compared with continuous medication treatment.
- Wish to start extended-release naltrexone (XR-NTX), which is also FDA-approved for the treatment of alcohol use disorder.
- Are entering a controlled environment or workplace that disallows opioid agonists (although this may be in violation of the American with Disabilities Act. Data conflict on the ideal duration of medically supervised withdrawal. Strong evidence finds that shorter term withdrawal management approaches alone (formerly "detoxification") are rarely effective.

Short-term medically supervised withdrawal alone is not recommended because of its high rate of return to illicit opioid use. If patients choose this approach, it should be provided with psychosocial treatment. XR-NTX treatment should always be considered to reduce the likelihood of return to use after medically supervised withdrawal is completed and an adequate opioid-free period has been achieved, as well as to reduce the likelihood of overdose death upon a potential return to opioid use.

If the patient chooses or needs short-term withdrawal management or medication tapering, the following strategies are recommended:

- Provide education about options, including the use of supportive medication (e.g., clonidine, ondansetron, loperamide) or nonsteroidal anti-inflammatory medications to manage withdrawal symptoms near the end of the taper.
- Provide education about the benefits of split dosing, or transition from methadone to buprenorphine once lower doses are reached if withdrawal or cravings emerge.
- Individualize the supervised withdrawal duration per the patient's preference and response to lower medication doses, including stopping a medication taper if the patient requests it.
- Consider discontinuing dose reduction and increasing the dose if the patient begins to use illicit opioids.
- Encourage patients to continue counseling, other medical and mental health care, and recovery support services during and after medication discontinuation. Urge patients to seek to restart MOUD promptly if they begin to experience cravings, urges, or return to use.
- Help patients by working with them to identify urges and cues before use happens. This aligns with cognitive–behavioral therapy, an evidence-based technique routinely used in OUD treatment that involves helping patients learn to identify the triggers, cues, and risks that precede substance use and alternatives for managing them.
- Ensure patients have naloxone or another opioid overdose reversal medication and a safety plan for how to reduce their overdose risk should return to use occur.
- Provide all patients with a simple process for returning to the OTP or clinic to restart MOUD when they notice an increase in the urge or risk of using illicit opioids. Plan for the crisis before it happens.

Because of the risk of fatal overdose if patients experience a recurrence of use, medically supervised withdrawal will need to be accompanied by recurrence prevention counseling, overdose prevention education, and harm reduction supplies that include naloxone. OTPs can offer a range of support options to patients tapering from opioid agonist therapy, such as increased counseling and peer supports, referral to other recovery support services, including mutual-support programs. More information is available on SAMHSA's Opioid Overdose webpage.

Because of the risk of harm to the pregnant person and fetus, medically supervised withdrawal is not recommended for pregnant people. [255]

Patient Decision To Leave Treatment

Patients have the right to leave treatment when they choose. When patients decide to terminate treatment and request voluntary medically supervised withdrawal from MOUD, they should be able to receive those services—even if doing so is against the medical advice of the OTP practitioner or clinical staff. Tapering from MOUD should not be used as the basis to deny patients services. Patients should be offered ongoing non-pharmacological support should they want that or be encouraged to return for medication and other services at any time unless threatening behavior has occurred.

At the time of readmission, OTPs should document the issues that caused the patient to leave treatment, the steps taken to retain the patient in care, and the circumstances of the readmission. If a patient is pregnant, the OTP should work with the patient to communicate with the patient's prenatal care provider while adhering to the privacy standards set forth in 42 CFR part 2.

Withdrawal Management in the Setting of the OTP: Asking the Patient To Leave

OTPs sometimes find themselves in the position of having to ask a patient to leave treatment, a situation historically known as involuntary discharge. Often, these situations occur when a patient has engaged in threatening or violent behavior toward another patient or an OTP staff member. Asking a patient to leave treatment should only be used when all other options for addressing the specific situation with a patient have been exhausted, and the decision to use it should consider special patient circumstances. For example, OTPs should avoid asking a pregnant patient to leave OTP care given the risk of fetal compromise due to withdrawal.

The preferred approach to addressing situations in which the risks of continuing care of a patient increases risks for other patients or OTP staff is for OTPs to refer or transfer patients to a suitable alternative treatment program while maintaining a therapeutic dosage of medications during the transfer process, provided there are no medical safety concerns with maintaining the dosage. In some instances, a temporary period of guest dosing at an alternative treatment program may give time for the home OTP to review and clarify the incident and determine clinically appropriate next steps for the patient and any others involved.

If a patient's continued enrollment in the OTP is no longer feasible, a careful and individualized approach to discontinuation of services is essential. Similar to voluntary withdrawal from medication, the OTP should establish a medically supervised tapering plan, adjusted based on clinical judgment and the patient's specific needs. Given the potential risks associated with treatment discontinuation, additional supports should be provided, such as overdose prevention education and naloxone or another opioid overdose reversal medication.

Circumstances warranting treatment discontinuation at the OTP include:

- **Behavioral disruptions:** Instances when a patient's continued disruptive behavior poses a significant risk to themselves, other patients, or staff, despite assessments and interventions for co-occurring mental health conditions or trauma-triggered responses, counseling, or modified treatment plans.
- **Violent or threatening behavior:** Situations involving physical or threatening verbal aggression towards patients, staff, or visitors.
- **Incarceration or other confinement:** Circumstances preventing continued participation in the OTP.

In all cases, OTPs should prioritize patient safety and well-being. This includes assessing for underlying medical or mental health conditions that may contribute to disruptive behaviors and providing

appropriate services and referrals for additional support. OTP practitioners should include an assessment of suicidal risk or harm to others as part of addressing any disruptive behaviors.

One concern for OTPs in continuing to provide care for patients occurs around payment of fees. As of January 2020, OTP services are covered by Medicare for Medicare-eligible patients, and the majority of states reimburse for OTP services under their Medicaid programs. Multiple federal grant programs support OTP services for uninsurable patients, and opioid settlement dollars are a potential new source of funds for patients unable to afford the costs of treatment. Rather than terminating care in circumstances of outstanding payments for treatment, OTPs are encouraged to consider funding options, such as county, state, or federal grant funding and working with patients on a modified payment plan. When nonpayment is a result of lost insurance, the OTP should explore and assist the patient in regaining that insurance in a timely manner. Terminating treatment for unpaid fees should be an absolute last resort.

Interim Treatment

42 CFR § 8.12(j). Interim treatment. (1) The program sponsor of an OTP may admit an individual, who is eligible for admission to comprehensive treatment, into interim treatment if comprehensive services are not readily available within a reasonable geographic area and within 14 days of the individual's seeking treatment. At least two drug tests shall be obtained from patients during the maximum of 180 days permitted for interim treatment. A program shall establish and follow reasonable criteria for establishing priorities for moving patients from interim to comprehensive treatment. These transition criteria shall be in writing and shall include, at a minimum, prioritization of pregnant patients in admitting patients to interim treatment and from interim to comprehensive treatment. Interim treatment shall be provided in a manner consistent with all applicable Federal and State laws, including sections 1923, 1927(a), and 1976 of the Public Health Service Act (21 U.S.C. 300x–23, 300x–27(a), and 300y–11).

(2) The program shall notify the SOTA when a patient begins interim treatment, when a patient leaves interim treatment, and before the date of transfer to comprehensive services, and shall document such notifications.

(3) The Secretary may revoke the interim authorization for programs that fail to comply with the provisions of this paragraph (j). Likewise, the Secretary will consider revoking the interim authorization of a program if the State in which the program operates is not in compliance with the provisions of § 8.11(h).

(4) All requirements for comprehensive treatment in this section apply to interim treatment with the following exceptions:

(i) A primary counselor is not required to be assigned to the patient, but crisis services should be available;

(ii) Interim treatment cannot be provided for longer than 180 days in any 12-month period;

(iii) By day 120, a plan for continuing treatment beyond 180 days must be created, and documented in the patient's clinical record; and

(iv) Formal counseling, vocational training, employment, economic, legal, educational, and other recovery support services described in paragraphs (f)(4) and (f)(5)(i) and (iii) of this section are not required to be offered to the patient. However, information pertaining to locally available, community-based resources for ancillary services should be made available to individual patients in interim treatment.

Interim treatment refers to services that patients receive from an OTP on a temporary basis while they wait for access to more comprehensive treatment. [256] OTPs may admit any patient who is eligible for admission to comprehensive treatment services into interim treatment if those comprehensive services are not readily available within a reasonable geographic area and within 14 days of the patient seeking treatment. OTPs may offer interim treatment to patients for up to a total of 180 days in any 12-month period. [257]

The goal of interim treatment remains consistent with previous iterations of the *Federal Guidelines for Opioid Treatment Programs* (the Guidelines). It is not meant to replace comprehensive treatment, but it provides OTPs with an additional tool they can use to support people in need of treatment for OUD. Interim treatment ensures individuals on wait-lists for comprehensive care can still receive services, [258] reduces patient and societal risks when comprehensive treatment is not currently available, [259] and has been shown to be more effective than wait-lists in reducing illicit opioid use. [260, 261]

With the expansion from 120 to 180 allowable days of treatment and the evolving use of telehealth, interim treatment is an increasingly flexible option that OTPs can offer without being bound by the requirements of offering comprehensive treatment (e.g., counseling, vocational training, employment, and educational services need not be offered). Interim treatment also provides OTPs with increased flexibility to address issues such as staffing shortages, program closures, transportation challenges, or lengthy wait-list times. The Guidelines make clear that OTPs should prioritize admitting pregnant patients into interim treatment and to transitioning them from interim to comprehensive treatment. [262]

To provide interim treatment services, OTPs need to receive the approval of both SAMHSA and their SOTA. As part of this approval process, OTPs should provide SAMHSA with documentation from the SOTA demonstrating that the OTP is unable to provide access for patients to comprehensive treatment program services within a reasonable geographic area within 14 days of the time patients seek treatment for OUD. OTPs also should demonstrate that offering interim treatment services will not otherwise reduce the capacity of the comprehensive treatment programs in its state to admit individuals.

OTPs providing interim treatment need to arrange for each patient's transfer to comprehensive treatment program services no later than 180 days from the date on which interim treatment began. By Day 120 of interim treatment, the OTP must develop a plan for providing comprehensive treatment beyond Day 180. This plan must be documented in the patient's record while awaiting transfer to a comprehensive treatment program. The plan helps ensure that the OTP has sufficient time to work on transferring the patient from interim to comprehensive care before Day 180. Individuals enrolled in interim treatment cannot have services terminated without the approval of an OTP practitioner. Interim treatment may be offered through a brick-and-mortar medication unit or mobile medication unit.

It is no longer required that OTPs administer only daily doses during interim treatment. Crisis services should be offered to patients, and information should be made available to interim treatment patients regarding community-based resources for ancillary services, as clinically indicated.

Strategies for Ensuring Continuity of Care

Continuity of care may be conceptualized as the continuation of quality care over time, [263] delivered in a timely, consistent, and logical way, within the healthcare agency setting, within the community, and across and between parts of the broader system of care. [264] The World Health Organization defines continuity of care as "the degree to which a series of discrete health care events is experienced by people as coherent and interconnected over time and consistent with their health needs and preferences." [265] For the scope of this document, continuity of care in an opioid treatment program (OTP) refers to the continuity of medication and continuing support services within the OTP, during transitions of care, or in circumstances in which a disruption in access to services is a known or predictable possibility.

Transitioning to a different provider, switching medication types, planning for periods of absence from the home OTP, potential emergency situations, and terminating treatment altogether present opportunities for OTPs to engage the patient in planning for continuity of care. As discussed in the previous chapter, OTPs should take as much care supporting patients during actual and potential changes in treatment status as they do during admission and initiation of treatment. OTPs can use several educational and recovery support tools to partner with patients as they look to initiate and make changes to their treatment, medication management, and recovery.

Continuity of care within the OTP must consider patients who express interest in leaving care or transferring to a different OTP and those who actually terminate or transfer from the program. OTPs also must consider patients who transition to and from additional levels of care or types of treatment while still enrolled. Patients who leave care may benefit from continued healthcare and community recovery support. SAMHSA recommends that OTPs ensure patients leaving care have a plan and referrals—mutually agreed on by the patient and OTP practitioner—linking the patients to services that will support ongoing recovery and maintain or improve patient health outcomes over the long term. [266] OTPs should also make sure patients have received overdose prevention education and have naloxone or another opioid overdose reversal medication.

Some strategies for ensuring medication continuity during transitions of care include utilizing the expanded take-home flexibilities afforded by the revised rule, with delivery or provision of medication through secure channels if the new location is unable to provide access to methadone or buprenorphine through other means. OTPs should also use coordinated referrals and warm handoffs to partnering providers who are proficient in evidence-based practices for opioid use disorder (OUD), encouraging the use of peer support during and after leaving treatment and providing linkages to harm reduction and overdose prevention services. OTPs should focus on continuity of care for patients regardless of the service setting in which the patient first receives care. [267] For warm handoffs between OTPs, as patients transfer from one to another, meaningful information about the patient and their response to treatment should be conveyed along with medication dose information.

The Care and Case Management section provides more information on this topic.

Effective Transition Planning

Transition planning is recommended for any patient whose care is changing in a significant way. For example, a transition plan is appropriate when patients are:

- Initiating long-term medically supervised withdrawal to taper off methadone or buprenorphine.

- Transferring to another facility.
- Planning surgeries or other medical procedures or anticipating consequences from outstanding legal issues.

The transition plan establishes steps for maintaining continuity of care, including any actions the OTP will take, and delineates the resources offered to patients that will best meet their ongoing needs. For patients leaving care, a good transition plan maximizes the likelihood that patients will continue receiving support [268] while protecting patients from withdrawal and reducing vulnerability to overdose.

Possible elements of a transition plan include:

- A warm handoff directly to the services a patient will need regardless of whether they are transferring to another OTP, engaging in medical or mental health services, or connecting with other community services.
- Naloxone or other opioid overdose reversal medication and overdose prevention information.
- 988 or other crisis numbers for patients to call in case they should experience a mental health or substance use crisis.

Community Engagement, Outreach, and Collaboration

To provide patients with optimal care throughout their treatment experience and beyond, OTPs need to effectively engage and collaborate with other healthcare, social services, educational, or employment resources and recovery organizations in the community. Building and maintaining such relationships is a fundamental part of providing comprehensive care and ensuring patients have access to services the OTP may not provide. *Community engagement* is defined as "a process of developing relationships that enable stakeholders to work together to address health-related issues and promote well-being to achieve positive health impact and outcomes." [269]

Community engagement begins with reaching out to the community and building relationships and trust. Community engagement is based on several core principles: [270]

- Transparency and trust.
- Careful planning and preparation.
- Inclusion and demographic diversity.
- Collaboration and shared purpose.
- Openness and learning.
- Impact and action.

OTPs can use these principles as part of a process to ensure that community stakeholders understand what the program offers and how it supports long-term recovery. This allows OTPs to share positive messaging about MOUD and how to access it. Additional benefits include establishing clear processes for warm handoffs among behavioral health service providers and recovery community organizations, increasing access to care, decreasing service duplication among providers, and ensuring community support. OTPs may benefit from developing and implementing policies and procedures addressing community relations in a patient-centered way.

Strong community relationships also benefit patients' long-term recovery. Collaboration efforts between OTPs and other organizations may lead to benefits for patients such as: [271]

- Identifying referral sources that serve patients with OUD in different systems.

- Establishing relationships with specific staff members who help plan for patient needs.
- Developing comprehensive care plans.
- Monitoring service delivery and ensuring timely implementation of services.
- Cross-training and development of staff and providers.

Community collaboration within a recovery-oriented system of care ensures seamless navigation, care coordination, and holistic support for patients.

Collaboration Support and Tools

OTPs can engage and build collaborations with the community using the following channels.

Peer Services

Peer support specialists help build connections and develop resources to support patients. Peer support specialists are highly trained in recovery management and are uniquely positioned for collaborative outreach to promote a visible and accessible presence within the community. As resource navigators, they may help patients and other OTP staff build resource libraries and databases. The Counseling Treatment and Recovery Support Services section provides more information on this topic.

Bridge Programs

Emergency departments can also be strong partners with OTPs. Partnerships between emergency departments and OTPs, in addition to other medical providers serving patients with OUD, are known as *bridge programs*. [272] Hospitals are often the first point of care for patients who may be experiencing an overdose. Emergency departments can dispense a short-term dose of MOUD before connecting patients to OTPs for additional care. Additionally, peer support specialists can be used to provide a warm handoff from the emergency department to the OTP, ensuring that the patient accesses OTP services after being released from the emergency department. Dedicated *bridge clinics* can dispense methadone under the "3-day rule," which allows for methadone to be dispensed outside of an OTP for the treatment of opioid withdrawal for up to 3 days while linkage to comprehensive care is established. [273]

The Drug Enforcement Administration's "3-Day Rule"

In 1974, the Drug Enforcement Administration (DEA) published regulations to implement the Narcotic Addict Treatment Act of 1974, allowing for practitioners to "administer and dispense certain narcotic medications for detoxification or maintenance treatment as long as they were separately registered as a narcotic treatment program (NTP)." In the revised 42 CFR part 8, an "emergency treatment" section was added to allow practitioners to administer (but not prescribe) 1 days' worth of narcotic drugs, for not more than 3 continuous days, "for the purpose of relieving acute withdrawal symptoms when necessary while arrangements are being made for referral for treatment." This rule is currently codified at 21 CFR § 1306.07(b).

Other Collaboration Models

The hub-and-spoke model is a network system of treatment for OUD that involves two levels of care. The first level is focused on a central site, or "hub," where patients receive initial treatment services. In general, these services are comprehensive and more intensive than what can be provided in a second-level network site, or "spoke." Practitioners at this location typically are trained and specialize in substance use treatment services. In most existing models, OTPs serve as the central hub site. Other locations that can serve as hubs include mental health treatment facilities, pain management clinics, outpatient specialty addiction treatment centers, or residential substance use disorder (SUD) treatment

facilities. [274] The Rural Health Information Hub highlights Vermont's statewide hub-and-spoke treatment access system, a model of care for OUD that increases treatment capacity across a collaborative continuum of coordinated care.

After some period of time receiving care in the hub, the hub practitioner makes referrals, and the patient transfers some or all of their care to spokes, which provide patients with ongoing treatment, medication management (in the case of buprenorphine), and support. [275] These sites often include community-based organizations, primary care offices, community mental health centers, tribal health care centers, and other agencies that support recovery. Spoke sites typically offer less intensive SUD treatment services and often are less specialized.

Connecting patients to such services ensures responsive, targeted, holistic care that addresses specific needs, including the evaluation and treatment of medical or psychiatric conditions beyond SUDs. [276] This model can help formalize care coordination networks that leverage the resources and expertise of each system and organization.

Mobile Medication Units

Mobile medication units, as defined under 42 CFR § 8.2, are crucial extensions of brick-and-mortar OTPs. These units enhance accessibility by delivering essential services directly to underserved or hard-to-reach populations. By doing so, they ensure individuals with OUD receive the necessary treatment and support despite facing barriers to accessing brick-and-mortar OTPs. The revised rule allows any activity performed by a comprehensive brick-and-mortar OTP to be carried out in a mobile unit, provided that appropriate space and privacy considerations are met.

The primary purpose of mobile medical units is to provide convenient, flexible, and immediate access to a range of medication, medical, and behavioral health services. This approach helps reduce logistical, geographic, and socioeconomic barriers, making timely and appropriate care available to more individuals. Staff in mobile medical units engage in various activities vital for treating and supporting individuals with OUD. These include dispensing and administering MOUD, including methadone, buprenorphine, and naltrexone, as ordered by an OTP practitioner. [277] Staffing at mobile units can vary but often includes a nurse practitioner, driver, and security personnel.

In addition to dispensing medications, mobile units are places where initial medical examinations—both the screening and comprehensive portions—can take place for a patient to start MOUD. These services may be provided in person by a practitioner on staff at the mobile unit or through telehealth, with other arrangements made to complete the in-person portion of the comprehensive examination. Mobile units may also have capability for collecting and processing drug testing samples and for counseling, either in-person or through telehealth platforms.

As an extension of the primary OTP, patients continue to have access to any of the services offered at the brick-and-mortar medication unit, including those services that are challenging to provide at a mobile unit because of the lack of space and privacy. To comply with current DEA regulations, mobile units must return to their OTP at the end of each day and ensure safe storage of medications unless the OTP has a waiver from DEA with adequate provisions for securing the mobile unit in a location other than the home OTP.

To operate a mobile medication unit, certified OTPs must comply with several regulatory requirements. They must notify the Secretary of the U.S. Department of Health and Human Services by submitting the necessary forms (e.g., Form SMA-162) and comply with the provisions of 21 CFR part 1300, ensuring the unit meets all federal and state regulatory standards. Privacy and confidentiality of patient information

must be maintained, adhering to Health Insurance Portability and Accountability Act of 1996 regulations. By adhering to regulatory standards, these units ensure high-quality, patient-centered care while addressing the logistical and geographic barriers many individuals face in accessing treatment.

Exemption Requests

> **42 CFR § 8.11(g). Exemptions.** An OTP may, at the time of application for certification or any time thereafter, request from the Secretary exemption from the regulatory requirements set forth under this section and § 8.12. An example of a case in which an exemption might be granted would be for a private practitioner who wishes to treat a limited number of patients in a non-metropolitan area with few physicians and no OUD treatment services geographically accessible, and requests exemption from some of the staffing and service standards. The OTP shall support the rationale for the exemption with thorough documentation, to be supplied in an appendix to the initial application for certification or in a separate submission. The Secretary will approve or deny such exemptions at the time of application, or any time thereafter, if appropriate. The Secretary shall consult with the appropriate State authority prior to taking action on an exemption request.

"Exemption requests" are sometimes confused with "exception requests for take-home medication." Exception requests are what the Substance Abuse and Mental Health Services Administration (SAMHSA) has historically called the type of exemptions that are submitted when OTP practitioners determine the take-home doses are therapeutically necessary but fall outside what is permitted in 42 CFR § 8.12(i) *Unsupervised or ''take-home'' medication doses*. As such, other exemption requests are those that deviate from the provisions in the remainder of 42 CFR § 8.11 and 42 CFR § 8.12, such as changes to clinic infrastructure, patient census, staffing patterns, or treatment and service standards.

For these non–take home medication-related exemption requests, OTP sponsors should email the request to the Division of Pharmacologic Therapies at SAMHSA (DPT@samhsa.hhs.gov) for review. The OTP sponsor should include the clinic record number in the request along with a rationale for the need, purpose, and timeframe of the exemption. State concurrence should be included in the request to SAMHSA. If the request involves deviation from medication dispensing regulations, Drug Enforcement Administration (DEA) concurrence will also be necessary.

Appendix A. 42 CFR Part 8 Crosswalk of Changes

Notes:

- All references to a waiver to prescribe buprenorphine have been removed.
- Changes to the rule are shown in blue in the "2024 Rule" column.
- Only definitions that have been removed or significantly revised are included in this crosswalk.
- In many instances, "SAMHSA" was changed to "the Secretary."
- **This document is intended to be used only for guidance purposes and does not have the force or effect of law.**

Location in Regulation	2001 Rule	2024 Rule
Subpart A—General Provisions		
Subpart A § 8.1 Scope (a)	(a) *[Previously referred to the waiver to prescribe buprenorphine]*	(a) **This subpart and** subparts **B** through **D** of this part establish the procedures by which **the Secretary** of Health and Human Services (**the Secretary**) will determine whether **an applicant seeking to become an Opioid Treatment Program (OTP)** is qualified under section 303**(h)** of the Controlled Substances Act (CSA) (21 U.S.C. 823**(h))** to dispense **Medications for Opioid Use Disorder (MOUD)** in the treatment of Opioid Use Disorder (OUD), and establishes **the Secretary's** standards regarding the appropriate quantities of **MOUD** that may be provided for unsupervised use by individuals undergoing such treatment (21 U.S.C. 823(h)). Under **this subpart and subparts B through D**, an **applicant seeking to become an OTP** must first obtain from the Secretary or, by delegation, from the **Assistant Secretary for Mental Health and Substance Use,** a certification that the **applicant** is qualified under **the Secretary's** standards and will comply with such standards. Eligibility for certification will depend upon the **applicant** obtaining accreditation from an Accreditation Body that has been approved by **the Secretary. This subpart and subparts B through D also** establish the procedures whereby an entity can apply to become an approved Accreditation Body, **and the** requirements and general standards for Accreditation Bodies to ensure that **OTPs** are

Location in Regulation	2001 Rule	2024 Rule
		consistently evaluated for compliance with **the Secretary's** standards for treatment of OUD with MOUD.
Subpart A § 8.1 (b)	(b) *[Previously referred to waiver to prescribe buprenorphine]*	**(b) Severability. Any provision of this part held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, or stayed pending further agency action, shall be construed so as to give it the maximum effect permitted by law, unless such holding shall be one of utter invalidity or unenforceability, in which event such provision shall be severable from this part and shall not affect the remainder thereof or the application of the provision to persons not similarly situated or to dissimilar circumstances.**
Subpart A § 8.2 Definitions	The following definitions apply to this part:	The following definitions apply to this part: ***[The definition "Additional credentialing" has been removed]*** ***[The definition "Approval term" has been removed]*** ***Care plan* means an individualized treatment and/or recovery plan that outlines attainable treatment goals that have been identified and agreed upon between the patient and the OTP clinical team, and which specifies the services to be provided, as well as the proposed frequency and schedule for their provision.** ***[The definition "Covered medication" has been removed]*** ***[The definition "Detoxification treatment" has been removed]*** ***Conditional certification* is a type of temporary certification granted to an OTP that has requested renewal of its certification and that has received temporary accreditation for one year by an approved Accreditation Body. The one-year accreditation period is to allow the OTP to address areas of significant non-conformance with accreditation standards that do not involve immediate, high-risk health and/or safety concerns.** ***Continuous medication treatment* means the uninterrupted**

Location in Regulation	2001 Rule	2024 Rule
		treatment for OUD involving the dispensing and administration of MOUD at stable dosage levels for a period in excess of 21 days.
	Diversion control plan means a set of documented procedures that reduce the possibility that controlled substances will be transferred or used illicitly.	*Diversion control plan* means a set of documented procedures that reduce the possibility that controlled **medications** will be transferred or **otherwise shared with others to whom the medication was not prescribed or dispensed.**
		[The definition "Emergency situation" has been removed]
		Harm reduction **refers to practical and legal evidence-based strategies, including: overdose education; testing and intervention for infectious diseases, including counseling and risk mitigation activities forming part of a comprehensive, integrated approach to address human immunodeficiency virus (HIV), viral hepatitis, sexually transmitted infections, and bacterial and fungal infections; distribution of opioid overdose reversal medications; linkage to other public health services; and connecting those who have expressed interest in additional support to peer services.**
		Individualized dose **means the dose of a medication for opioid use disorder, ordered by an OTP practitioner and dispensed to a patient, that sufficiently suppresses opioid withdrawal symptoms. Individualized doses may also include split doses of a medication for opioid use disorder, where such dosing regimens are indicated.**
		[The definition "Long-term detoxification" has been removed.]
		Long-term ***care facilities*** **mean those facilities that provide rehabilitative, restorative, and/or ongoing services to those in need of assistance with activities of daily living. Long-term care facilities include: extended acute care facilities; rehabilitation centers; skilled nursing facilities; permanent supportive housing; assisted living facilities; and chronic care hospitals.**
		[The definition "Maintenance treatment" has been removed]

Location in Regulation	2001 Rule	2024 Rule
	Medical director means a physician, licensed to practice medicine in the jurisdiction in which the opioid treatment program is located, who assumes responsibility for administering all medical services performed by the program, either by performing them directly or by delegating specific responsibility to authorized program physicians and healthcare professionals functioning under the medical director's direct supervision.	*Medical director* means a physician, licensed to practice medicine in the jurisdiction in which the OTP is located, who assumes responsibility for **all** medical and **behavioral health** services provided by the program, including their administration. A medical director **may delegate** specific **responsibilities** to authorized program physicians**, appropriately licensed non-physician practitioners with prescriptive authority functioning** under the medical director's supervision**, or appropriately licensed and/or credentialed non-physician healthcare professionals providing services in the OTP, in compliance with applicable Federal and State laws. Such delegations will not eliminate the medical director's responsibility for all medical and behavioral health services provided by the OTP.** ***[The definition "Medical and rehabilitative services" has been removed]*** ***[The definition "Medication-Assisted Treatment (MAT)" has been removed]*** ***Medication for Opioid Use Disorder* or *MOUD* means medications, including opioid agonist medications, approved by the Food and Drug Administration under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), for use in the treatment of OUD. As used in this part, "continuous medication treatment" is intended to be synonymous with the term "maintenance" treatment as used in 21 U.S.C. 823(h)(1), and the term "withdrawal management" is intended to be synonymous with the term "detoxification" as used in 21 U.S.C. 823(h)(1).** ***[The definition "Opioid agonist treatment medication" has been removed]*** ***[The definition "Opioid dependence" has been removed]*** ***[The definition "Opioid drug" has been removed]***
	Opioid use disorder treatment means the dispensing of an	*Opioid Use Disorder treatment* means the dispensing of **MOUD**, along

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	opioid agonist treatment medication, along with a comprehensive range of medical and rehabilitative services, when clinically necessary, to an individual to alleviate the adverse medical, psychological, or physical effects incident to an opioid use disorder. This term includes a range of services including detoxification treatment, short-term detoxification treatment, long-term detoxification treatment, maintenance treatment, comprehensive maintenance treatment, and interim maintenance treatment.	with the **provision of a** range of medical and **behavioral health** services, **as** clinically necessary **and based on an individualized assessment and a mutually agreed-upon care plan**, to an individual to alleviate the **combination of** adverse medical, psychological, or **physical effects associated with an OUD.** ***[The definition "Patient limit" has been removed]*** ***Physical and behavioral health services* include services such as medical and psychiatric screening, assessments, evaluations, examinations, and interventions, counseling, health education, peer support services, and social services (e.g., vocational and educational guidance, employment training), that are intended to help patients receiving care in OTPs achieve and sustain remission and recovery.**
	Practitioner means a physician who is appropriately licensed by the State to dispense covered medications and who possesses a waiver under 21 U.S.C. 823(g)(2).	*Practitioner*, **for purposes of this part,** means a **health care professional** who is appropriately licensed by a State to **prescribe and/or** dispense medications **for opioid use disorders and, as a result, is authorized to practice within an OTP**. ***[The definition "Practitioner incapacity" has been removed]*** ***[The definition "Short-term detoxification treatment" has been removed]*** ***Recovery support services* means:** **(1) *Recovery* is the process of change through which people improve their health and wellness, live self-directed lives, and strive to reach their full potential.** **(2) *Recovery support services* can include, but are not limited to, community-based recovery housing, peer recovery support services, social support, linkage to and coordination among allied service providers and a full range of human services that facilitate recovery and wellness contributing to an improved quality of life. The services extend the continuum of care by strengthening and complementing**

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		substance use disorder (SUD) treatment interventions in different settings and stages. ***Split dosing* means dispensing of a single dose of MOUD as separate portions to be taken within a 24-hour period. Split dosing is indicated among, but not limited to, those patients who: possess a genetic variant which increases methadone metabolism; concurrently take other medications or drink alcohol that also induce hepatic enzymes leading to more rapid metabolism of methadone; who are pregnant; or for whom methadone or buprenorphine are being used to treat a concurrent pain indication in addition to the diagnosis of OUD. This leads to more stable, steady-state medication levels.** ***[The definition "Treatment plan" has been removed]*** ***Telehealth* or *telemedicine, for purposes of this part,* is the delivery and facilitation of health and health-related services including medical care, counseling, practitioner, provider and patient education, health information services, and self-care via telecommunications and digital communication technologies. This includes Health Insurance Portability and Accountability Act (HIPAA)-compliant video and audio-only communication platforms.** ***Withdrawal management* means the dispensing of a MOUD in decreasing doses to an individual to alleviate adverse physical effects incident to withdrawal from the continuous or sustained use of an opioid and as a method of bringing the individual to an opioid-free state within such period. Long-term withdrawal management refers to the process of medication tapering that exceeds 30 days.**
Subpart B—Accreditation of Opioid Treatment Programs	(a) Eligibility. Private nonprofit organizations or State governmental entities, or political subdivisions thereof, capable of meeting the requirements of this part may apply for approval as an accreditation body.	(a) Eligibility. Private nonprofit organizations, State or **territorial** governmental entities, or political subdivisions thereof, **and Indian Tribes as defined by the Federally Recognized Indian Tribe List Act of 1994**, that are capable of meeting the requirements of this part may apply for approval as an Accreditation Body.

Location in Regulation	2001 Rule	2024 Rule
§ 8.3 Application for approval as an accreditation body (a)		
Subpart B § 8.3 (b)(4)(v)	*[Relocated to Subpart B § 8.3 (b)(4)(vi) in 2024 rule]*	***[Originally found in Subpart B § 8.3 (b)(4)(v) in 2001 rule]*** **(v) Policies and procedures for determining OTPs level of adherence to this part and Accrediting Body standards and level of accreditation;**
Subpart B § 8.3 (b)(4)(vi)	*[Relocated to Subpart B § 8.3 (b)(4)(vi) in 2024 rule]*	***[Originally found in Subpart B § 8.3 (b)(4)(v) in 2001 rule]*** **(vi)** Policies and procedures for suspending or revoking an OTP's accreditation;
Subpart B § 8.3 (b)(4)(vii)	*[Relocated to Subpart B § 8.3 (b)(4)(viii) in 2024 rule]*	*[Originally found in Subpart B § 8.3 (b)(4)(vi) in 2001 rule]* (vii) Policies and procedures that will ensure processing of applications for accreditation and applications for renewal of accreditation within a timeframe approved by **the Secretary**; and
Subpart B § 8.3 (b)(4)(viii)	*[New numbering in 2024 rule]*	*[Originally found in Subpart B § 8.3 (b)(4)(vii) in 2001 rule]* (viii) A description of the applicant's appeals process to allow OTPs to contest adverse accreditation decisions;
Subpart B § 8.3 (b)(6)	(6) A description of the education, experience, and training requirements for the applicant's professional staff, accreditation survey team membership, and the identification of at least one licensed physician on the applicant's staff;	(6) A description of the education, experience, and training requirements for the applicant's professional staff, accreditation survey team membership, and the identification of at least one licensed physician **with experience treating OUD with MOUD** on the applicant's staff;
Subpart B § 8.3 (b)(7)	(7) A description of the applicant's training policies;	(7) A description of the applicant's **survey team** training policies;

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Subpart B § 8.3 (b)(11)	(11) Any other information SAMHSA may require.	(11) Any other **supporting** information **the Secretary** may require.
Subpart B § 8.3 (h)	(h) State accreditation bodies. State governmental entities, including political subdivisions thereof, may establish organizational units that may act as accreditation bodies, provided such units meet the requirements of this section, are approved by SAMHSA under this section, and have taken appropriate measures to prevent actual or apparent conflicts of interest, including cases in which State or Federal funds are used to support opioid treatment services.	(h) State, **territorial, or Indian Tribe** Accreditation Bodies. State, **territorial, and Indian Tribe** entities, including political subdivisions thereof, may establish organizational units that may act as Accreditation Bodies, provided such units meet the requirements of this section, are approved by **the Secretary** under this section, and have taken appropriate measures to prevent actual or apparent conflicts of interest, including cases in which State or Federal funds are used to support **MOUD**.
Subpart B § 8.4—Accreditation Body responsibilities (a)(1)	(1) Accreditation bodies shall conduct routine accreditation surveys for initial, renewal, and continued accreditation of each OTP at least every 3 years.	(1) Accreditation Bodies shall conduct routine accreditation surveys for initial accreditation, and **then** at least every three years **to allow for renewal of certification.**
Subpart B § 8.4 (b)(1)	(1) If an accreditation body receives or discovers information that suggests that an OTP is not meeting Federal opioid treatment standards, or if survey of the OTP by the accreditation body otherwise demonstrates one or more deficiencies in the OTP, the accreditation body shall as appropriate either require and monitor corrective action or shall suspend or revoke accreditation of the OTP, as appropriate based on the significance of the deficiencies.	(1) If an Accreditation Body receives or discovers information that suggests that an OTP is not meeting **applicable accreditation or certification standards established or authorized under this part**, or if **a** survey of the OTP by the Accreditation Body demonstrates **that such standards are not being met, the Accreditation Body shall, within 60 days following discovery of the non-compliant condition(s) or applicable survey date:**
Subpart B § 8.4 (b)(1)(i)	(i) Accreditation bodies shall either not accredit or shall revoke the accreditation of any OTP that substantially fails to meet the Federal opioid treatment standards.	(i) **Provide written notice to the OTP that identifies each area of non-compliance, categorizes each non-compliant condition as either "minor" or "significant" as determined by the Accrediting Body, and requires the OTP to take corrective action to address the area(s) of non-compliance within a schedule, not to exceed 180 days, that the Accrediting Body deems appropriate based on the severity of the non-compliant conditions; and**

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Subpart B § 8.4 (b)(1)(ii)	(ii) Accreditation bodies shall notify SAMHSA as soon as possible but in no case longer than 48 hours after becoming aware of any practice or condition in an OTP that may pose a serious risk to public health or safety or patient care.	**(ii) Provide the Secretary with a copy of the written notice required under paragraph (b)(1)(i) of this section.**
Subpart B § 8.4 (b)(1)(iii)	(iii) If an accreditation body determines that an OTP is substantially meeting the Federal opioid treatment standards, but is not meeting one or more accreditation elements, the accreditation body shall determine the necessary corrective measures to be taken by the OTP, establish a schedule for implementation of such measures, and notify the OTP in writing that it must implement such measures within the specified schedule in order to ensure continued accreditation. The accreditation body shall verify that the necessary steps are taken by the OTP within the schedule specified and that all accreditation elements are being substantially met or will be substantially met.	***[Subpart B § 8.4 (b)(1)(iii) has been removed]***
Subpart B § 8.4 (b)(2)	(2) Nothing in this part shall prevent accreditation bodies from granting accreditation, contingent on promised programmatic or performance changes, to OTPs with less substantial violations. Such accreditation shall not exceed 12 months. OTPs that have been granted such accreditation must have their accreditation revoked if they fail to make changes to receive unconditional accreditation upon resurvey or reinspection.	**(2) Once an Accreditation Body provides an OTP with the notice described in paragraph (b)(1)(i) of this section, it shall verify the implementation of the corrective measures by the OTP within the specified schedule. Within 30 days following the last day of the specified schedule, the Accreditation Body shall provide written notice to the Secretary regarding whether the OTP has implemented the corrective measures.**
Subpart B § 8.4 (b)(3)	*[New in 2024 rule]*	**(3) OTPs that are meeting the requirements of § 8.12 but are only required to correct minor non-compliant conditions shall be granted a three-year accreditation, beginning from the end date of the current and expiring accreditation period. Minor non-compliant conditions, found at the time of the survey that are not resolved, as determined by the Accreditation Body, within the OTP's three-year accreditation period and that remain areas of non-compliance**

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		during the OTP's subsequent three-year accreditation renewal survey, shall automatically be categorized as "significant" non-compliant conditions for purposes of the renewal survey and must be corrected in accordance with paragraph (b)(1)(i) of this section.
Subpart B § 8.4 (b)(4)	*[New in 2024 rule]*	**(4) OTPs that are required to correct significant non-compliant conditions shall be granted a one-year accreditation, beginning from the end date of the current and expiring accreditation period. An OTP's accreditation must be revoked if it fails to correct significant non-compliant conditions within the schedule provided under paragraph (b)(1)(i) of this section. If an Accrediting Body verifies that an OTP has corrected the significant non-compliant conditions identified within the specified schedule, it shall extend the OTP's accreditation period by an additional two years.**
Subpart B § 8.4 (b)(5)	*[New in 2024 rule]*	**(5) In cases of severe non-compliance with the requirements of section 8.12 that pose immediate risks to patient health and safety, the Accreditation Body shall inform the OTP and Secretary within 48 hours and provide a detailed written report of the non-compliance within 5 business days. The Accreditation Body shall give the OTP 30 days from the date of the non-compliance report to correct the non-compliance issue(s). A follow-up survey shall be conducted by the Accreditation Body within 30 days of the expected correction date to ensure successful remediation. Should the OTP not rectify the non-compliance within the 30-day period, the Accreditation Body shall revoke the OTP's accreditation. The Secretary will then make a decision regarding the OTP's certification in accordance with the procedures under section 8.13.**
Subpart B § 8.4 (c)(1)	(1) Accreditation bodies shall maintain records of their accreditation activities for at least 5 years from the creation of the record. Such records must contain sufficient detail to support each accreditation decision made by the accreditation body.	(1) Accreditation Bodies shall maintain, **and make available as requested by the Secretary**, records of their accreditation activities for at least 5 years from the creation of the record. Such records must contain sufficient detail to support each accreditation decision made by the Accreditation Body.

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Subpart B § 8.4 (d)(2)	(2) Accreditation bodies shall make a summary of the results of each accreditation survey available to SAMHSA upon request. Such summaries shall contain sufficient detail to justify the accreditation action taken.	(2) Accreditation Bodies shall **submit** a summary of the results of each accreditation survey **to the Secretary within 90 days following the survey visit**. Such summaries shall contain sufficient detail to justify the accreditation action taken.
Subpart B § 8.4 (e)	(e) Complaint response. Accreditation bodies shall have policies and procedures to respond to complaints from SAMHSA, patients, facility staff, and others, within a reasonable period of time but not more than 5 days of the receipt of the complaint. Accreditation bodies shall also agree to notify SAMHSA within 48 hours of receipt of a complaint and keep SAMHSA informed of all aspects of the response to the complaint.	(e) Complaint response. Accreditation Bodies shall have policies and procedures **in place** to respond to complaints **received** from **the Secretary**, patients, facility staff, and others within 5 **business** days **from** the receipt of the complaint. Accreditation Bodies shall also agree to notify **the Secretary** within **5 business days** of receipt of a complaint **from a patient, facility, staff or others**, and to inform **the Secretary** of their response to the complaint.
Subpart B § 8.4 (h)(1)	(1) An accreditation body survey team shall consist of healthcare professionals with expertise in drug abuse treatment and, in particular, opioid treatment. The accreditation body shall consider factors such as the size of the OTP, the anticipated number of problems, and the OTP's accreditation history, in determining the composition of the team. At a minimum, survey teams shall consist of at least two healthcare professionals whose combined expertise includes:	(1) An Accreditation Body survey team shall consist of healthcare professionals with expertise in **OUD treatment**. The Accreditation Body shall consider factors such as the size of the OTP, the anticipated number of **survey non-compliance issues**, and the OTP's accreditation history in determining the composition of the team. At a minimum, survey teams shall consist of at least two healthcare professionals whose combined expertise includes:
Subpart B § 8.4 (h)(1)(i)	(i) The dispensing and administration of drugs subject to control under the Controlled Substances Act (21 U.S.C. 801 et seq.);	(i) The dispensing and administration of **medications** subject to control under the Controlled Substances Act (21 U.S.C. 801 et seq.);
Subpart B § 8.4 (h)(1)(ii)	(ii) Medical issues relating to the dosing and administration of opioid agonist treatment medications for the treatment of opioid use disorder;	(ii) Medical issues relating to the dosing and administration of **MOUD** for the treatment of OUD;
Subpart B § 8.4 (h)(1)(iii)	(iii) Psychosocial counseling of individuals undergoing opioid treatment; and	(iii) Psychosocial counseling of individuals **receiving OUD** treatment; and

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Subpart B § 8.4 (h)(2)	(2) Members of the accreditation team must be able to recuse themselves at any time from any survey in which either they or the OTP believes there is an actual conflict of interest or the appearance of a conflict of interest.	(2) Members of the accreditation team must be able to recuse themselves at any time from any survey in which either they or the OTP believes there is an actual conflict of interest or the appearance of a conflict of interest. **Conflict or perceived conflict of interest must be documented by the Accreditation Body and made available to the Secretary.**
Subpart B § 8.5 Periodic evaluation of Accreditation Bodies	SAMHSA will evaluate periodically the performance of accreditation bodies primarily by inspecting a selected sample of the OTPs accredited by the accrediting body and by evaluating the accreditation body's reports of surveys conducted, to determine whether the OTPs surveyed and accredited by the accreditation body are in compliance with the Federal opioid treatment standards. The evaluation will include a determination of whether there are major deficiencies in the accreditation body's performance that, if not corrected, would warrant withdrawal of the approval of the accreditation body under § 8.6.	**The Secretary** will **periodically evaluate** the performance of Accreditation Bodies primarily by inspecting a selected sample of the OTPs accredited by the Accrediting Body, and by evaluating the Accreditation Body's reports of surveys conducted, to determine whether the OTPs surveyed and accredited by the Accreditation Body are in compliance with **applicable standards under this part**. The evaluation will include a determination of whether there are major deficiencies in the Accreditation Body's performance that, if not corrected, would warrant withdrawal of the approval of the Accreditation Body under § 8.6.
Subpart C—Certification and Treatment Standards for Opioid Treatment Programs **§ 8.11 Opioid Treatment Program certification (a)**	*[No change]*	
Subpart C § 8.11 (a)(3)	(3) Certification shall be granted for a term not to exceed 3 years, except that certification may be extended during the third year if an application for accreditation is pending.	(3) **OTPs are expected to maintain certification with the Secretary and to comply with any other conditions for certification established by the Secretary.** Certification shall be granted for a term not to exceed 3 years, except that certification may be **renewed** during the

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		final certification year if **the OTP applies for certification renewal in accordance with the steps outlined in paragraph (a)(4) of this section.**
Subpart C § 8.11 (a)(4)	*[New in 2024 rule]*	**(4) OTPs which satisfy the criteria for certification under this section may apply for renewal of their certification. OTPs are expected to apply for certification renewal during the final year of the OTP's certification period. OTPs should take steps to ensure that administrative tasks associated with renewal are completed before the OTP's certification expires. OTPs may apply for certification renewal in accordance with the procedures as outlined in paragraph (b) of this section. If an OTP anticipates any delays in routine certification renewal, an extension may be requested by submitting to the Secretary a statement justifying the extension in accordance with paragraph (e) of this section.**
Subpart C § 8.11 (a)(5)	*[New in 2024 rule]*	**(5) OTPs that are certified and are seeking certification renewal, and who have been granted accreditation for one year by an Accreditation Body as provided under § 8.4(b)(1)(iii), may receive a conditional certification for one year unless the Secretary determines that such conditional certification would adversely affect patient health. An OTP must obtain a standard 3-year certification, as described in paragraph (a)(3) of this section, within the 1-year conditional certification period. If standard accreditation is not obtained by the OTP within the 1-year conditional certification period, the OTP's conditional certification will lapse, and the Attorney General will be notified that the OTP's registration should be revoked.**
Subpart C § 8.11 (a)(6)	*[New in 2024 rule]*	**(6) OTPs whose certification has expired, and who seek re-certification, will be considered "new" programs and will be required to apply for provisional certification in accordance with paragraph (d) of this section.**

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Subpart C § 8.11 (b)	(b) Application for certification. Three copies of an application for certification must be submitted by the OTP to the address identified in § 8.3(b). SAMHSA will consider and accept the electronic submission of these materials when electronic submission systems are developed and available. The application for certification shall include:	(b) Application for **initial or renewal** certification**s and re-certification**. Application**s** for certification must be submitted by the OTP **using form SMA-162. The application for initial or renewal of certification shall include, as determined by the Secretary:**
Subpart C § 8.11 (b)(8)	*[New in 2024 rule]*	**(8) Applications for re-certification shall include an explanation of why the OTP's most recent certification expired and information regarding the schedule for an accreditation survey.**
Subpart C § 8.11 (d)	*[Subpart C § 8.11 (d) Transitional certification has been removed]*	***[Originally found in Subpart C § 8.11 (e) and (e)(1) in 2001 rule]*** (d) Provisional certification. **New** OTPs that have **not received the Secretary's certification previously, except as provided in paragraph (a)(6) of this section, who are applying for certification from the Secretary, and who have applied for accreditation with an Accreditation Body,** are eligible to receive provisional certification for up to 1 year. To receive provisional certification, an OTP shall submit the information required by paragraph (b) of this section to **the Secretary** along with a statement identifying the Accreditation Body to which the OTP has applied for accreditation, the date on which the OTP applied for accreditation, the dates of any accreditation surveys that have taken place or are expected to take place, and the expected schedule for completing the accreditation process. Provisional certification for up to 1 year will be granted, following receipt of the information described in this paragraph **(d)**, unless **the Secretary** determines that patient health would be adversely affected by the granting of provisional certification.
Subpart C § 8.11 (e)	*[Relocated to Subpart C § 8.11 (d) in 2024 rule]*	**(e) Requirements** for certification.

Location in Regulation	2001 Rule	2024 Rule
Subpart C § 8.11 (e)(1)	*[Relocated to Subpart C § 8.11 (d) in 2024 rule]*	(1) OTPs shall comply with all pertinent **Federal and** State laws and regulations. Nothing in this part is intended to limit the authority of State and, as appropriate, local governmental entities to regulate the use of **MOUD** in the treatment of OUD. The provisions of this section requiring compliance with requirements imposed by State law, or the submission of applications or reports required by the State authority, do not apply to OTPs operated directly by the Department of Veterans Affairs, the Indian Health Service, or any other department or agency of the United States.
Subpart C § 8.11 (e)(2)	*[Relocated to Subpart C § 8.11 (a)(4) in 2024 rule]*	*[Originally found in Subpart C § 8.11 (f)(2) in 2001 rule]* (2) OTPs shall allow, in accordance with Federal controlled substances laws and Federal confidentiality laws, inspections and surveys by duly authorized employees of the **Department of Health and Human Services (HHS) or** Substance Abuse and Mental Health Services Administration (SAMHSA), by Accreditation Bodies, by the Drug Enforcement Administration (DEA), and by authorized employees of any **other Federal governmental entity with legal authority to conduct inspections or surveys on an OTP's premises.**
Subpart C § 8.11 (e)(3)	*[New numbering in 2024 rule]*	***[Originally found in Subpart C § 8.11 (f)(3) in 2001 rule]*** (3) Disclosure of patient records maintained by an OTP is governed by the provisions of 42 CFR part 2 **and 45 CFR parts 160 and 164**, and every program must comply with **these regulations, as applicable**. Records on the receipt, storage, and distribution of **MOUD** are also subject to inspection under Federal controlled substances laws and under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 et seq.). Federally sponsored treatment programs are subject to applicable Federal confidentiality statutes.
Subpart C § 8.11 (e)(4)	*[New numbering in 2024 rule]*	***[Originally found in Subpart C § 8.11 (f)(4) in 2001 rule]*** (4) An OTP or medication unit or any part thereof, including any facility or any individual, shall permit a duly authorized employee of

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		the Department of Health and Human Services or SAMHSA to have access to and to copy all records on the use of **MOUD** in accordance with the provisions of 42 CFR part 2 **and 45 CFR parts 160 and 164**.
Subpart C § 8.11 (e)(5)	*[New numbering in 2024 rule]*	***[Originally found in Subpart C § 8.11 (f)(5) in 2001 rule]*** (5) OTPs shall notify **the Secretary** in writing within 3 weeks of any replacement or other change in the status of the program sponsor or medical director.
Subpart C § 8.11 (e)(6)	*[New numbering in 2024 rule]*	***[Originally found in Subpart C § 8.11 (f)(6) in 2001 rule]*** (6) OTPs shall comply with all regulations enforced by the DEA under 21 CFR chapter II and must be registered by the DEA before administering or dispensing **MOUD**.
Subpart C § 8.11 (e)(7)	*[New numbering in 2024 rule]*	***[Originally found in Subpart C § 8.11 (f)(7) in 2001 rule]*** (7) OTPs must operate in accordance with Federal Opioid **Use Disorder** treatment standards and approved accreditation elements.
Subpart C § 8.11 (f)	*[Relocated to Subpart C § 8.11 (e) in 2024 rule]*	***[Originally found in Subpart C § 8.11 (g) in 2001 rule]*** (f) Conditions for interim treatment program approval
Subpart C § 8.11 (f)(1)	*[Relocated to Subpart C § 8.11 (e)(1) in 2024 rule]*	***[Originally found in Subpart C § 8.11 (g)(1) in the 2001 rule]*** (1) Before an OTP may provide interim treatment, the OTP must receive the approval of both **the Secretary** and the **SOTA** of the State in which the OTP operates.
Subpart C § 8.11 (f)(2)	*[Relocated to Subpart C § 8.11 (e)(2) in 2024 rule]*	***[Originally found in Subpart C § 8.11 (g)(2) in 2001 rule]*** (2) Before **the Secretary** may grant such approval, the OTP must provide **the Secretary** with documentation from the SOTA of the State in which the OTP operates demonstrating that:

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Subpart C § 8.11 (f)(2)(i)	*[New numbering in 2024 rule]*	***[Originally found in Subpart C § 8.11 (g)(2)(i) in 2001 rule]*** (i) Such officer does not object to the providing of interim treatment in the State;
Subpart C § 8.11 (f)(2)(ii)	*[New numbering in 2024 rule]*	***[Originally found in Subpart C § 8.11 (g)(2)(ii) in 2001 rule]*** (ii) The OTP seeking to provide such treatment is unable to **provide access for** patients in a comprehensive treatment program within a reasonable geographic area within 14 days of the time patients seek **treatment for OUD**;
Subpart C § 8.11 (f)(2)(iii)	*[New numbering in 2024 rule]*	***[Originally found in Subpart C § 8.11 (g)(2)(iii) in 2001 rule]*** (iii) The authorization of the OTP to provide interim treatment will not otherwise reduce the capacity of comprehensive treatment programs in the State to admit individuals (relative to the date on which such officer so certifies); and
Subpart C § 8.11 (f)(2)(iv)	*[New numbering in 2024 rule]*	***[Originally found in Subpart C § 8.11 (g)(2)(iv) in 2001 rule]*** (iv) **OTPs providing interim treatment will arrange for each individual's transfer** to a comprehensive treatment program no later than **180** days from the date on which each individual first requested treatment. **Individuals enrolled in interim treatment shall not be discharged without the approval of an OTP practitioner, who shall consider on-going and patient-centered treatment needs, which are to be documented in the patient record, while awaiting transfer to a comprehensive treatment program.**
Subpart C § 8.11 (f)(3)	*[Relocated to Subpart C § 8.11 (e)(3) in 2024 rule]*	***[Originally found in Subpart C § 8.11 (g)(3) in 2001 rule]*** (3) **The Secretary** will provide notice to the OTP denying or approving the request to provide interim treatment. The OTP shall not provide such treatment until it has received such notice from **the Secretary**.

Location in Regulation	2001 Rule	2024 Rule
Subpart C § 8.11 (f)(4)	*[The substance of this provision was relocated to Subpart C § 8.11 (e)(4) in 2024 rule]*	***[Subpart C § 8.11 (f)(4) has been removed]***
Subpart C § 8.11 (f)(5)	*[Relocated to Subpart C § 8.11 (e)(5) in 2024 rule]*	***[Subpart C § 8.11 (f)(5) has been removed]***
Subpart C § 8.11 (f)(6)	*[Relocated to Subpart C § 8.11 (e)(6) in 2024 rule]*	***[Subpart C § 8.11 (f)(6) has been removed]***
Subpart C § 8.11 (f)(7)	*[Relocated to Subpart C § 8.11 (e)(7) in 2024 rule]*	***[Subpart C § 8.11 (f)(7) has been removed]***
Subpart C § 8.11 (g)	*[Relocated to Subpart C § 8.11 (f) in 2024 rule]*	***[Originally found in Subpart C § 8.11 (h) in 2001 rule]*** (g) Exemptions. An OTP may, at the time of application for certification or any time thereafter, request from **the Secretary** exemption from the regulatory requirements set forth under this section and § 8.12. An example of a case in which an exemption might be granted would be for a private practitioner who wishes to treat a limited number of patients in a non-metropolitan area with few physicians and no **OUD treatment** services geographically accessible, and requests exemption from some of the staffing and service standards. The OTP shall support the rationale for the exemption with thorough documentation, to be supplied in an appendix to the initial application for certification or in a separate submission. **The Secretary** will approve or deny such exemptions at the time of application, or any time thereafter, if appropriate. **The Secretary** shall consult with the appropriate State authority prior to taking action on an exemption request.
Subpart C § 8.11 (h)	*[Relocated to Subpart C § 8.11 (g) in 2024 rule]*	***[Originally found in Subpart C § 8.11 (i) in 2001 rule]*** (h) Medication units, long-term care facilities and hospitals.

Location in Regulation	2001 Rule	2024 Rule
Subpart C § 8.11 (h)(1)	*[New numbering in 2024 rule]*	***[Originally found in Subpart C § 8.11 (i)(1) in 2001 rule]*** (1) Certified OTPs may establish medication units that are authorized to dispense **MOUD**. Before establishing a medication unit, a certified OTP must notify **the Secretary** by submitting form SMA-162. The OTP must also comply with the provisions of 21 CFR part 1300 before establishing a medication unit. Medication units shall comply with all pertinent State laws and regulations. **Medication units include both mobile and brick and mortar facilities.**
Subpart C § 8.11 (h)(2)	*[New in 2024 rule]*	**(2) Specifically, any services that are provided in an OTP may be provided in the medication unit, assuming compliance with all applicable Federal, State, and local law, and the use of units that provide appropriate privacy and have adequate space.**
Subpart C § 8.11 (h)(3)	*[New numbering in 2024 rule]*	***[Originally found in Subpart C § 8.11 (i)(2) in 2001 rule]*** (3) Certification as an OTP under this part is not required for the **initiation or continuity of medication treatment or withdrawal management** of a patient who is admitted to a hospital, long-term care facility, **or correctional facility, that is registered with the Drug Enforcement Administration as a hospital/clinic,** for the treatment of medical conditions other than OUD, and who requires **treatment of OUD with methadone during their stay, when such treatment is permitted under applicable Federal law.**
Subpart C § 8.11 (i)	*[Relocated to Subpart C § 8.11 (h)(3)(i) in 2024 rule]* (i) Medication units, long-term care facilities and hospitals.	***[Originally found in Subpart C § 8.11 (i)(2) in 2001 rule]*** (i) The term "long-term care facility" **is defined in § 8.2**. Nothing in this section is intended to relieve hospitals, or long-term care facilities **and correctional facilities that are registered with the Drug Enforcement Administration as a hospital/clinic**, from **their** obligations to obtain **appropriate** registration from the Attorney General, under section 303(g) of the Controlled Substances Act.

Location in Regulation	2001 Rule	2024 Rule
		Treatment provided under this section should always comply with applicable Federal laws.
Subpart C § 8.11 (i)(1)	*[Relocated to Subpart C § 8.11 (h)(1) in 2024 rule]*	*[Subpart C § 8.11 (i)(1) has been removed]*
Subpart C § 8.11 (i)(2)	*[Relocated to Subpart C § 8.11 (h)(3) and Subpart C § 8.11 (i) in 2024 rule]*	*[Subpart C § 8.11 (i)(2) has been removed]*
Subpart C § 8.11 (h)(3)(ii)	*[New in 2024 rule]*	**(ii) *[Reserved]***
Subpart C § 8.12 Federal Opioid Use Disorder treatment standards (a)	(a) General. OTPs must provide treatment in accordance with the standards in this section and must comply with these standards as a condition of certification.	(a) General. OTPs must provide treatment in accordance with the standards in this section and must comply with these standards as a condition of certification.
Subpart C § 8.12 (b)	*[Relocated to Subpart C § 8.12 (b), (b)(1), and (b)(2) in 2024 rule]*	(b) Administrative and organizational structure.
Subpart C § 8.12 (b)(1)	*[New numbering in 2024 rule]*	***[Originally found in Subpart C § 8.12 (b) in 2001 rule]*** (1) An OTP's organizational structure and facilities shall be adequate to ensure quality patient care and to meet the requirements of all pertinent Federal, State, and local laws and regulations. At a minimum, each OTP shall formally designate a program sponsor and medical director. The program sponsor shall agree on behalf of the OTP to adhere to all requirements set forth in this part.
Subpart C § 8.12 (b)(2)	*[New numbering in 2024 rule]*	***[Originally found in Subpart C § 8.12 (b) in 2001 rule]*** (2) The medical director shall assume responsibility for all medical **and behavioral health** services performed by the OTP. In addition, the medical director shall be responsible for ensuring that the OTP is in

Location in Regulation	2001 Rule	2024 Rule
		compliance with all applicable Federal, State, and local laws and regulations.
Subpart C § 8.12 (c)(2)	(2) An OTP must maintain a current "Diversion Control Plan" or "DCP" as part of its quality assurance program that contains specific measures to reduce the possibility of diversion of controlled substances from legitimate treatment use and that assigns specific responsibility to the medical and administrative staff of the OTP for carrying out the diversion control measures and functions described in the DCP.	(2) An OTP must maintain a current "Diversion Control Plan" or "DCP" as part of its quality assurance program that contains specific measures to reduce the possibility of diversion of **dispensed MOUD**, and that assigns specific responsibility to the OTP **providers** and administrative staff for carrying out the diversion control measures and functions described in the DCP.
Subpart C § 8.12 (d)	(d) Staff credentials. Each person engaged in the treatment of opioid use disorder must have sufficient education, training, and experience, or any combination thereof, to enable that person to perform the assigned functions. All physicians, nurses, and other licensed professional care providers, including addiction counselors, must comply with the credentialing requirements of their respective professions.	(d) Staff credentials. Each person engaged in the treatment of OUD must have sufficient education, training, and experience, or any combination thereof, to enable that person to perform the assigned functions. All **practitioners** and other licensed/**certified health** care providers, including counselors, must comply with the credentialing **and maintenance of licensure and/or certification** requirements of their respective professions.
Subpart C § 8.12 (e)(1)	(1) Maintenance treatment. An OTP shall maintain current procedures designed to ensure that patients are admitted to maintenance treatment by qualified personnel who have determined, using accepted medical criteria such as those listed in the Diagnostic and Statistical Manual for Mental Disorders (DSM-IV), that the person is currently addicted to an opioid drug, and that the person became addicted at least 1 year before admission for treatment. In addition, a program physician shall ensure that each patient voluntarily chooses maintenance treatment and that all relevant facts concerning the use of the opioid drug are clearly and adequately explained to the patient, and that each patient provides informed written consent to treatment.	(1) **Comprehensive** treatment. An OTP shall maintain current procedures designed to ensure that patients are admitted to treatment by qualified personnel who have determined, using accepted medical criteria, that: **The person meets diagnostic criteria for a moderate to severe OUD; the individual has an active moderate to severe OUD, or OUD in remission, or is at high risk for recurrence or overdose. Such decisions must be appropriately documented in the patient's clinical record**. In addition, a **health care practitioner** shall ensure that each patient voluntarily chooses **treatment with MOUD** and that all relevant facts concerning the use of **MOUD** are clearly and adequately explained to the patient, and that each patient provides informed consent to treatment.

Location in Regulation	2001 Rule	2024 Rule
Subpart C § 8.12 (e)(2)	(2) Maintenance treatment for persons under age 18. A person under 18 years of age is required to have had two documented unsuccessful attempts at short-term detoxification or drug-free treatment within a 12-month period to be eligible for maintenance treatment. No person under 18 years of age may be admitted to maintenance treatment unless a parent, legal guardian, or responsible adult designated by the relevant State authority consents in writing to such treatment.	(2) **Comprehensive** treatment for persons under age 18. **Except in States where State law grants persons under 18 years of age the ability to consent to OTP treatment without the consent of another**, no person under 18 years of age may be admitted to **OTP** treatment unless a parent, legal guardian, or responsible adult designated by the relevant State authority consents in writing to such treatment.
Subpart C § 8.12 (e)(3)	*[New numbering in 2024 rule]*	***[Originally found in Subpart C § 8.12 (e)(4) in 2001 rule]*** (3) **Withdrawal management**. An OTP shall maintain current procedures that are designed to ensure that those patients **who choose to taper from MOUD are provided the opportunity to do so with informed consent and at a mutually agreed-upon rate that minimizes taper-related risks. Such consent must be documented in the clinical record by the treating practitioner.**
Subpart C § 8.12 (e)(4)	*[Relocated to Subpart C § 8.12 (e)(3) in 2024 rule and revised from "detoxification" to "withdrawal management"]* (4) Detoxification treatment. An OTP shall maintain current procedures that are designed to ensure that patients are admitted to short- or long-term detoxification treatment by qualified personnel, such as a program physician, who determines that such treatment is appropriate for the specific patient by applying established diagnostic criteria. Patients with two or more unsuccessful detoxification episodes within a 12-month period must be assessed by the OTP physician for other forms of treatment. A program shall not admit a patient for more than two detoxification treatment episodes in one year.	***[Subpart C § 8.12 (e)(4) has been removed]***

Location in Regulation	2001 Rule	2024 Rule
Subpart C § 8.12 (f)(1)	(1) General. OTPs shall provide adequate medical, counseling, vocational, educational, and other assessment and treatment services. These services must be available at the primary facility, except where the program sponsor has entered into a formal, documented agreement with a private or public agency, organization, practitioner, or institution to provide these services to patients enrolled in the OTP. The program sponsor, in any event, must be able to document that these services are fully and reasonably available to patients.	(1) General. OTPs shall provide adequate medical, counseling, vocational, educational, and other **screening**, assessment, and treatment services **to meet patient needs, with the combination and frequency of services tailored to each individual patient based on an individualized assessment and the patient's care plan that was created after shared decision making between the patient and the clinical team**. These services must be available at the primary facility, except where the program sponsor has entered into a documented agreement with a private or public agency, organization, practitioner, or institution to provide these services to patients enrolled in the OTP. The program sponsor, in any event, must be able to document that these services are fully and reasonably available to patients.
Subpart C § 8.12 (f)(2)	*[Relocated to Subpart C § 8.12 (f)(2) and (f)(2)(i) in 2024 rule]* (2) Initial medical examination services. OTPs shall require each patient to undergo a complete, fully documented physical evaluation by a program physician or a primary care physician, or an authorized healthcare professional under the supervision of a program physician, before admission to the OTP. The full medical examination, including the results of serology and other tests, must be completed within 14 days following admission.	(2) Initial medical examination.
Subpart C § 8.12 (f)(2)(i)	*[New numbering in 2024 rule]*	***[Originally found in Subpart C § 8.12 (f)(2) in 2001 rule]*** **(i)** OTPs shall require each patient to undergo **an initial medical examination. The initial medical examination is comprised of two parts:**
Subpart C § 8.12 (f)(2)(i)(A)	*[New in 2024 rule]*	**(A) A screening examination to ensure that the patient meets criteria for admission and that there are no contraindications to treatment with MOUD; and**

Location in Regulation	2001 Rule	2024 Rule
Subpart C § 8.12 (f)(2)(i)(B)	*[New in 2024 rule]*	**(B) A full history and examination, to determine the patient's broader health status, with lab testing as determined to be required by an appropriately licensed practitioner. A patient's refusal to undergo lab testing for co-occurring physical health conditions should not preclude them from access to treatment, provided such refusal does not have potential to negatively impact treatment with medications.**
Subpart C § 8.12 (f)(2)(ii)	*[New in 2024 rule]*	**(ii) Assuming no contraindications, a patient may commence treatment with MOUD after the screening examination has been completed. Both the screening examination and full examination must be completed by an appropriately licensed practitioner. If the licensed practitioner is not an OTP practitioner, the screening examination must be completed no more than seven days prior to OTP admission. Where the examination is performed outside of the OTP, the written results and narrative of the examination, as well as available lab testing results, must be transmitted, consistent with applicable privacy laws, to the OTP, and verified by an OTP practitioner.**
Subpart C § 8.12 (f)(2)(iii)	*[New in 2024 rule]*	**(iii) A full in-person physical examination, including the results of serology and other tests that are considered to be clinically appropriate, must be completed within 14 calendar days following a patient's admission to the OTP. The full exam can be completed by a non-OTP practitioner, if the exam is verified by a licensed OTP practitioner as being true and accurate and transmitted in accordance with applicable privacy laws.**
Subpart C § 8.12 (f)(2)(iv)	*[New in 2024 rule]*	**(iv) Serology testing and other testing as deemed medically appropriate by the licensed OTP practitioner based on the screening or full history and examination, drawn not more than 30 days prior to admission to the OTP, may form part of the full history and examination.**

Location in Regulation	2001 Rule	2024 Rule
Subpart C § 8.12 (f)(2)(v)	*[New in 2024 rule]*	**(v) The screening and full examination may be completed via telehealth for those patients being admitted for treatment at the OTP with either buprenorphine or methadone, if a practitioner or primary care provider, determines that an adequate evaluation of the patient can be accomplished via telehealth. When using telehealth, the following caveats apply:**
Subpart C § 8.12 (f)(2)(v)(A)	*[New in 2024 rule]*	**(A) In evaluating patients for treatment with schedule II medications (such as Methadone), audio-visual telehealth platforms must be used, except when not available to the patient. When not available, it is acceptable to use audio-only devices, but only when the patient is in the presence of a licensed practitioner who is registered to prescribe (including dispense) controlled medications. The OTP practitioner shall review the examination results and order treatment medications as indicated.**
Subpart C § 8.12 (f)(2)(v)(B)	*[New in 2024 rule]*	**(B) In evaluating patients for treatment with schedule III medications (such as Buprenorphine) or medications not classified as a controlled medication (such as Naltrexone), audio-visual or audio only platforms may be used. The OTP practitioner shall review the examination results and order treatment medications as indicated.**
Subpart C § 8.12 (f)(3)	(3) Special services for pregnant patients. OTPs must maintain current policies and procedures that reflect the special needs of patients who are pregnant. Prenatal care and other gender specific services or pregnant patients must be provided either by the OTP or by referral to appropriate healthcare providers.	(3) Special services for pregnant patients. OTPs must maintain current policies and procedures that reflect the special needs **and priority for treatment admission** of patients **with OUD** who are pregnant. **Pregnancy should be confirmed. Evidence-based treatment protocols for the pregnant patient, such as split dosing regimens, may be instituted after assessment by an OTP practitioner and documentation that confirms the clinical appropriateness of such an evidence-based treatment protocol. Prenatal care and other sex-specific services, including reproductive health services, for pregnant and postpartum patients must be provided and documented either by the OTP or by referral to appropriate healthcare practitioners.**

Location in Regulation	2001 Rule	2024 Rule
		Specific services, including reproductive health services, for pregnant and postpartum patients must be provided and **documented** either by the OTP or by referral to appropriate healthcare practitioners.
Subpart C § 8.12 (f)(4)	*[Section has been revised in subpart title and content]* (4) Initial and periodic assessment services.	(4) Initial and periodic **physical and behavioral health** assessment services.
Subpart C § 8.12 (f)(4)(i)	*[New numbering in 2024 rule]*	***[Originally part of Subpart C § 8.12 (f)(4) in 2001 rule]*** (i) Each patient **admitted** to an OTP shall be given a physical and **behavioral health assessment, which includes but is not limited to screening for imminent risk of harm to self or others, within 14 calendar days following admission, and** periodically by **appropriately licensed/credentialed personnel**. These assessments must **address the need for and/or response to treatment, adjust treatment interventions, including MOUD, as necessary, and provide a patient-centered plan of care. The full, initial psychosocial assessment must be completed within 14 calendar days of admission and include preparation of a care plan that includes the patient's goals and mutually agreed-upon actions for the patient to meet those goals, including harm reduction interventions;** the patient's **needs and goals** in the areas of education, vocational training, and employment; and the medical and psychiatric, psychosocial, economic, legal, **housing**, and other **recovery** support services that a patient needs and wishes to **pursue**. The **care** plan also must identify the recommended frequency with which services are to be provided. The plan must be reviewed and updated to reflect **responses to treatment and recovery support services,** and adjustments made that reflect changes in the context of the person's life, their current needs for and interests in medical, psychiatric, social, and psychological services, and current needs for **and interests** in education, vocational training, and employment services.

Location in Regulation	2001 Rule	2024 Rule
Subpart C § 8.12 (f)(4)(ii)	*[New in 2024 rule]*	**(ii) The periodic physical examination should occur not less than one time each year and be conducted by an OTP practitioner. The periodic physical examination should include review of MOUD dosing, treatment response, other substance use disorder treatment needs, responses and patient-identified goals, and other relevant physical and psychiatric treatment needs and goals. The periodic physical examination should be documented in the patient's clinical record.**
Subpart C § 8.12 (f)(5)	(5) Counseling services.	(5) Counseling and **psychoeducational** services.
Subpart C § 8.12 (f)(5)(i)	(i) OTPs must provide adequate substance abuse counseling to each patient as clinically necessary. This counseling shall be provided by a program counselor, qualified by education, training, or experience to assess the psychological and sociological background of patients, to contribute to the appropriate treatment plan for the patient and to monitor patient progress.	(i) OTPs must provide adequate substance use **disorder** counseling and **psychoeducation** to each patient as clinically necessary and **mutually agreed-upon, including harm reduction education and recovery-oriented counseling**. This counseling shall be provided by a program counselor, qualified by education, training, or experience to assess the psychological and sociological background of patients, and **engage with patients**, to contribute to the appropriate **care** plan for the patient and to monitor and update patient progress. **Patient refusal of counseling shall not preclude them from receiving MOUD**.
Subpart C § 8.12 (f)(5)(ii)	(ii) OTPs must provide counseling on preventing exposure to, and the transmission of, human immunodeficiency virus (HIV) disease for each patient admitted or readmitted to maintenance or detoxification treatment.	(ii) OTPs must provide counseling on preventing exposure to, and the transmission of, human immunodeficiency virus (HIV), **viral hepatitis, and sexually transmitted infections (STIs) and either directly provide services and treatments or actively link to treatment** each patient admitted or readmitted to treatment **who has received positive test results for these conditions from initial and/or periodic medical examinations.**
Subpart C § 8.12 (f)(5)(iii)	(iii) OTPs must provide directly, or through referral to adequate and reasonably accessible community resources, vocational rehabilitation, education, and employment services for patients who either request such services or who	(iii) OTPs must provide directly, or through referral to adequate and reasonably accessible community resources, vocational training, education, and employment services for patients who request such

Location in Regulation	2001 Rule	2024 Rule
	have been determined by the program staff to be in need of such services.	services or for whom these needs have been **identified and mutually agreed-upon as beneficial by the patient and program staff.**
Subpart C § 8.12 (f)(6)	(6) Drug abuse testing services. OTPs must provide adequate testing or analysis for drugs of abuse, including at least eight random drug abuse tests per year, per patient in maintenance treatment, in accordance with generally accepted clinical practice. For patients in short-term detoxification treatment, the OTP shall perform at least one initial drug abuse test. For patients receiving long-term detoxification treatment, the program shall perform initial and monthly random tests on each patient.	(6) Drug testing services. **When conducting random drug testing, OTPs must use drug tests that have received the Food and Drug Administration's (FDA) marketing authorization for commonly used and misused substances that may impact patient safety, recovery, or otherwise complicate substance use disorder treatment, at a frequency that is in accordance with generally accepted clinical practice and as indicated by a patient's response to and stability in treatment, but no fewer than eight random drug tests per year patient, allowing for extenuating circumstances at the individual patient level. This requirement does not preclude distribution of legal harm reduction supplies that allow an individual to test their personal drug supply for adulteration with substances that increase the risk of overdose.**
Subpart C § 8.12 (g)(2)	(2) OTPs shall include, as an essential part of the recordkeeping system, documentation in each patient's record that the OTP made a good faith effort to review whether or not the patient is enrolled any other OTP. A patient enrolled in an OTP shall not be permitted to obtain treatment in any other OTP except in exceptional circumstances. If the medical director or program physician of the OTP in which the patient is enrolled determines that such exceptional circumstances exist, the patient may be granted permission to seek treatment at another OTP, provided the justification for finding exceptional circumstances is noted in the patient's record both at the OTP in which the patient is enrolled and at the OTP that will provide the treatment.	(2) OTPs shall include, as an essential part of the recordkeeping system, documentation in each patient's record that the OTP made a good faith effort to determine whether the patient is enrolled in any other OTP. A patient enrolled in an OTP shall not be permitted to obtain treatment in any other OTP except in circumstances **involving an inability to access care at the patient's OTP of record. Such circumstances include, but are not limited to, travel for work or family events, temporary relocation, or an OTP's temporary closure**. If the medical director or program practitioner of the OTP in which the patient is enrolled determines that such circumstances exist, the patient may seek treatment at another OTP, provided the justification for the **particular** circumstances are noted in the patient's record both at the OTP in which the patient is enrolled and at the OTP that will provide the **MOUD**.
Subpart C § 8.12 (h)	(h) Medication administration, dispensing, and use.	(h) Medication administration, dispensing, and use.

Location in Regulation	2001 Rule	2024 Rule
Subpart C § 8.12 (h)(1)	(1) OTPs must ensure that opioid agonist treatment medications are administered or dispensed only by a practitioner licensed under the appropriate State law and registered under the appropriate State and Federal laws to administer or dispense opioid drugs, or by an agent of such a practitioner, supervised by and under the order of the licensed practitioner. This agent is required to be a pharmacist, registered nurse, or licensed practical nurse, or any other healthcare professional authorized by Federal and State law to administer or dispense opioid drugs.	(1) OTPs must ensure that **MOUD** are administered or dispensed only by a practitioner licensed under the appropriate State law and registered under the appropriate State and Federal laws to administer or dispense **MOUD**, or by an agent of such a practitioner, supervised by and under the order of the licensed practitioner and if consistent with Federal and State law.
Subpart C § 8.12 (h)(2)(ii)	(ii) Levomethadyl acetate (LAAM);	***[Subpart C § 8.12 (h)(2)(ii) Levomethadyl acetate (LAAM) has been removed]*** (ii) Buprenorphine and buprenorphine combination products that have been approved for use in the treatment of OUD; and
Subpart C § 8.12 (h)(2)(iii)	*[Relocated to Subpart C § 8.12 (h)(2)(ii) in 2024 rule]*	**(iii) Naltrexone.**
Subpart C § 8.12 (h)(3)(ii)	(ii) For each new patient enrolled in a program, the initial dose of methadone shall not exceed 30 milligrams and the total dose for the first day shall not exceed 40 milligrams, unless the program physician documents in the patient's record that 40 milligrams did not suppress opioid abstinence symptoms.	(ii) For each new patient enrolled in an OTP, the initial dose of methadone shall be **individually determined and shall include consideration of the type(s) of opioid(s) involved in the patient's opioid use disorder, other medications or substances being taken, medical history, and severity of opioid withdrawal. The total dose for the first day should not exceed 50 milligrams unless the OTP practitioner, licensed under the appropriate State law and registered under the appropriate State and Federal laws to administer or dispense MOUD, finds sufficient medical rationale, including but not limited to if the patient is transferring from another OTP on a higher dose that has been verified, and documents in the patient's record that a higher dose was clinically indicated**.

Location in Regulation	2001 Rule	2024 Rule
Subpart C § 8.12 (h)(4)	(4) OTPs shall maintain current procedures adequate to ensure that each opioid agonist treatment medication used by the program is administered and dispensed in accordance with its approved product labeling. Dosing and administration decisions shall be made by a program physician familiar with the most up-to-date product labeling. These procedures must ensure that any significant deviations from the approved labeling, including deviations with regard to dose, frequency, or the conditions of use described in the approved labeling, are specifically documented in the patient's record.	(4) OTPs shall maintain current procedures adequate to ensure that each **MOUD** used by the program is administered and dispensed in accordance with its **FDA** approved product labeling. The **program** must ensure that any significant deviations from the approved labeling, including deviations with regard to dose, frequency, or the conditions of use described in the approved labeling, are specifically documented in the patient's record.
Subpart C § 8.12 (i)	(i) Unsupervised or "take-home" use**.** To limit the potential for diversion of opioid agonist treatment medications to the illicit market, opioid agonist treatment medications dispensed to patients for unsupervised use shall be subject to the following requirements.	(i) Unsupervised or "take-home" medication doses. **Unsupervised or "take-home" medication doses may be provided under the following circumstances:**
Subpart C § 8.12 (i)(1)	(1) Any patient in comprehensive maintenance treatment may receive a single take-home dose for a day that the clinic is closed for business, including Sundays and State and Federal holidays.	(1) Any patient in comprehensive treatment may receive their **individualized** take-home doses as ordered for **days** that the clinic is closed for business, **including one weekend day (e.g., Sunday)** and State and Federal holidays, **no matter their length of time in treatment**.
Subpart C § 8.12 (i)(2)	(2) Treatment program decisions on dispensing opioid treatment medications to patients for unsupervised use beyond that set forth in paragraph (i)(1) of this section, shall be determined by the medical director. In determining which patients may be permitted unsupervised use, the medical director shall consider the following take-home criteria in determining whether a patient is responsible in handling opioid drugs for unsupervised use.	(2) **OTP** decisions on dispensing **MOUD** to patients for unsupervised use beyond that set forth in paragraph (i)(1) of this section shall be determined by an **appropriately licensed OTP medical practitioner or** the medical director. In determining which patients may **receive** unsupervised **medication doses**, the medical director **or program medical practitioner** shall consider, **among other pertinent factors that indicate that the therapeutic benefits of unsupervised doses outweigh the risks, the following criteria:**
Subpart C § 8.12 (i)(2)(i)	(i) Absence of recent abuse of drugs (opioid or nonnarcotic), including alcohol;	(i) Absence of **active substance use disorders, other physical or behavioral health conditions that increase the risk of patient harm**

Location in Regulation	2001 Rule	2024 Rule
		as it relates to the potential for overdose, or the ability to function safely;
Subpart C § 8.12 (i)(2)(ii)	(ii) Regularity of clinic attendance;	(ii) Regularity of **attendance for supervised medication administration;**
Subpart C § 8.12 (i)(2)(iii)	(iii) Absence of serious behavioral problems at the clinic;	(iii) Absence of serious behavioral problems **that endanger the patient, the public or others;**
Subpart C § 8.12 (i)(2)(iv)	(iv) Absence of known recent criminal activity, e.g., drug dealing;	(iv) Absence of known recent **diversion** activity;
Subpart C § 8.12 (i)(2)(v)	(v) Stability of the patient's home environment and social relationships;	**(v) Whether take-home medication can be safely transported and stored; and**
Subpart C § 8.12 (i)(2)(vi)	(vi) Length of time in comprehensive maintenance treatment;	**(vi) Any other criteria that the medical director or medical practitioner considers relevant to the patient's safety and the public's health.**
Subpart C § 8.12 (i)(2)(vii)	(vii) Assurance that take-home medication can be safely stored within the patient's home; and	***[Subpart C § 8.12 (i)(2)(vii) has been removed]***
Subpart C § 8.12 (i)(2)(viii)	(viii) Whether the rehabilitative benefit the patient derived from decreasing the frequency of clinic attendance outweighs the potential risks of diversion.	***[Subpart C § 8.12 (i)(2)(viii) has been removed]***
Subpart C § 8.12 (i)(3)	(3) Such determinations and the basis for such determinations consistent with the criteria outlined in paragraph (i)(2) of this section shall be documented in the patient's medical record. If it is determined that a patient is responsible in handling opioid drugs, the dispensing restrictions set forth in paragraphs (i)(3)(i) through (vi) of this section apply. The dispensing restrictions set forth in paragraphs (i)(3)(i) through (vi) of this section do not apply to	(3) Such determinations and the basis for such determinations consistent with the criteria outlined in paragraph (i)(2) of this section shall be documented in the patient's medical record. If it is determined that a patient is **safely able to manage unsupervised doses of MOUD**, the dispensing restrictions set forth in paragraphs (i)(3)(i) through (**iii**) of this section apply. The dispensing restrictions set forth in paragraphs (i)(3)(i) through (**iii**) of this section do not apply

Location in Regulation	2001 Rule	2024 Rule
	buprenorphine and buprenorphine products listed under paragraph (h)(2)(iii) of this section.	to buprenorphine and buprenorphine products listed under paragraph (h)(2)(**ii**) of this section.
Subpart C § 8.12 (i)(3)(i)	(i) During the first 90 days of treatment, the take-home supply (beyond that of paragraph (i)(1) of this section) is limited to a single dose each week and the patient shall ingest all other doses under appropriate supervision as provided for under the regulations in this subpart.	(i) During the first 14 days of treatment, the take-home supply (beyond that of paragraph (i)(1) of this section) is limited to **7 days. It remains within the OTP practitioner's discretion to determine the number of take-home doses up to 7 days, but decisions must be based on the criteria listed in paragraph (i)(2) of this section. The rationale underlying the decision to provide unsupervised doses of methadone must be documented in the patient's clinical record, consistent with paragraph (g)(2) of this section.**
Subpart C § 8.12 (i)(3)(ii)	(ii) In the second 90 days of treatment, the take-home supply (beyond that of paragraph (i)(1) of this section) are two doses per week.	(ii) From **15** days of treatment, the take-home supply (beyond that of paragraph (i)(1) of this section) is **limited to 14 days. It remains within the OTP practitioner's discretion to determine the number of take-home doses up to 14 days, but this determination must be based on the criteria listed in paragraph (i)(2) of this section. The rationale underlying the decision to provide unsupervised doses of methadone must be documented in the patient's clinical record, consistent with paragraph (g)(2) of this section.**
Subpart C § 8.12 (i)(3)(iii)	(iii) In the third 90 days of treatment, the take-home supply (beyond that of paragraph (i)(1) of this section) are three doses per week.	**(iii) From 31 days of treatment, the take-home supply (beyond that of paragraph (i)(1) of this section) provided to a patient is not to exceed 28 days. It remains within the OTP practitioner's discretion to determine the number of take-home doses up to 28 days, but this determination must be based on the criteria listed in paragraph (i)(2) of this section. The rationale underlying the decision to provide unsupervised doses of methadone must be documented in the patient's clinical record, consistent with paragraph (g)(2) of this section.**
Subpart C § 8.12 (i)(3)(iv)	(iv) In the remaining months of the first year, a patient may be given a maximum 6-day supply of take-home medication.	***[Subpart C § 8.12 (i)(3)(iv) has been removed]***

Location in Regulation	2001 Rule	2024 Rule
Subpart C § 8.12 (i)(3)(v)	(v) After 1 year of continuous treatment, a patient may be given a maximum 2-week supply of take-home medication.	***[Subpart C § 8.12 (i)(3)(v) has been removed]***
Subpart C § 8.12 (i)(3)(vi)	(vi) After 2 years of continuous treatment, a patient may be given a maximum one-month supply of take-home medication but must make monthly visits.	***[Subpart C § 8.12 (i)(3)(vi) has been removed]***
Subpart C § 8.12 (i)(4)	(4) No medications shall be dispensed to patients in short-term detoxification treatment or interim maintenance treatment for unsupervised or take-home use.	**(4) OTPs must maintain current procedures adequate to identify the theft or diversion of take-home medications, including labeling containers with the OTP's name, address, and telephone number. Programs also must ensure that each individual take-home dose is packaged in a manner that is designed to reduce the risk of accidental ingestion, including child-proof containers (see Poison Prevention Packaging Act, Pub. L. 91-601 (15 U.S.C. 1471 et seq.)). Programs must provide education to each patient on: Safely transporting medication from the OTP to their place of residence; and the safe storage of take-home doses at the individual's place of residence, including child and household safety precautions. The provision of this education should be documented in the patient's clinical record.**
Subpart C § 8.12 (i)(5)	(5) OTPs must maintain current procedures adequate to identify the theft or diversion of take-home medications, including labeling containers with the OTP's name, address, and telephone number. Programs also must ensure that take-home supplies are packaged in a manner that is designed to reduce the risk of accidental ingestion, including child-proof containers (see Poison Prevention Packaging Act, Public Law 91–601 (15 U.S.C. 1471 et seq.)).	***[Subpart C § 8.12 (i)(5) has been combined with Subpart C § 8.12 (i)(4) in 2024 rule]***
Subpart C § 8.12 (j)	(j) Interim maintenance treatment.	(j) Interim treatment.
Subpart C § 8.12 (j)(1)	(1) The program sponsor of a public or nonprofit private OTP may place an individual, who is eligible for admission to	(1) The program sponsor of **an** OTP may **admit** an individual, who is eligible for admission to comprehensive treatment, **into** interim

Location in Regulation	2001 Rule	2024 Rule
	comprehensive maintenance treatment, in interim maintenance treatment if the individual cannot be placed in a public or nonprofit private comprehensive program within a reasonable geographic area and within 14 days of the individual's application for admission to comprehensive maintenance treatment. An initial and at least two other urine screens shall be taken from interim patients during the maximum of 120 days permitted for such treatment. A program shall establish and follow reasonable criteria for establishing priorities for transferring patients from interim maintenance to comprehensive maintenance treatment. These transfer criteria shall be in writing and shall include, at a minimum, a preference for pregnant women in admitting patients to interim maintenance and in transferring patients from interim maintenance to comprehensive maintenance treatment. Interim maintenance shall be provided in a manner consistent with all applicable Federal and State laws, including sections 1923, 1927(a), and 1976 of the Public Health Service Act (21 U.S.C. 300x–23, 300x–27(a), and 300y–11).	treatment if comprehensive **services are not readily available** within a reasonable geographic area and within 14 days of the individual's **seeking treatment**. At least two **drug tests** shall be **obtained** from patients during the maximum of **180** days permitted for **interim** treatment. A program shall establish and follow reasonable criteria for establishing priorities for **moving** patients from interim to comprehensive treatment. These **transition** criteria shall be in writing and shall include, at a minimum, **prioritization of** pregnant **patients** in admitting patients to interim **treatment** and from interim to comprehensive treatment. Interim **treatment** shall be provided in a manner consistent with all applicable Federal and State laws, including sections 1923, 1927(a), and 1976 of the Public Health Service Act (21 U.S.C. 300x-23, 300x-27(a), and 300y-11).
Subpart C § 8.12 (j)(2)	(2) The program shall notify the State health officer when a patient begins interim maintenance treatment, when a patient leaves interim maintenance treatment, and before the date of mandatory transfer to a comprehensive program and shall document such notifications.	(2) The program shall notify the **SOTA** when a patient begins interim treatment, when a patient leaves interim treatment, and before the date of transfer to comprehensive **services**, and shall document such notifications.
Subpart C § 8.12 (j)(3)	(3) SAMHSA may revoke the interim maintenance authorization for programs that fail to comply with the provisions of this paragraph (j). Likewise, SAMHSA will consider revoking the interim maintenance authorization of a program if the State in which the program operates is not in compliance with the provisions of § 8.11(g).	**(3) The Secretary** may revoke the interim authorization for programs that fail to comply with the provisions of this paragraph (j). Likewise**, the Secretary** will consider revoking the interim authorization of a program if the State in which the program operates is not in compliance with the provisions of **§ 8.11(h).**

Location in Regulation	2001 Rule	2024 Rule
Subpart C § 8.12 (j)(4)	(4) All requirements for comprehensive maintenance treatment apply to interim maintenance treatment with the following exceptions:	(4) All requirements for comprehensive treatment apply to interim treatment with the following exceptions:
Subpart C § 8.12 (j)(4)(i)	(i) The opioid agonist treatment medication is required to be administered daily under observation;	***[Originally found in Subpart C § 8.12 (j)(4)(iv) in 2001 rule]*** (i) A primary counselor is not required to be assigned to the patient, **but crisis services, including shelter support, should be available**;
Subpart C § 8.12 (j)(4)(ii)	(ii) Unsupervised or "take-home" use is not allowed;	***[Originally found in Subpart C § 8.12 (j)(4)(v) in 2001 rule]*** (ii) Interim **treatment** cannot be provided for longer than **180** days in any 12-month period;
Subpart C § 8.12 (j)(4)(iii)	(iii) An initial treatment plan and periodic treatment plan evaluations are not required;	**(iii) By day 120, a plan for continuing treatment beyond 180 days must be created, and documented in the patient's clinical record; and**
Subpart C § 8.12 (j)(4)(iv)	*[Relocated to Subpart C § 8.12 (j)(4)(i) in 2024 rule]* (iv) A primary counselor is not required to be assigned to the patient;	***[Originally found in Subpart C § 8.12 (j)(4)(vi) in 2001 rule]*** (iv) **Formal counseling, vocational training, employment, economic, legal**, educational, and other **recovery support** services described in paragraphs (f)(4) and (f)(5)(i) and (iii) of this section are not required to be **offered** to the patient. **However, information pertaining to locally available, community-based resources for ancillary services should be made available to individual patients in interim treatment.**
Subpart C § 8.12 (j)(4)(v)	*[Relocated to Subpart C § 8.12 (j)(4)(iv) in 2024 rule]* (v) Interim maintenance cannot be provided for longer than 120 days in any 12-month period; and	***[Subpart C § 8.12 (j)(4)(v) has been removed]***
Subpart C § 8.12 (j)(4)(vi)	*[Relocated to Subpart C § 8.12 (j)(4)(iv) in 2024 rule]*	***[Subpart C § 8.12 (j)(4)(vi) has been removed]***

Location in Regulation	2001 Rule	2024 Rule
	(vi) Rehabilitative, education, and other counseling services described in paragraphs (f)(4), (f)(5)(i), and (f)(5)(iii) of this section are not required to be provided to the patient.	
Subpart C § 8.13 Revocation of accreditation and Accreditation Body approval (a)	(a) SAMHSA action following revocation of accreditation.	(a) The Secretary's action following revocation of accreditation.
Subpart C § 8.13 (b)	(b) Accreditation body approval.	(b) Accreditation Body approval.
Subpart C § 8.14 Suspension or revocation of certification (a)(1)	(1) Has been found guilty of misrepresentation in obtaining the certification;	(1) Has been found **to have engaged in** misrepresentation in obtaining the certification;
Subpart C § 8.14 (b)	(b) Suspension. Whenever SAMHSA has reason to believe that revocation may be required and that immediate action is necessary to protect public health or safety, SAMHSA may immediately suspend the certification of an OTP before holding a hearing under subpart C of this part. SAMHSA may immediately suspend as well as propose revocation of the certification of an OTP before holding a hearing under subpart C of this part if SAMHSA makes a finding described in paragraph (a) of this section and also determines that:	(b) Suspension. Whenever **the Secretary** has reason to believe that revocation may be required and that immediate action is necessary to protect public health or safety, **the Secretary** may immediately suspend the certification of an OTP and **notify the Attorney General that the OTP's registration should be suspended,** before holding a hearing under this subpart. **The Secretary** may immediately suspend as well as propose revocation of the certification of an OTP before holding a hearing under this subpart if **the Secretary** makes a finding described in paragraph (a) of this section and also determines that:
Subpart C § 8.14 (c)	(c) Written notification. In the event that SAMHSA suspends the certification of an OTP in accordance with paragraph (b) of this section or proposes to revoke the certification of an OTP in accordance with paragraph (a) of this section, SAMHSA shall promptly provide the sponsor of the OTP with written notice of the suspension or proposed revocation by facsimile transmission, personal service, commercial	(c) Written notification. In the event that **the Secretary** suspends the certification of an OTP in accordance with paragraph (b) of this section or proposes to revoke the certification of an OTP in accordance with paragraph (a) of this section, **the Secretary** shall promptly provide the sponsor of the OTP with written notice of the suspension or proposed revocation by facsimile transmission, personal service, commercial overnight delivery service, or certified

Location in Regulation	2001 Rule	2024 Rule
	overnight delivery service, or certified mail, return receipt requested. Such notice shall state the reasons for the action and shall state that the OTP may seek review of the action in accordance with the procedures in subpart C of this part.	mail, return receipt requested. Such notice shall state the reasons for the action, state that the OTP may seek review of the action in accordance with the procedures in this subpart and **identify the reviewing official to whom a written request for review may be submitted.**
Subpart C § 8.14 (d)	*[Relocated to Subpart D in 2024 rule]*	(d) **Procedure.**
Subpart D Procedures for Informal Review of Suspension or Proposed Revocation of OTP Certification, and of Adverse Action Regarding Withdrawal of Approval of an Accreditation Body § 8.21 Applicability	The procedures in this subpart apply when:	The procedures in this subpart apply when:
Subpart D § 8.22 Definitions	*[Subparts D § 8.22 (a) through (c) have been removed]*	***[Originally found in Subpart D § 8.22 (a) through (c) in 2001 rule]*** The following definitions apply to this **subpart**: **Appellant means:** **(1) The OTP which has been notified of its suspension or proposed revocation of its certification under the regulations of this part and has requested a review of the suspension or proposed revocation; or** **(2) The Accreditation Body which has been notified of adverse action regarding withdrawal of approval under the regulations of this subpart and has requested a review of the adverse action.**

Location in Regulation	2001 Rule	2024 Rule
		Respondent means SAMHSA. **Reviewing official means the person or persons designated by the Secretary who will informally review the suspension or proposed revocation. The reviewing official may be assisted by one or more Department of Health and Human Services (HHS) officers or employees or consultants in assessing and weighing the scientific and technical evidence and other information submitted by the appellant and respondent on the reasons for the suspension and proposed revocation.**
Subpart D § 8.23 Limitation on issues subject to review	The scope of review shall be limited to the facts relevant to any suspension, or proposed revocation, or adverse action, the necessary interpretations of the facts the regulations, in the subpart, and other relevant law.	The scope of **this informal** review shall be limited to the facts relevant to any suspension, or proposed revocation, or adverse action, the necessary interpretations of the facts**,** the regulations in **this** subpart, and other relevant law.
Subpart D § 8.24 Specifying who represents the parties	The appellant's request for review shall specify the name, address, and phone number of the appellant's representative. In its first written submission to the reviewing official, the respondent shall specify the name, address, and phone number of the respondent's representative.	The appellant's request for **an informal** review shall specify the name, address, and phone number of the appellant's representative. In its first written submission to the reviewing official, the respondent shall specify the name, address, and phone number of the respondent's representative.
Subpart D § 8.27 Opportunity for oral presentation (b)	(b) Presiding official. The reviewing official or designee will be the presiding official responsible for conducting the oral presentation.	(b) Presiding official. The reviewing official or designee will be the presiding official responsible for **managing** the oral presentations.
Subpart D § 8.27 (c)	(c) Preliminary conference. The presiding official may hold a prehearing conference (usually a telephone conference call) to consider any of the following: Simplifying and clarifying issues; stipulations and admissions; limitations on evidence and witnesses that will be presented at the hearing; time allotted for each witness and the hearing altogether; scheduling the hearing; and any other matter that will assist in the review process. Normally, this conference will be	(c) Preliminary conference. The presiding official may hold a prehearing conference (usually a telephone conference call) to consider any of the following: Simplifying and clarifying issues; stipulations and admissions; limitations on evidence and witnesses that will be presented at the hearing; time allotted for each witness and the hearing altogether; scheduling the hearing; and any other matter that will assist in the review process. Normally, this conference will be conducted informally and off the record; however, the

Location in Regulation	2001 Rule	2024 Rule
	conducted informally and off the record; however, the presiding official may, at the presiding official's discretion, produce a written document summarizing the conference or transcribe the conference, either of which will be made a part of the record.	presiding official may, at the presiding official's discretion, produce a written document summarizing the conference or transcribe the conference.
Subpart D § 8.27 (e)(5)	(5) Transcripts. The presiding official shall have the oral presentation transcribed and the transcript shall be made a part of the record. Either party may request a copy of the transcript and the requesting party shall be responsible for paying for its copy of the transcript.	(5) Transcripts. The presiding official shall have the oral presentation transcribed. Either party may request a copy of the transcript and the requesting party shall be responsible for paying for its copy of the transcript.
Subpart D § 8.28 Expedited procedures for review of immediate suspension (f)	(f) Transmission of written communications. Because of the importance of timeliness for these expedited procedures, all written communications between the parties and between either party and the reviewing official shall be sent by facsimile transmission, personal service, or commercial overnight delivery service.	(f) Transmission of written communications. Because of the importance of timeliness for **the** expedited procedures **in this section**, all written communications between the parties and between either party and the reviewing official shall be sent by facsimile transmission, personal service, or commercial overnight delivery service.
Subpart D § 8.29 Ex parte communications	Except for routine administrative and procedural matters, a party shall not communicate with the reviewing or presiding official without notice to the other party.	**For the purposes of maintaining the equity of informal review proceedings,** except for routine administrative and procedural matters **or as described in 8.22(2) and 8.27(e),** a party shall not communicate with the reviewing or presiding official without notice to the other party.

Appendix B. Applying for Certification and Recertification

Applications for certification and recertification must be submitted by the opioid treatment program (OTP) using Form SMA-162. The application must include: [278]

- A description of the current accreditation status of the OTP.
- A description of the organizational structure of the OTP.
- The names of the persons responsible for the OTP.
- The addresses of the OTP and of each medication unit or other facility under the OTP.
- The sources of funding for the OTP and the name and address of each governmental entity that provides funding.
- A statement that the OTP will comply with the conditions of certification set forth in the regulation.

The application must be signed by the program sponsor who certifies that the information submitted in the application is truthful and accurate.

Applications for recertification must include an explanation of why the OTP's most recent certification expired and information regarding the schedule for an accreditation survey. An accreditation survey is an on-site evaluation of an OTP by a Substance Abuse and Mental Health Services Administration (SAMHSA)-approved accreditation body for the purpose of determining compliance with Title 42 of the Code of Federal Regulations (42 CFR) § 8.12.

Following review of the application for certification, and after consultation with the appropriate State Opioid Treatment Authority (SOTA), SAMHSA may grant the application for certification, renew an existing certification, or deny the application.

Within 5 days after it reaches a final determination that an OTP meets the requirements for certification, SAMHSA will notify the Drug Enforcement Administration (DEA) that the OTP has been determined to be qualified to provide opioid use disorder (OUD) treatment under section 303(h) of the Controlled Substances Act. [279]

42 CFR § 8.11 and SAMHSA's webpage on certification of OTPs contain more information on these topics.

Provisional Certification

New OTPs that have not received SAMHSA certification in the past can apply for provisional certification as they work toward becoming accredited through a SAMHSA-approved accrediting body. The provisional certification is a temporary certification granted to a new OTP for up to 1 year, during which time it must become accredited. [280]

To receive provisional certification, an OTP must submit the information required to apply for the initial application along with:

- A statement identifying the accreditation body to which the OTP has applied for accreditation.
- The date on which the OTP applied for accreditation.
- The dates of any accreditation surveys that have taken place or are expected to take place.

- The expected schedule for completing the accreditation process.

After a provisionally certified program becomes accredited, it must apply to SAMHSA for full certification via the renewal application. Once certified, OTPs must renew certification annually or every 3 years, depending on the accreditation timeframe awarded. SAMHSA's OTP Compliance Officers will review all documentation to confirm the OTP is eligible for certification to provide treatment under 42 CFR part 8.

Certification Extension Requests

Certification extensions may be granted in extraordinary circumstances to protect public health. To apply for a certification extension, an OTP shall submit to SAMHSA a written statement explaining its efforts to obtain accreditation, in addition to a schedule for obtaining accreditation as expeditiously as possible. The written statement must include the following:

- The OTP name and number.
- The date of certification expiration.
- The reason accreditation was not obtained in a timely manner (prior to certification expiration).
- The date of the scheduled accreditation survey and the name of the accreditation body.
- If the program has been unable to schedule the accreditation survey, a description of efforts and barriers.

The request must be signed by the OTP sponsor who certifies that the information submitted in the request is truthful and accurate. Upon receipt, SAMHSA will review and provide a determination of approval or denial of the request.

Opening a New Brick-and-Mortar or Mobile Medication Unit

To open a new brick-and-mortar medication unit, OTPs should submit Form SMA-162 with all requested attachments and signed documents to SAMHSA; this can be done online using SAMHSA's Extranet (https://otp-extranet.samhsa.gov) In Item 14 of the application, "Purpose of Application," check off "Medication Unit." SAMHSA will process the form and forward it for approval to the DEA, which will arrange an inspection. The program also should submit all required materials to the SOTA to seek state approval, as appropriate.

Once the DEA approves the medication unit, it will assign a new DEA registration number as a Narcotic Treatment Program (NTP) for that medication unit. The SAMHSA-assigned number will stay the same for both the original site and the medication unit(s). The required documents are:

- A description of how the medication unit receives the medication supply from the primary facility.
- An affirmative statement that the medication unit is limited to administering and dispensing the treatment medication and collecting samples for drug testing or analysis.
- An affirmative statement that the sponsor agrees to retain responsibility for patient care.
- A diagram and description of the facilities to be used as a medication unit.
- Total number of patients to be served by the primary facility and medication unit.
- Total number of patients that will be served only at the medication unit.
- A justification for need to establish a medication unit.
- Indication if there are there any other active medication units attached to the primary facility. If so, the name of the medication unit(s) and address must be provided.

Appendix C. Revocation of Accreditation

42 CFR § 8.13. Revocation of accreditation and Accreditation Body approval. (a) *The Secretary's action following revocation of accreditation.* If an Accreditation Body revokes an OTP's accreditation, the Secretary may conduct an investigation into the reasons for the revocation. Following such investigation, the Secretary may determine that the OTP's certification should no longer be in effect, at which time the Secretary will initiate procedures to revoke the program's certification in accordance with § 8.14. Alternatively, the Secretary may determine that another action or combination of actions would better serve the public health, including the establishment and implementation of a corrective plan of action that will permit the certification to continue in effect while the OTP seeks reaccreditation.

(b) *Accreditation Body approval.* (1) If the Secretary withdraws the approval of an Accreditation Body under § 8.6, the certifications of OTPs accredited by such Body shall remain in effect for a period of 1 year after the date of withdrawal of approval of the Accreditation Body, unless the Secretary determines that to protect public health or safety, or because the Accreditation Body fraudulently accredited treatment programs, the certifications of some or all of the programs should be revoked or suspended or that a shorter time period should be established for the certifications to remain in effect. The Secretary may extend the time in which a certification remains in effect under this paragraph (b)(1) on a case-by-case basis. (2) Within 1 year from the date of withdrawal of approval of an Accreditation Body, or within any shorter period of time established by the Secretary, OTPs currently accredited by the Accreditation Body must obtain accreditation from another Accreditation Body. The Secretary may extend the time period for obtaining reaccreditation on a case-by-case basis.

42 CFR § 8.14. Suspension or revocation of certification. (a) *Revocation.* Except as provided in paragraph (b) of this section, the Secretary may revoke the certification of an OTP if the Secretary finds, after providing the program sponsor with notice and an opportunity for a hearing in accordance with this subpart, that the program sponsor, or any employee of the OTP:

(1) Has been found to have engaged in misrepresentation in obtaining the certification;

(2) Has failed to comply with the Federal Opioid Use Disorder treatment standards in any respect;

(3) Has failed to comply with reasonable requests from the Secretary or from an Accreditation Body for records, information, reports, or materials that are necessary to determine the continued eligibility of the OTP for certification or continued compliance with the Federal Opioid Use Disorder treatment standards; or

(4) Has refused a reasonable request of a duly designated inspector, Drug Enforcement Administration (DEA) Inspector, State Inspector, or Accreditation Body representative for permission to inspect the program or the program's operations or its records.

(b) *Suspension.* Whenever the Secretary has reason to believe that revocation may be required and that immediate action is necessary to protect public health or safety, the Secretary may immediately suspend the certification of an OTP and notify the Attorney General that the OTP's registration should be suspended, before holding a hearing under this subpart. The Secretary may immediately suspend as well as propose revocation of the certification of an OTP before holding a hearing under this subpart if the Secretary makes a finding described in paragraph (a) of this section and also determines that:

(1) The failure to comply with the Federal Opioid Use Disorder treatment standards presents an imminent danger to the public health or safety;

(2) The refusal to permit inspection makes immediate suspension necessary; or

(3) There is reason to believe that the failure to comply with the Federal Opioid Use Disorder treatment standards was intentional or was associated with fraud.

An accreditation body may revoke an opioid treatment program's (OTP) accreditation. If this occurs, the Substance Abuse and Mental Health Services Administration (SAMHSA) may investigate the reasons for

the revocation. Following the investigation, SAMHSA may determine that the OTP's certification should no longer be in effect and can initiate procedures to revoke the program's certification. [281]

As discussed in 42 CFR § 8.14, after providing the program sponsor with an opportunity for a hearing, SAMHSA may decide to revoke the certification of an OTP if it finds that the program sponsor or any employee of the OTP has: [282]

- Engaged in misrepresentation in obtaining the certification.
- Failed to comply with the regulations in any respect.
- Failed to comply with reasonable requests from SAMHSA or from an accreditation body for records, information, reports, or materials that are necessary to determine the continued eligibility of the OTP for certification or continued compliance with 42 CFR § 8.12.
- Refused a reasonable request of a duly designated inspector, Drug Enforcement Administration, state inspector, or accreditation body representative for permission to inspect the program or the program's operations or its records.

If SAMHSA determines that revocation may be required and that immediate action is necessary to protect public health or safety, it may immediately suspend the certification of an OTP and notify the Attorney General that the OTP's registration should be suspended.

Appendix D. Resources

Treatment Locators

SAMHSA:

- **Buprenorphine Dispensing by Opioid Treatment Programs (OTPs)** (https://www.samhsa.gov/medications-substance-use-disorders/become-accredited-opioid-treatment-program/buprenorphine-dispensing-by-program)
- **Buprenorphine Pharmacy Lookup** (https://www.samhsa.gov/medications-substance-use-disorders/pharmacist-verification/data-waiver-lookup)
- **Opioid Treatment Program Directory** (https://dpt2.samhsa.gov/treatment/directory.aspx)

FindTreatment.gov (https://findtreatment.gov)

Accreditation and Compliance

SAMHSA:

- **Approved Accreditation Bodies** (https://www.samhsa.gov/medications-substance-use-disorders/become-accredited-opioid-treatment-program/approved-accreditation-bodies)
- **Certification of Opioid Treatment Programs: How To Become an Accredited and Certified Opioid Treatment Program (OTP)** (https://www.samhsa.gov/medications-substance-use-disorders/become-accredited-opioid-treatment-program)
- **Opioid Treatment Program (OTP) Compliance Officers** (https://www.samhsa.gov/medications-substance-use-disorders/about-dpt/otp-compliance-officers)
- **State Opioid Treatment Authorities** (https://www.samhsa.gov/medications-substance-use-disorders/sota)

Consumer Rights and Protections, National Library of Medicine (https://medlineplus.gov/ency/article/001947.htm)

National Certification Commission for Addiction Professionals (NCCAP) (https://www.naadac.org/certification)

Laws and Regulations Related to Medications for the Treatment of Opioid Use Disorders

SAMHSA:

- **42 Code of Federal Regulations (CFR) Part 2: Confidentiality of Substance Use Disorder Patient Records** (https://www.ecfr.gov/current/title-42/chapter-I/subchapter-A/part-2)
- **42 CFR Part 8 Final Rule—Frequently Asked Questions** (https://www.samhsa.gov/medications-substance-use-disorders/statutes-regulations-guidelines/42-cfr-part-8/faqs)
- **42 CFR Part 8 Final Rule Table of Changes** (https://www.samhsa.gov/medications-substance-use-disorders/statutes-regulations-guidelines/42-cfr-part-8/final-rule-table-changes)
- **42 CFR Part 8: Medications for the Treatment of Opioid Use Disorder** (https://www.ecfr.gov/current/title-42/chapter-I/subchapter-A/part-8)

- **Statutes, Regulations, and Guidelines** (https://www.samhsa.gov/medications-substance-use-disorders/statutes-regulations-guidelines)

The Americans with Disabilities Act (ADA) (https://www.ada.gov)

Americans with Disabilities Act Title III Regulations (https://www.ada.gov/law-and-regs/regulations/title-iii-regulations)

Health Insurance Portability and Accountability Act of 1996 (HIPAA) and Updates (https://www.cms.gov/priorities/key-initiatives/burden-reduction/administrative-simplification/hipaa/statutes-regulations)

Occupational Safety and Health Administration (OSHA): Laws and Regulations (https://www.osha.gov/laws-regs)

Other CFR:

- **21 CFR Chapter II: Drug Enforcement Administration, Department of Justice** (https://www.ecfr.gov/current/title-21/chapter-II)
- **21 CFR Part 1306.07: Administering or Dispensing of Narcotic Drugs** (https://www.ecfr.gov/current/title-21/chapter-II/part-1306/subject-group-ECFR1eb5bb3a23fddd0/section-1306.07)
- **45 CFR Part 160: General Administrative Requirements** (https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-C/part-160)
- **45 CFR Part 164: Security and Privacy** (https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-C/part-164)

Poison Prevention Packaging Act (https://www.cpsc.gov/s3fs-public/pdfs/blk_media_pppa.pdf)

Public Law 111-274—Plain Writing Act of 2010 (https://www.govinfo.gov/app/details/PLAW-111publ274)

U.S. Department of Health and Human Services: (HHS) Summary of the HIPAA Security Rule (https://www.hhs.gov/hipaa/for-professionals/security/laws-regulations/index.html)

Waiver Elimination (MAT Act) (https://www.samhsa.gov/medications-substance-use-disorders/waiver-elimination-mat-act)

42 CFR Part 8 Implementation

SAMHSA:

- **Expanding Access, Flexibility, and Empowerment for Patients** (https://www.samhsa.gov/medications-substance-use-disorders/statutes-regulations-guidelines/42-cfr-part-8/expanding-access-patients)
- **Medications, Counseling, and Related Conditions** (https://www.samhsa.gov/medications-substance-use-disorders/medications-counseling-related-conditions)
- **Medications for Substance Use Disorders** (https://www.samhsa.gov/medications-substance-use-disorders)
- **Notify SAMHSA of Program Changes** (https://www.samhsa.gov/medications-substance-use-disorders/otp-resources/program-changes)

- **Pharmacist Verification of Buprenorphine Providers** (https://www.samhsa.gov/medications-substance-use-disorders/pharmacist-verification)
- **The Physical Evaluation of Patients Who Will Be Treated With Buprenorphine at Opioid Treatment Programs** (https://www.samhsa.gov/medications-substance-use-disorders/statutes-regulations-guidelines/buprenorphine-at-opioid-treatment-programs)
- **Shared Decision-Making Tools** (https://www.samhsa.gov/brss-tacs/recovery-support-tools/shared-decision-making)
- **Submit an Opioid Treatment Take-Home Medication Related Exemption Request** (https://www.samhsa.gov/medications-substance-use-disorders/otp-resources/submit-exception-request)

Screening Tools and Prevention (https://nida.nih.gov/nidamed-medical-health-professionals/screening-tools-prevention)

Harm Reduction and Overdose Prevention

SAMHSA:

- **Harm Reduction** (https://www.samhsa.gov/find-help/harm-reduction)
- **Opioid Overdose** (https://www.samhsa.gov/medications-substance-use-disorders/medications-counseling-related-conditions/opioid-overdose)
- **Opioid Overdose Reversal Medications (OORM)** (https://www.samhsa.gov/medications-substance-use-disorders/medications-counseling-related-conditions/opioid-overdose-reversal-medications)

Harm Reduction (https://nida.nih.gov/research-topics/harm-reduction)

North American Syringe Exchange Network (https://nasen.org)

Overdose Prevention (https://www.cdc.gov/overdose-prevention/index.html)

Poison Control (https://www.poison.org)

Prescribe To Prevent (https://prescribetoprevent.org)

Training and Technical Assistance

SAMHSA:

- **Behavioral Health Information Technology Initiative** (https://www.samhsa.gov/blog/samhsa-onc-launch-behavioral-health-information-technology-initiative)
- **Provider Support and Training Resources**
  - **Center of Excellence for Protected Health Information** (https://coephi.org)
  - **National Center on Substance Abuse and Child Welfare Resources for Professionals Working With Pregnant and Parenting People Affected by Substance Use Disorders and Involved With Child Welfare** (https://ncsacw.acf.hhs.gov/files/ncsacw-resources-professionals-pregnant-parenting-sud.pdf)
  - **Opioid Response Network** (https://opioidresponsenetwork.org)
  - **Providers Clinical Support System (PCSS)** (https://pcssnow.org/about)
  - **Provider Support** (https://www.samhsa.gov/medications-substance-use-disorders/provider-support)

- **Training Materials and Resources** (https://www.samhsa.gov/medications-substance-use-disorders/training-resources)
- **Training Requirements (MATE Act) Resources** (https://www.samhsa.gov/medications-substance-use-disorders/training-requirements-mate-act-resources)

National Institute on Alcohol Abuse and Alcoholism (NIAAA), Health Professionals and Communities (https://www.niaaa.nih.gov/health-professionals-communities)

Prescription Drug Monitoring Program (PDMP) Training and Technical Assistance Center (TTAC) (https://www.pdmpassist.org/state)

Information Provided by Operating Divisions Within the U.S. Department of Health and Human Services

Agency for Healthcare Research and Quality (AHRQ), The Academy: Integrating Behavioral Health and Primary Care (https://integrationacademy.ahrq.gov)

Centers for Medicare & Medicaid Services (CMS): Telehealth (https://www.cms.gov/medicare/coverage/telehealth)

Medicaid.gov: Telehealth (https://www.medicaid.gov/medicaid/benefits/telehealth/index.html)

Organizations

American Academy of Addiction Psychiatry (AAAP) (https://www.aaap.org)

American Association for the Treatment of Opioid Dependence (AATOD) (https://www.aatod.org)

American Osteopathic Academy of Addiction Medicine (AOAAM) (https://www.aoaam.org)

American Society of Addiction Medicine (ASAM) (https://www.asam.org)

Publications

SAMHSA:

- **Advisory:** ***Evidence-Based, Whole-Person Care of Pregnant People Who Have Opioid Use Disorder*** (https://store.samhsa.gov/product/advisory-evidence-based-whole-person-care-pregnant-people-who-have-opioid-use-disorder)
- ***Buprenorphine Quick Start Guide*** (https://www.samhsa.gov/sites/default/files/quick-start-guide.pdf)
- ***Buprenorphine Quick Start Pocket Guide*** (https://www.samhsa.gov/sites/default/files/quick-start-pocket.pdf)
- ***Consumer Guide: How Can a Peer Specialist Support My Recovery From Problematic Substance Use? For People Seeking Recovery*** (https://store.samhsa.gov/product/how-can-peer-specialist-support-my-recovery-problematic-substance-use-for-people-seeking-recovery/pep23-02-01-004)
- ***Harm Reduction Framework*** (https://www.samhsa.gov/find-help/harm-reduction/framework)
- ***Low-Barrier Models of Care for Substance Use Disorders*** (https://store.samhsa.gov/product/advisory-low-barrier-models-care-substance-use-disorders/pep23-02-00-005)

- ***Medicaid Coverage of Medications To Reverse Opioid Overdose and Treat Alcohol and Opioid Use Disorders*** (https://store.samhsa.gov/product/medicaid-coverage-medications-reverse-opioid-overdose-treat-alcohol-opioid-use-disorders/pep22-06-01-009)
- ***Overdose Prevention and Response Toolkit*** (https://store.samhsa.gov/product/overdose-prevention-response-toolkit/pep23-03-00-001)
- ***Practical Guide for Implementing a Trauma-Informed Approach*** (https://store.samhsa.gov/product/practical-guide-implementing-trauma-informed-approach/pep23-06-05-005)
- ***A Provider's Introduction to Substance Abuse Treatment for Lesbian, Gay, Bisexual, & Transgender (LGBT) Individuals*** (https://store.samhsa.gov/product/providers-introduction-substance-abuse-treatment-lesbian-gay-bisexual-transgender-lgbt)
- ***Resources for Professionals Working with Pregnant and Parenting People Affected by Substance Use Disorders*** (https://store.samhsa.gov/product/resources-professionals-working-pregnant-and-parenting-people-affected-substance-use)
- **Treatment Improvement Protocol (TIP 42),** ***Substance Use Treatment for Persons With Co-Occurring Disorders*** (https://store.samhsa.gov/product/tip-42-substance-use-treatment-persons-co-occurring-disorders/pep20-02-01-004)
- **TIP 26,** ***Treating Substance Use Disorder in Older Adults*** (https://store.samhsa.gov/product/tip-26-treating-substance-use-disorder-older-adults/pep20-02-01-011)
- **TIP 63,** ***Medications for Opioid Use Disorder*** (https://store.samhsa.gov/product/tip-63-medications-opioid-use-disorder/pep21-02-01-002)
- **TIP 64,** ***Incorporating Peer Support Into Substance Use Disorder Treatment Services*** (https://store.samhsa.gov/product/tip-64-incorporating-peer-support-substance-use-disorder-treatment-services/pep23-02-01-001)
- **TIP 65,** ***Counseling Approaches To Promote Recovery From Problematic Substance Use and Related Issues*** (https://store.samhsa.gov/product/tip-65-counseling-approaches-promote-recovery-problematic-substance-use-and-related-issues)
- **Working with Child Protective Services to Support Pregnant and Parenting People, Their Infants, and Families Affected by Substance Use Disorders: A Factsheet for Health Care Providers** (https://store.samhsa.gov/product/working-child-protective-services-support-pregnant-and-parenting-people-their-infants-and)

ASAM:

- ***The ASAM National Practice Guideline for the Treatment of Opioid Use Disorder*** (https://www.asam.org/quality-care/clinical-guidelines/national-practice-guideline)
- ***Opioid Addiction Treatment: A Guide for Patients, Families, and Friends*** (https://www.asam.org/docs/default-source/publications/asam-opioid-patient-piece_-5bopt2-5d_3d.pdf)

Community Relations Tips for Opioid Treatment Programs
(https://carf.org/accreditation/programs/opioid-treatment)

Guidelines for the Psychosocially Assisted Pharmacological Treatment of Opioid Dependence
(https://www.ncbi.nlm.nih.gov/books/NBK143183)

Medication-Assisted Treatment Models of Care for Opioid Use Disorder in Primary Care Settings
(https://www.ncbi.nlm.nih.gov/books/NBK402352)

Role of the State Opioid Treatment Authority (SOTA): Core and Common Responsibilities under Current Federal Regulations (https://nasadad.org/wp-content/uploads/2023/05/SOTA-Role-5.1.2023.pdf)

VA/DoD Clinical Practice Guideline for Substance Use Disorders
(https://www.healthquality.va.gov/guidelines/MH/sud/VADoDSUDCPGRevised22216.pdf)

Working With Child Protective Services To Support Pregnant and Parenting People, Their Infants, and Families Affected by Substance Use Disorders: A Fact Sheet for Health Care Providers
(https://ncsacw.acf.hhs.gov/files/healthcare-cps-pregnant-parenting-sud.pdf)

Sample Forms

Example of Standard Consent for Opioid Use Disorder Treatment With a Medication

Consent for Participation in Opioid Pharmacotherapy Treatment

Patient's Name: _____ Date: _____

I hereby authorize and give voluntary consent to [*Name of Provider Organization*] and its medical personnel to dispense and administer medication as part of the treatment for my opioid use disorder. This treatment may include medications like methadone or buprenorphine. Treatment procedures have been explained to me, and I understand that this will involve taking the medication as directed by the opioid treatment program (OTP) practitioner, in accordance with federal and state regulations.

Like all medications, I can experience potential side effects and should take the medications as directed. I also understand methadone and buprenorphine can produce physical dependence, which is different from addiction. My healthcare provider has explained the potential benefits and risks of medications for the treatment of opioid use disorder (MOUD), including alternative treatment options.

I understand that it is essential to inform all healthcare providers about my participation in MOUD to ensure safe and coordinated care. They can then avoid prescribing medications that might interact with MOUD.

I also understand that my OTP treatment team members will advise me on the safest way to transport and secure any take-home medication I may receive, but I understand that I am responsible for safely and securely transporting and storing any take-home medication the OTP may give me.

I understand that [*Name of Provider Organization*] is committed to providing ongoing care and support to help me manage my opioid use disorder. This includes assisting me with any necessary medication adjustments or referrals to additional services as my treatment needs evolve.

I understand that I can voluntarily withdraw from MOUD at any time. If I choose to do so, I will be offered medically supervised withdrawal.

For individuals who may become pregnant during MOUD: There is evidence supporting the safe use of MOUD during pregnancy. If I am or become pregnant, I understand the importance of informing my healthcare provider immediately to receive appropriate care and support.

I acknowledge that the clinic has provided me with information regarding my patient rights, including those outlined in the Americans with Disabilities Act (ADA) and the Health Insurance Portability and Accountability Act (HIPAA). I understand my rights and responsibilities as a patient.

_____	_____	_____
Signature of Patient	Date of Birth	Date

Witness: _____

Source: Adapted with permission from Department of Psychiatry and Behavioral Sciences, Montefiore Medical Center, Division of Services for Addiction, Bronx, NY.

Example of Medication Chain-of-Custody Record

Date: _____

Name of Treatment Program: _____

Name of Treatment Program Dispensing Nurse: _____

Medication To Be Delivered (Methadone/Buprenorphine/Buprenorphine +Naloxone):

_____

Number of Doses To Be Delivered: _____

Medication Provided From _____ to _____
(Date) (Date)

Name of Person Transporting Medication: _____

License Number of Person Transporting Medication: _____

Date Medication Received: _____ Number of Doses Received: _____

Medication Received Covering _____ to _____
(Date) (Date)

COMMENTS: _____

_____ _____
Signature of person receiving medication Signature of person transporting medication

Date of Administration and Initials of Patient Receiving Medication

Date	Patient Initials	Date	Patient Initials
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____

Client Information on Revised Regulations

Expanding Access, Flexibility, and Empowerment for Patients: Understanding the Revised Opioid Treatment Program (OTP) Regulations

More Options and Support on Your Road to Recovery

Did you know the new federal regulations (rules), for opioid treatment programs (OTPs), seek to improve access to high-quality, evidence-based care focusing on your personal and treatment needs and goals? If you are currently a patient or plan to receive treatment at an OTP, you should know that the new federal rules that govern OTPs, where methadone and other life-saving medications and a host of other services are provided for the treatment of opioid use disorder (OUD), were updated for the first time in over 20 years. The new federal rules aim to help more people recover in a supportive and empowering environment. It is important for you to be aware that states may have additional requirements to the federal rules, so it is always best to check your state requirements as well.

How Do the Changes Help You?

More Individualized Care Choices

The updates to the rules for OTPs promote a treatment environment that offers the flexibility to create plans of care that center on your aims and health status today. Admission requirements no longer rely on one-year of opioid addiction for adults and two unsuccessful attempts at withdrawal management (what used to be called “detox”) for people under 18 years of age. Also, the federal rules for counseling are now based on the patient’s needs and goals. These changes increase access to OTPs, support your recovery, and honor you individualized choices.

Your Voice Matters

Your preferences and needs will contribute more directly to your treatment plan under the new “shared decision-making” guidelines. You and your care team will work together to plan your treatment, based on the information you provide, your situation, your needs, and what is most important to you. Dosage changes, counseling approaches, access to take-home methadone doses, and other services will better reflect the goals that you help determine. The new rules promote trust and teamwork, and they respect your needs and circumstances.

“Meeting Patients Where They Are”

The approach of “meeting patients where they are” adds another dimension of understanding and compassion to care. OTPs can also help you by providing information on ways to protect yourself if you are still using substances, without refusing services or treatment. Medications for the treatment of OUD, especially methadone and buprenorphine, help people manage cravings and withdrawal symptoms, making it possible for people to feel better so they reduce or even stop using. With today’s dangerous drug supply, which can be lifesaving. People can also make other positive changes in their lives with the help of services provided the care team at their OTP. However, treatment varies from person to person. What helps one person might not work for someone else. With these new rules, your treatment team will continue to work with you to find the effective dose for you and what other services you might find helpful in reaching your goals.

OTPs can also help you by providing information on ways to protect yourself if you are still using substances, offering resources to help with housing, food, and your other healthcare needs, with the goal of helping you improve your quality of life and help to keep you stay in care.

More Providers and Convenient Access

The new rules expand the type of practitioners who can help, open access to screening, and help to bring treatment to where it is needed.

- Adding new types of licensed practitioners who can order treatment, such as nurse practitioners, will help with staff shortages that impact many programs and specifically rural areas.
- Access to telehealth expands access by allowing non-OTP practitioners to complete the initial screening exams for new patients.
- Use of mobile medication units will reduce travel distances for patients to receive their medication and other OTP treatment services.
- Expands access to interim care, allows OTPs at full capacity to offer immediate medications to patients for OUD while working on referrals to the full array of comprehensive OTP services.

Lowering Barriers With Safeguards

The new rules remove obstacles to treatment that made it difficult for some people to enter or remain in treatment in the past. Practitioners are no longer required to follow rigid criteria to determine the number of take-home methadone doses for a given patient. Instead, they are now guided by harm reduction approaches, shared decision-making with you, and considerations of your safety and unique circumstances. That helps balance the benefits and risks of methadone take-home doses, with an approach that is similar to how healthcare practitioners weigh and talk with their patients about the benefits and risks of other types of medications.

Why Are These Changes Important?

These changes are about respect, trust, understanding, and compassion. Trusting that you, as a patient, understand what you need, while highly skilled OTP practitioners respect your values, needs, and preferences. The new rules allow them to provide you with the best care available. Flexibilities put into place during COVID-19, showed that less burdensome treatment rules improve patient outcomes, and helps patients stay in care longer. The new rules balance the need for responsive patient care with responsible ways to make sure you're getting good care, all while providing you with consistency, humanity, support, and empowerment through your recovery journey.

They say the longest journeys start with a single step. Wherever you are on your road to recovery, these new regulations provide a more supportive and person-centered approach to care among OTPs. Join the millions of people who are living their lives in recovery with medications because recovery is possible!

Source: Substance Abuse and Mental Health Services Administration. [*https://www.samhsa.gov/medications-substance-use-disorders/statutes-regulations-guidelines/42-cfr-part-8/expanding-access-patients*](https://www.samhsa.gov/medications-substance-use-disorders/statutes-regulations-guidelines/42-cfr-part-8/expanding-access-patients)

Appendix E. Consulting Experts

SAMHSA convened a panel of nonfederal and federal experts to provide guidance on the revised Guidelines. These experts included opioid treatment program (OTP) medical directors, addiction medicine physicians, addiction psychiatrists, OTP program sponsors and clinical directors, representatives from state opioid treatment authorities and accreditation bodies, individuals with lived experience receiving medication for the treatment of opioid use disorders, policy leaders, peer engagement and outreach specialists, physician assistants, and nurse practitioners. The title and affiliations recognized below were as of the panel meetings and may not reflect the participants' current positions.

Nonfederal Participants

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Endnotes

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SAMHSA

Substance Abuse and Mental Health
Services Administration

PEP24-02-011

SAMHSA's mission is to lead public health and service delivery efforts that promote mental health, prevent substance misuse, and provide treatments and supports to foster recovery while ensuring equitable access and better outcomes.

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